FOREWORD INTRODUCTION

SOLUBLE SILICATES

Silicic acid, sodium salt: 1344-09-8

Silicic acid (H_2SiO_3), disodium salt: 6834-92-0

Silicic acid (H_2SiO_3), disodium salt, pentahydrate: 10213-79-3

Silicic acid (H_2SiO_3), disodium salt, nonahydrate: 13517-24-3

Silicic acid, potassium salt: 1312-76-1

SIDS Initial Assessment Report

for

SIAM 18

Paris, France 20-23 April, 2004

1. Category:	Soluble Silicates	
2. CAS No. and Chemical Name:	1344-09-8	Silicic acid, sodium salt
	6834-92-0	Silicic acid (H_2SiO_3), disodium salt
	10213-79-3	Silicic acid (H_2SiO_3), disodium salt, pentahydrate
	13517-24-3	Silicic acid (H_2SiO_3), disodium salt, nonahydrate
	1312-76-1	Silicic acid, potassium salt
3. Sponsor Country:	Germany Contact Point: BMU (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit) **Prof. Dr. Ulrich Schlottmann** Postfach 12 06 29 D- 53048 Bonn-Bad Godesberg	
4. Shared Partnership With:		
5. Roles/Responsibilities of the Partners:		
Name of industry sponsor/consortium	Soluble Silicates Consortium Mr. Joël Wilmot Centre Européen d'Etude des Silicates (CEES) Avenue E. van Nieuwenhuyse 4 B-1160 Brussels	
Process used	see next page	
6. Sponsorship History		
How was the chemical or category brought into the OECD HPV Chemicals Programme?	by ICCA Initiative	
7. Review Process Prior to the SIAM:	last literature search (update): 8 October2003 (Human Health): databases medline, toxline; search profile CAS-No. and special search terms 11 April 2003 (Ecotoxicology): databases CA, biosis; search profile CAS-No. And special search terms	
8. Quality Check Process:	As basis for the SIDS-Dossier the IUCLID was used. All data	

have been checked and validated by BUA.

9. Date of Submission: Deadline for circulation: 23 January 2004

10. Comments:

OECD/ICCA - The BUA* Peer Review Process

Qualified BUA personnel (toxicologists, ecotoxicologists) perform a quality control on the full SIDS dossier submitted by industry. This quality control process follows internal BUA guidelines/instructions for the OECD/ICCA peer review process and includes:

– a full (or update) literature search to verify completeness of data provided by industry in the IUCLID/HEDSET
– Review of data and assessment of the quality of data
– Review of data evaluation
– Check of adequacy of selection process for key studies for OECD endpoints, and, where relevant, for non-OECD endpoints by checking original reports/publications
– Review of key study description according robust summaries requirements; completeness and correctness is checked against original reports/publications
(if original reports are missing: reliability (4), i.e. reliability not assignable)
– Review of validity of structure-activity relationships
– Review of full SIDS dossier (including SIAR, SIAP and proposal for conclusion and recommendation for further work)
– In case of data gaps, review of testing plan or rationale for not testing

*BUA (GDCh-Beratergremium für Altstoffe): Advisory Committee on Existing Chemicals of the Association of German Chemists (GDCh)

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	1344-09-8 6834-92-0 10213-79-3 13517-24-3 1312-76-1
Chemical Name	Silicic acid, sodium salt Silicic acid (H_2SiO_3), disodium salt Silicic acid (H_2SiO_3), disodium salt, pentahydrate Silicic acid (H_2SiO_3), disodium salt, nonahydrate Silicic acid, potassium salt
Structural Formula	**$M_2O \bullet n\ SiO_2$** (M = Na or K; n = molar ratio, defining the number of moles SiO_2 per mole of M_2O; a molar ratio of 1 designates metasilicates, **M_2SiO_3**)

SUMMARY CONCLUSIONS OF THE SIAR

Category Rationale

The soluble silicates are structurally very similar. Silicon-oxide tetrahedra as the basic structural units are linked with each other via Si-O-Si bonds resulting in an infinite three-dimensional network. The negative charge of unshared oxygen atoms is balanced by the presence of sodium or potassium cations which are randomly spaced in the interstices. The extent to which balancing alkali ions are present in a given silicate is defined by the molar ratio SiO_2/M_2O (M = Na or K). The higher the molar ratio, the less sodium or potassium ions are present in the silica network and consequently the less alkaline the silicates are. Whereas the sodium and potassium salts have an amorphous three-dimensional structure, the disodium salts (= metasilicate) are crystalline with penta- and nonahydrate differing from the anhydrous form only by their water of crystallisation. Once in aqueous solution, all soluble silicates are subject to the same molecular speciation resulting in a mixture of monomeric tetrahedral ions, oligomeric linear or cyclic silicate ions and polysilicate ions. At environmental pH values the soluble silicates are present as poorly soluble amorphous silica and monomeric silicic acid. The biological properties of soluble silicates are mainly governed by their intrinsic alkalinity. Based on the available data the members of the soluble silicates category exhibit a similar toxicological profile.

Human Health

The limited toxicokinetic studies on rats, cats, dogs and guinea pigs all showed that the excretion of silicon with the urine was markedly increased after ingestion of silicates. The excretion rate was independent of the doses applied indicating that the limiting factor is the rate of production of soluble or absorbable silicon in the gastrointestinal tract.

The oral LD_{50} in rats was 1152 – 5700 mg/kg bw depending on the molar ratio of the silicate species, i.e. toxicity decreases with increasing molar SiO_2:M_2O ratio. Clinical signs included apathy, staggering gait, tonic cramps, dyspnoea, cyanosis, piloerection and signs of abdominal discomfort.

Sodium and potassium silicates can be irritating to corrosive to the skin of rabbits, depending on their molar ratio and concentration. The nature of the counterion (Na^+ or K^+) has no influence as sodium and potassium silicates behave similarly with respect to skin irritation. Any effects on the skin decrease with increasing molar ratio, superimposed by increasing irritancy with increasing concentrations. At concentrations of 35 % and 29 % (highest tested concentrations) potassium silicates with molar ratios of 3.4 and 3.9 were only slightly, and not irritating to the eyes of rabbits, respectively. Results from non-validated *in vitro* assays indicate that the severity of eye effects is inversely correlated with the molar ratio, with corrosive effects found in the enucleated rabbit eye test after exposure to disodium silicate powder with a molar ratio of 1.0.

In a mouse local lymph node assay, sodium metasilicate was not sensitising. In humans, a single case of contact urticaria elicited by sodium silicate is reported.

Soluble silicates have been tested in a number of repeated dose studies with exposures ranging from 28 to 180 days. The NOAELs (90d) of sodium metasilicate were 227 - 237 mg/kg bw/d for rats and 260 - 284 mg/kg bw/d for mice (highest tested dose levels, respectively). Sodium silicate had a NOAEL (180d) of 159 mg/kg bw/d for rats (highest tested dose). In mice the LOAEL (90 d) of sodium metasilicate was 716 - 892 mg/kg bw/d with reduction of pituitary glands weight in female mice as adverse effect. Adverse effects in rats, dogs and turkeys were polydipsia, polyuria and soft stools, reduction of blood plasma Ca and Mg levels, and of liver Zn concentrations, gross cortical lesions of the kidneys or increased blood plasma P and decreased Cu at doses above 1000 mg/kg bw/d.

In vitro, soluble silicates did not induce gene mutations in bacteria: sodium silicate was negative in an *E. coli* reverse mutation assay and sodium metasilicate exerted no mutagenic activity in *B. subtilis* and *S. typhimurium*. In a modern guideline study that was performed in accordance with OECD TG 473, an aqueous sodium silicate solution (36% active ingredient) induced no chromosomal aberrations in V79 cells, both in the absence and in the presence of metabolic activation. *In vivo*, sodium metasilicate did not induce chromosomal aberrations in bone marrow cells of mice in a study performed similarly to OECD TG 475, with the restriction that no information on the use of positive controls was available for this study. Although the reliability of this study can therefore not be fully evaluated, the negative result is corroborated by the fact that the chemical structure does not contain elements that raise concern for a genotoxic activity and by the negative results of genotoxicity tests with sodium silicate. For the group of soluble silicates under review here, it is therefore concluded that there is no evidence of a genotoxic potential.

There were no valid carcinogenicity studies available.

The available data on toxicity to reproduction are limited. In a 4-generation study, the total number of offspring born at 79 mg/kg bw/d was reduced to 67 % and of offspring weaned to 46 % of the control, respectively. Severe limitations of the study and intercurrent deaths, including controls, make it however difficult to draw any firm conclusions from this study. In mice, litter size and fertility index were unaffected at sodium metasilicate concentrations up to and including 200 mg/kg bw/d. No developmental effects were observed in mice up to and including 200 mg/kg bw/d. In repeat dose toxicity studies with rats, mice and dogs the macroscopic and microscopic examination of reproductive organs did not reveal treatment-related effects.

Environment

Solid crystalline silicates have discrete melting points which depend on the content of crystallisation water: anhydrous sodium metasilicate melts at 1089 °C while sodium penta- and nonahydrate melt at 72 °C and 48 °C, respectively. Due to their glass nature, solid amorphous silicates do not have discrete melting points but rather flow points. Aqueous silicate solutions have a melting point only slightly lower than that of water.

The specific gravity or density of silicate solutions depends on the concentration (solids content), the temperature, and the silica to alkali ratio. Commercial silicate solutions have densities ranging from ca. 1.2 – 1.7 g/cm^3 at 20 °C.

The vapour pressures that have been measured for three solid sodium silicates are extremely low: 0.0103 hPa at 1175 °C (MR 1.0, metasilicate), 0.0031 hPa at 1165 °C (MR 2.0) and 0.0016 hPa at 1172°C (MR 3.0). This indicates that the respective pressures at ambient temperature will be unmeasurably small.

Crystalline silicates like sodium metasilicate are readily soluble in water. Amorphous silicate glasses are only slightly attacked by water at ambient temperatures. They can be solubilised only at elevated temperature and pressure (ca. 150 °C and $\geq$ 5 bar). The solutions are infinitely dilutable with water. Silicate powders obtained by water evaporation from silicate solutions are readily soluble in water. The water solubility depends on the pH and pH is elevated upon dissolution of soluble silicates. Above a pH of 11 - 12 stable solutions of monomeric and polymeric silicate ions exist. Solubility rapidly decreases when the pH is lowered to 9 leading to increasing precipitation of amorphous silica. Below pH 9 only a small proportion is present as soluble monomeric silicate ions, the majority existing as insoluble amorphous silica gel. Soluble silicates are insoluble in alcohols, like n-octanol, making determination of a log Kow not feasible.

As inorganic substances, soluble silicates are not amenable to photo- or biodegradation. Respiration of activated sludge is not inhibited at sodium metasilicate concentrations >=100 mg/l. Continuous dosing of 25 mg sodium silicate/l has no adverse effects on the operation of a model sewage treatment plant simultaneously fed with easily degradable nutrients; no significant elimination occurred with >90% detected in the effluent.

Acute toxicity testing in fish, invertebrates, and algae indicate a low order of toxicity with effect concentrations between 210 and 1700 mg/l. The following results were obtained in acute tests:

Danio rerio	LC_{50} (96 h) = 210 mg/l (Na, MR 1.0)
Danio rerio	LC_{50} (96 h) = 1108 mg/l (Na, MR 3.46)
Oncorhynchus mykiss	LC_{50} (96 h) = 260 - 310 mg/l (Na, MR 3.1)
Leuciscus idus	LC_{50} (48 h) > 146 mg/l (K, MR 3.9- 4.1)
Daphnia magna	EC_{50} (48 h) = 1700 mg/l (Na, MR 3.2)
Daphnia magna	EC_{50} (24 h) > 146 mg/l (K, MR 3.9- 4.1)
Scenedesmus subspicatus	EbC_{50} (72 h) = 207 mg/l
	ErC_{50} (72 h) > 345 mg/l (Na, MR 3.0)

No long-term tests are available for fish, invertebrates or algae.

As a result of the low molar ratio, sodium metasilicate and its hydrates (MR 1.0) exhibit a higher alkalinity than the silicates of higher molar ratio. With the assumption that the primary hazard of soluble silicates is their alkalinity, it is expected that sodium metasilicate generally exhibits a higher toxicity than silicates of molar ratios 3 - 4. This is confirmed by toxicity data available for fish. Concerning invertebrate and algal toxicity, studies are available only for silicates of molar ratios 3-4 or of unknown ratio. Because of their higher alkalinity, the sodium metasilicates are expected to exhibit a higher daphnid and algal toxicity. The extent to which this toxicity will be increased should be similar to that observed for fish toxicity in *Danio rerio*. This would result in metasilicate toxicities in the same order of magnitude as observed for fish.

Exposure

The worldwide production volume is approximately 3-4 million metric tons per year. In the year 2000, ca. 770,000 metric tons of sodium silicates and disodium metasilicates were produced in Western Europe with a total consumption of ca. 890,000 metric tons. Potassium silicates were produced at approximately 22,000 metric tons. Sodium silicates are used as raw materials for industrial products, like silicas or zeolites (51 %), in detergents and cleaners (21 %), pulp & paper production (15 %) and numerous other applications, including soil stabilization, TiO_2 production, refractories, ceramic binders, water treatment etc. (13 %). Applications for potassium silicates are the building industry (45 %), welding rods (19 %), detergents (16 %), molecular sieves (9 %), and miscellaneous uses (11 %).

About 50% of the combined sodium and potassium silicates production (460 ktons SiO2/year) is further processed to derivatives. Emissions to the environment may take place during production and processing, but no quantitative information is available. Another 10 % (ca. 80 - 90 ktons SiO2/year) go into direct uses which result in inclusion into or onto a matrix (e.g. refractories, TiO2, ceramic binders, welding rods, building industry). There is potential for release to the aqueous and terrestrial environment during production, processing and use, but no emission data are available. The remaining soluble silicates (ca. 40 % or 360 ktons SiO2/year)) are used in applications with likely emissions into the hydro- and/or geosphere (e.g. detergents, pulp & paper, water/wastewater treatment and soil stabilization). Detergents (188 ktons SiO2/year) and pulp & paper (136 ktons SiO2/year) are the most important water-relevant applications and together make up about 90 % of the soluble silicates used in these application areas. Once they reach the hydrosphere, they are diluted and depolymerize rapidly to give molecular species indistinguishable from natural dissolved silica (H4SiO4 or SiO2 [aq.]) in the hydrosphere. Workers or professional users may be exposed to liquid or powder products. Since the primary hazard of soluble silicates is their alkalinity, precautions must be observed to prevent contact with clothes, skin and in particular with the eyes. Workers are recommended to wear protective equipment (safety gloves and glasses, dust masks when handling powders). Dust exposure should be limited to 2 mg/m^3, the limit concentration foreseen for caustic soda (NaOH) and potash (KOH).

Consumer exposure may occur primarily by contact with laundry or automatic dishwashing detergents and by ingestion of drinking water. Background exposure via the environment can be expected, as compounds of silicon and oxygen are the primary constituents of earth's landmasses, and an important compound in the biomass. Silicon is a ubiquitous constituent of foods.

RECOMMENDATION

The chemicals in this category are currently of low priority for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

Human Health:

Soluble silicates possess properties indicating a hazard for human health (irritancy/corrosivity). In the Sponsor country, adequate risk reduction measures are in place (classification and labelling). No further work is recommended. In situations where this is not the case, risk assessment and, if necessary, risk reduction measures are recommended.

Environment:

Soluble silicates are currently of low priority for further work because of their low hazard profile.

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1 IDENTITY

1.1 General description and characterisation of category members

Soluble silicates are produced by fusing high purity quartz sand (SiO_2) and alkali carbonate (soda, Na_2CO_3 or potash, K_2CO_3) at temperatures of 1300-1500 °C. The resulting product is an amorphous glass that can be dissolved in water to produce silicate solutions. The fusion reaction follows the equation

$$M_2CO_3 + n\ SiO_2 \rightarrow M_2O{\cdot}nSiO_2 + CO_2 \qquad M = Na \text{ or } K$$

The various products are obtained by varying the mixing ratio of the two components. They are therefore characterised primarily by the weight ratio (WR) or molar ratio (MR), SiO_2 to Na_2O or K_2O, respectively. Soluble silicates are generally not distinct stoichiometric chemical substances (with a specific chemical formula and molecular weight), but rather glasses or aqueous solutions of glasses.

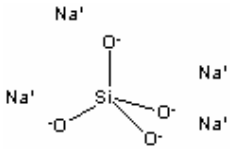
Soluble silicates used in industry are divided into two groups:

Amorphous silicates solidified as a glass from the melt (solid or lump glasses). These amorphous glasses are essentially anhydrous and differ from ordinary glasses in that they are soluble in water at elevated temperature and pressure leading to silicate solutions (liquid glasses). Both solid and liquid glasses are often referred to as waterglass. Silicate solutions are defined by their density and viscosity, which together with the silica to metal-oxide ratio defines a unique composition for the silicate solution. By evaporation of silicate solutions, normally in the sodium form, fine powders or granules are obtained that have a residual water content of ca. 20 %. Unlike ground lump glass, these materials dissolve readily in water to give silicate solutions.

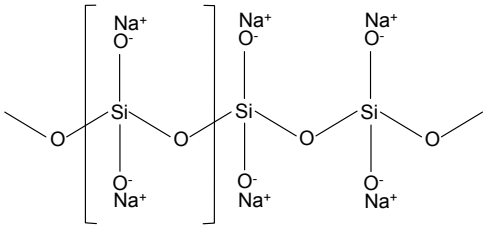
Crystalline silicates, exclusively in the sodium form, by controlled crystallisation of silicate solutions. Commercial products of this type are sodium orthosilicate (MR 0.5) or sodium metasilicate (MR 1.0). Sodium metasilicate can be prepared in anhydrous form, or with water of crystallisation as the penta- or nonahydrate. It is readily soluble in water.

Sodium silicates

Name:	Silicic acid, sodium salt
CAS number:	1344-09-8
EINECS number:	215-687-4
Molecular formula:	$Na_2O \cdot nO_2Si$
Molecular weight:	184.04 (tetrasodium orthosilicate); soluble silicates are generally not distinct stoichiometric chemical substances (with a specific chemical formula and molecular weight), but rather glasses or aqueous solutions of glasses.
Molar ratio:	0.5 for tetrasodium orthosilicate. Commercial sodium silicates have molar ratios between 1.5 and 4.0
Synonyms:	Water glass; soluble glass; silicate of soda; sodium orthosilicate; sodium silicate glass.

Structural formula:		The formula describes tetrasodium orthosilicate (monomer). For common silicates structural formulae are complex: monomer, linear and planar cyclic oligo-, and three-dimensional polysilicate anions with sodium cations as counterions.

Sodium metasilicates

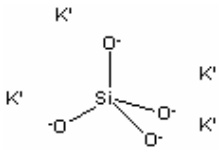
Name:	Silicic acid, disodium salt (anhydrous)
CAS number:	6834-92-0
EINECS number:	229-912-9
Molecular formula:	Na_2O_3Si
Molecular weight:	Not applicable, sodium metasilicate is comprised of infinite chains of Na_2SiO_3 units of variable length.
Molar ratio:	1.0
Synonyms:	Sodium metasilicate; disodium monosilicate; silicic acid (H_2SiO_3), disodium salt.
Structural formula:	

Name:	Silicic acid, disodium salt (crystalline pentahydrate)
CAS number:	10213-79-3
EINECS number:	229-912-9
Molecular formula:	$Na_2O_3Si \cdot 5H_2O$
Molecular weight:	Not applicable, see anhydrous metasilicate
Molar ratio:	1.0

Name:	Silicic acid, disodium salt (crystalline nonahydrate)
CAS number:	13517-24-3
EINECS number:	229-912-9
Molecular formula:	$Na_2O_3Si \cdot 9H_2O$
Molecular weight:	Not applicable, see anhydrous metasilicate

Molar ratio:	1.0

Potassium silicates

Name:	Silicic acid, potassium salt
CAS number:	1312-76-1
EINECS number:	215-199-1
Molecular formula:	$K_2O \cdot nO_2Si$
Molecular weight:	248.44 (tetrapotassium orthosilicate); soluble silicates are generally not distinct stoichiometric chemical substances (with a specific chemical formula and molecular weight), but rather glasses or aqueous solutions of glasses.
Molar ratio:	0.5 for tetrapotassium orthosilicate. Commercial potassium silicates have molar ratios between 1.5 and 5.0
Synonyms:	Potassium silicate; potassium waterglass.
Structural formula:	 The formula describes tetrapotassium orthosilicate (monomer). For common silicates structural formulae are complex: monomer, linear or planar cyclic oligo-, and three-dimensional polysilicate anions with potassium cations as counterions.

1.2 Impurities

Soluble silicates are very pure substances with impurities less than 1 %: The impurities stem from the quartz sand used rather than from the potash or soda components of the fusion mixture. Therefore, impurities of potassium silicates are similar to sodium silicates of comparable molar ratios.

The following impurities were reported for sodium silicate lumps of MR 3.46 (Engler 1974):

Na_2SO_4	0.06 %	CaO	0.03 %
NaCl	0.06 %	MgO	0.02 %
Fe_2O_3	0.033 %	TiO_2	0.019 %
Al_2O_3	0.097 %		

In Falcone (1997) the composition range of a typical sodium silicate solution with MR 3.4 is given (all contents in ppm):

K	20 - 50	S	10 - 30
Mg	5 - 20	Ti	30 - 80
Ca	1 - 80	Fe	25 - 100
Sr	1 - 5	Ce	<0.3 - 2

Ba	<1 - 5	Zr	5 - 20
Al	50 - 200	W	<1 - 25
P	<1 - 10		

The following elements were found in quantities below 1 ppm: Li, V, Cr, Mn, Co, Ni, Cu, Zn, La and Ce.

1.3 Physico-chemical properties of silicates

Melting point

Solid crystalline silicates have discrete melting points which depend on the content of crystallisation water: anhydrous sodium metasilicate melts at 1089 °C (Kracek 1930), while sodium penta- and nonahydrate melt at 72 °C and 48 °C, respectively (Baker et al. 1933). Due to their glass nature, solid amorphous silicates do not have discrete melting points but rather flow points. They reversibly solidify and soften within a broad temperature range depending on their molar ratio. Sodium silicate lumps start to soften at 550 - 670 °C and reach the flow point at 730 - 870°C, potassium silicate lumps start to soften at 700 °C and reach the flow point at 900°C (Engler 1974). Aqueous silicate solutions have a melting point only slightly lower than that of water.

Vapour pressure

The vapour pressures that have been measured for three solid sodium silicates are extremely low: 0.0103 hPa at 1175 °C (MR 1.0, metasilicate), 0.0031 hPa at 1165 °C (MR 2.0) and 0.0016 hPa at 1172°C (MR 3.0). This indicates that the respective pressures at ambient temperature will be unmeasurably small. The penta- and nonahydrates of sodium metasilicate contain significant amounts of hydration water (pentahydrate: 43 %; nonahydrate: 57 %). In commercial silicate solutions the water content is still higher and can reach up to 70 %. Therefore, the vapour pressures of the solid hydrates and the solutions are expected to be significantly higher. However, this would be governed by the high water content and reflect rather the vapour pressure of water than that of the respective silicates. The vapour pressures of potassium silicates have not been determined, but they are not expected to vary significantly from those determined for the respective sodium silicates.

Solubility and stability in water

Crystalline silicates like sodium metasilicate are readily soluble in water. For example, the solubilities for anhydrous sodium metasilicate and the pentahydrate are 210 g/l at 20 °C and 610 g/l at 30 °C, respectively. These company technical data are supported by qualitative statements from peer-reviewed handbooks. Amorphous silicate glasses are only slightly attacked by water at ambient temperatures. They can be solubilised only at elevated temperature and pressure (ca. 150 °C and $\geq$ 5 bar). The solutions are infinitely dilutable with water. Silicate powders obtained by water evaporation from silicate solutions are readily soluble in water. Amorphous silica which precipitates when alkaline solutions are neutralized has a water solubility of 115 mg/l at 25 °C and neutral pH (Morey et al. 1964).

Upon dissolution, the soluble silicates give rise to molecular speciation (Figure 1). Depending on both pH and concentration the respective solutions contain varying proportions of monomeric tetrahedral ions, oligomeric linear or cyclic silicate ions (for example di- or trisilicate ions) and polysilicate ions of three-dimensional structure (Fig. 2) which are in a dynamic equilibrium. The degree of polymerisation of the silicate anions increases with increasing concentration and increasing SiO_2/M_2O ratio of the solution. On the other hand, pH is also strongly influencing the

polymerisation-depolymerisation equilibrium: above a pH of 11 - 12 stable solutions of monomeric and polymeric silicate ions exist and no insoluble amorphous silica is present. Acidification below pH 11 - 12 leads to increasing precipitation of amorphous silica which is characterised by the loss of interstitial alkali ions from the three-dimensional network (cf. Fig. 2 c). The soluble content rapidly decreases when the pH is lowered to 9. At pH values below 9 only a low but constant amount remains in solution as monomeric silicate ions. Consideration of the high dissociation constants of silicic acid (pKa 9.9, 11.8, 12 & 12 at 30 °C, Lide & Frederikse 1995) also leads to the conclusion that at environmental pH values of 6.5 – 8.5 only a small proportion of silicate ions will be in solution.

Alkalinity

The pH of silicate solutions is inversely correlated with the silica to alkali ratio and ranges from pH 10 - 13 (CEES, 2003). Dilution reduces the pH, but less than might be expected due to the buffering action of the silicate: the pH of a 1 wt% solution is lowered by only about 1 unit compared to the concentrated solution (Minihan and Lovell 2000).

Octanol solubility and partition coefficient

Soluble silicates are insoluble in alcohol (Budavari 2001) indicating that this will also apply to n-octanol. The octanol/water partition coefficient is therefore not applicable or relevant.

Specific gravity

The specific gravity or density of silicate solutions depends on the concentration (solids content), the temperature, and the silica to alkali ratio. At a given solids content the density will increase with decreasing ratio. According to company technical data and review articles commercial silicate solutions have densities ranging from ca. 1.2 – 1.7 g/cm^3 at 20 °C (Falcone 1997; Henkel undated; Minihan and Lovell 2000).

Viscosity

Among the many factors that influence the viscosity of sodium silicate solutions the ratio, concentration, and temperature are the most important. The viscosity increases with rising concentration and ratio. It decreases with rising temperatures. For a given ratio there is a limiting concentration above which the solution becomes too viscous for handling (Crosfield undated).

1.4 Category justification

Sodium and potassium silicates only differ from each other by their counterions. The basic structural unit of soluble silicates is a tetrahedral arrangement of four oxygen atoms surrounding a central silicon atom. Tetrahedra are linked with each other via Si-O-Si bonds resulting in an infinite three-dimensional network where the oxygen atoms at the corners of a given tetrahedron are shared with neighbouring tetrahedra. Not all corners in the tetrahedra are shared; the negative charge of unshared oxygen atoms is balanced by the presence of sodium or potassium cations which are randomly spaced in the interstices of the silicate structure (Fig. 2). The extent to which balancing alkali ions are present in a given silicate is defined by the molar ratio SiO_2/M_2O (M = Na or K). The higher the molar ratio, the less sodium or potassium ions are present in the silica network and the less alkaline the silicates are. The various ratios determining the application properties are adjusted by the mixing ratio of quartz (SiO_2) and soda or potash, respectively. Due to the equimolar ratio SiO_2/Na_20, sodium metasilicate has a regular crystalline structure. The penta- and nonahydrate differ from anhydrous metasilicate only by their water of crystallisation. Metasilicate is readily solubilized in water. In the solubilized form it is indistinguishable from solubilized amorphous silicates. In addition, once in aqueous solution, all soluble silicates give rise to the same molecular

speciation (Fig. 1). At environmental pH values soluble silicates are present as poorly soluble amorphous silica and soluble monomeric silicic acid.

Biological properties of solutions

Irrespective of the molecular structure and the nature of the cation all soluble silicates have the same structural unit, the silicon-oxide tetrahedron. The biological properties of soluble silicates are mainly governed by their intrinsic alkalinity. At a given concentration the alkalinity of silicate solutions is inversely correlated with the ratio SiO_2/M_2O: the lower the ratio, the higher the alkalinity. A clear correlation exists between oral toxicity as well as skin and eye irritation and the molar ratio; the toxicity and irritation increasing with decreasing ratio. Soluble silicates can react with multivalent cationic metal ions to form the corresponding insoluble metal silicate and may thus lead to reduced bioavailability of these ions for the body or cause depletion of these ions in the body. However, the fact that silicates are resorbed by the gastrointestinal tract as monosilicic acid which has no complexing properties, makes the latter possibility less likely.

The soluble silicates exhibit aquatic toxicities in excess of 100 mg/l irrespective of molar ratio or metal cation. The aquatic toxicities of the penta- and nonahydrate forms are expected to be in the same range as those for the anhydrous disodium salt.

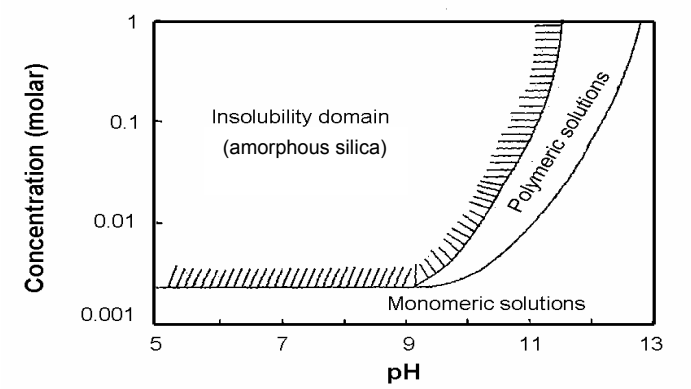


Figure 1: Soluble silicate speciation. Derived from Schleyer and Blumberg (1982)

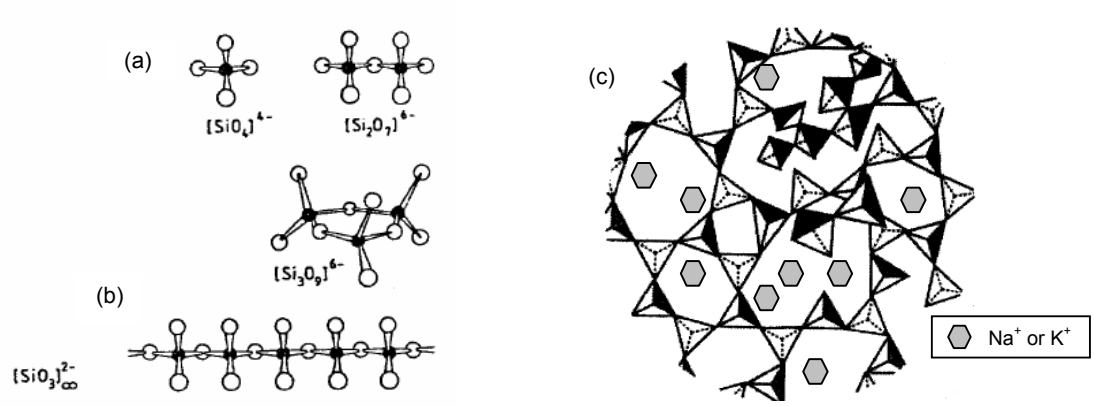


Figure 2: Silicate anion structures (a), metasilicate chain (b) and amorphous silicate glass (c). Derived from Christophliemk (1985) and Fine (1991).

1.5 Datamatrix of available data

Physicochemical Properties					
Test	**Silicic acid**				
	sodium salt **CAS-No. 1344-09-8**	**disodium salt** **CAS-No. 6834-92-0**	**disodium salt, 5-hydrate** **CAS-No. 10213-79-3**	**disodium salt, 9-hydrate** **CAS-No. 13517-24-3**	**potassium salt** **CAS-No. 1312-76-1**
Physical State	Amorphous glass melt (lumps), aqueous solution or spray-dried powder with ca. 20 % of residual water	Crystalline anhydrous powder	Crystalline powder with water of crystallisation	Crystalline powder with water of crystallisation	Amorphous glass melt; aqueous solution or spray-dried powder with ca. 20 % of residual water
Melting Point	730 - 870 °C (flow point); aqueous solutions have a melting point only slightly lower than that of water	1089 °C	72.2 °C	48 °C	905 °C (flow point); aqueous solutions have a melting point only slightly lower than that of water
Density	1.26 - 1.71 g/cm^3 (solutions); 700 - 800 kg/m^3 (bulk density;spray-dried powders)	2.61 g/cm^3 1200 kg/m^3 (bulk density)	1.75 g/cm^3 1000 kg/m^3 (bulk density)	1.65 g/cm^3 800 kg/m^3 (bulk density)	1.25 - 1.6 g/cm^3 (solutions); 750 kg/m^3 (bulk density; spray-dried powders)
Vapour Pressure	0.0031 hPa at 1165 °C (solid, MR 2.0). 0.0016 hPa at 1172 °C (solid; MR 3.0)	0.0103 hPa at 1175 °C	not available	not available	not available
	At ambient temperatures the vapour pressure of soluble silicates is negligible.				
Partition Coeff.	The oil/water partition coefficient is not relevant, as alkali silicates are ionisable inorganic compounds.				
Water Solubility	Anhydrous solid dissolves extremely slow at ambient conditions; solutions are infinitely miscible with water; spray-dried solutions readily dissolve in water	210 g/l at 20 °C	610 g/l at 30 °C	not available	Anhydrous solid dissolves extremely slow at ambient conditions; solutions are infinitely miscible with water; spray-dried solutions readily dissolve in water
General Comments on Water Solubility	Determination of quantitative water solubilities is not feasible. Aqueous solutions are characterised by a dynamic polymerisation/hydrolysis equilibrium of monomeric SiO_2 (aq.), oligomeric silicate ions and polysilicate ions which is strongly pH-dependant. At pH below 9 silicates are present as amorphous silica (SiO_2) whose water solubility is 115 mg/l at 25°C. At pH values above 9 undissolved amorphous silica rapidly diminishes, soluble polysilicate ions aggregate and solubility of monomeric silica increases to up to 300 mg/l.				

1.5 Datamatrix of available data (continued)

Environmental Fate					
Test	**Silicic acid**				
	sodium salt **CAS-No. 1344-09-8**	**disodium salt** **CAS-No. 6834-92-0**	**disodium salt, 5-hydrate** **CAS-No. 10213-79-3**	**disodium salt, 9-hydrate** **CAS-No. 13517-24-3**	**potassium salt** **CAS-No. 1312-76-1**
Photodegradation	No photodegradation is to be expected.				
Stability in Water	See General Comments on Water Solubility				
Monitoring Data	Dissolved silica from commercial soluble silicates is indistinguishable from natural dissolved silica. Of the elemental composition of the earth's crust, SiO_2 makes up 59% and similar percentages are present in many sediments and soils. Thus, silicon is the second most abundant element on earth. Compounds of silicon and oxygen are ubiquitous in the environment; they are present in inorganic matter, like minerals and soils as well as in organic matter, like plants, animals and man. By weathering of soil, rocks and sediments and by atmospheric deposition, silica is released into surface and ground waters from where it may be removed by precipitation and sedimentation or taken up by living organisms, especially diatoms. Dead sedimenting diatoms also contribute significantly to sediment silica (diatomaceous earth). Silica is found in all natural waters with an average concentration of 10-20 mg SiO_2/l.				
Transport and Distribution	Due to a strong dependance on pH and concentration which leads to a dynamic polymerisation-depolymerisation equilibrium with speciation into a variety of mono-, oligo., and polymeric anions and amorphous silica, calculations on the distribution in various environmental compartments are not feasible. The contribution of anthropogenic inputs to the occurrence in the various compartments will be negligible compared to the concentrations contributed to by the natural silica flux.				
Biodegradation	Not applicable (inorganic substances)				

1.5 Datamatrix of available data (continued)

Ecotoxicity					
Test	**Silicic acid**				
	sodium salt **CAS-No. 1344-09-8**	**disodium salt** **CAS-No. 6834-92-0**	**disodium salt, 5-hydrate** **CAS-No. 10213-79-3**	**disodium salt, 9-hydrate** **CAS-No. 13517-24-3**	**potassium salt** **CAS-No. 1312-76-1**
Acute Fish	*Danio rerio*: LC_{50} (96 h) = 1108 mg/l (MR 3.46) *Oncorhynchus mykiss*: LC_{50} (96 h) = 260 - 310 mg/l (MR 3.1)	*Danio rerio*: LC_{50} (96 h) = 210 mg/l	not available	not available	*Leuciscus idus*: LC_{50} (48 h) = >146 mg/l (MR 4.0)
Acute Daphnid	*Daphnia magna*: EC_{50} (48 h) = 1700 mg/l (MR 3.2)	not available	not available	not available	*Daphnia magna*: EC_{50} (24 h) = >146 mg/l (MR 4.0)
Microorganisms	*Pseudomonas putida*: EC_0 (18 h) >348 mg/l (MR 3.46; not neutralized) EC_0 (18 h) >3480 mg/l (MR 3.46; neutralized) EC_0 (30 min) = 3454 mg/l (MR 3.0)	*Pseudomonas putida*: EC_0 (30 min) = 1000 mg/l *Activated sludge*: EC_{50} (3 h) = >100 mg/l	not available	not available	not available
Alga	*Scenedesmus subspicatus*: EbC_{50} (72 h) = 207 mg/l (MR 3.0) ErC_{50} (72 h) = >345 mg/l (MR 3.0)	not available	not available	not available	not available
Terrestrial	not available	not available	not available	not available	not available

1.5 Datamatrix of available data (continued)

Human Health Effects					
Test	**Silicic acid**				
	sodium salt **CAS-No. 1344-09-8**	**disodium salt** **CAS-No. 6834-92-0**	**disodium salt, 5-hydrate** **CAS-No. 10213-79-3**	**disodium salt, 9-hydrate** **CAS-No. 13517-24-3**	**potassium salt** **CAS-No. 1312-76-1**
Acute Oral (LD50)	Rat: 5150 mg/kg bw (MR 3.27) 3400 mg/kg bw (MR 2.0)	Rat: 1152 – 1349 mg/kg bw Mouse: 770 – 820 mg/kg bw	not available	not available	Rat: 5700 mg/kg bw (MR 2.25)
Acute Inhalation	not available	not available	not available	not available	not available
Acute Dermal	not available	not available	not available	not available	not available
Skin Irritation	Rabbit: Corrosive (53.5 %, MR 1.6) Irritating (40.9 %, MR 2.0) Corrosive (82 %, MR 2.4) Not irritating (39 %, MR 2.8) Not irritating (38.3 %, MR 3.3) Not irritating (34.5 %, MR 3.4)	Rabbit: Corrosive (moistened) Irritating (50% solution) Slightly irritating (10% solution)	Rabbit: Corrosive (moistened)	Rabbit: Corrosive (moistened)	Rabbit: Slightly irritating (36 %, MR 2.0) Moderately (33 %, MR 3.0) Not irritating (8.8 %, MR 3.4) Not irritating (35 %, MR 3.4) Not irritating (7 %, MR 3.9) Not irritating (29 %, MR 3.9)
Eye Irritation	Enucleated rabbit eye (in vitro, powders tested; non-validated test system) Severely irritating (MR 2.0) Severely irritating (MR 2.4) Moderately/severely irritating (MR 2.6) Moderately irritating (MR 2.8) Slightly irritating (MR 3.0) Slightly irritating (MR 3.3)	Enucleated rabbit eye (in vitro; powder tested; non-validated test system): Corrosive (MR 1.0)	not available	not available	Rabbit: Not irritating (8.8 %, MR 3.4) Slightly irritating (35 %, MR 3.4) Not irritating (7 %, MR 3.9) Not irritating (29 %, MR 3.9)

1.5 Datamatrix of available data (continued)

Human Health Effects					
Test	**Silicic acid**				
	sodium salt **CAS-No. 1344-09-8**	**disodium salt** **CAS-No. 6834-92-0**	**disodium salt, 5-hydrate** **CAS-No. 10213-79-3**	**disodium salt, 9-hydrate** **CAS-No. 13517-24-3**	**potassium salt** **CAS-No. 1312-76-1**
Sensitization	not available	Not sensitizing	not available	not available	not available
Repeated Dose	Rat: NOAEL (180 d): 159 mg/kg bw/d (highest tested dose)	Rat: NOAEL (90 d): 227 - 237 mg/kg bw/d (highest tested dose) Mouse: NOAEL (90 d): 260 - 284 mg/kg bw/d (highest tested dose)	not available	not available	not available
Genotoxicity (in vitro - bacteria)	*Escherichia coli*: negative	*Bacillus subtilis* : negative *Salmonella typhimurium* (Ames): negative	not available	not available	not available
Genotoxicity (in vitro - non-bacterial)	Chinese hamster V79 cells: no chromosomal aberrations	not available	not available	not available	not available
Genotoxicity (in vivo)	not available	Mouse (chromosomal aberration): Negative	not available	not available	not available
Carcinogenicity	not available	not available	not available	not available	not available
Toxicity to Fertility	Rat: no dose-related effect on litter size up to and including 159 mg/kg bw/d. Total no. of offspring born reduced to 67 % of control and of offspring weaned to 46 % at 79 mg/kg bw/d	Mouse: no significant effect on litter size and fertility index up to and including 200 mg/kg bw/d	not available	not available	not available
Developmental Toxicity	not available	Mouse: no significant developmental effects up to and including 200 mg/kg bw/d	not available	not available	not available

2 GENERAL INFORMATION ON EXPOSURE

2.1 Production and use

The worldwide production volume is approximately 3-4 million metric tons per year (Kuhr 1998). Production of sodium silicates and disodium metasilicates (calculated as SiO_2) in Western Europe was estimated to be 770,000 metric tons in 2000. The European consumption (including imports and excluding exports) was ca. 890,000 metric tons SiO_2. Potassium silicates were produced at approximately 22,000 metric tons (Lauriente and Sakuma 2002). Sodium silicates are produced at 34 locations in Western Europe; 11 plants are reported for potassium silicates (Briggs 2001).

Typically, solid glasses are produced in tank furnaces or rotary kilns by fusion of quartz sand and soda or potash at temperatures of 1100 - 1300 °C. The vast majority of soluble silicates produced is in the form of sodium silicates. The resulting lump glass is almost exclusively converted to aqueous solutions either at 100 °C and normal pressure or at 150 °C in the autoclave. Concentration or dilution with water and addition of alkali hydroxide is used to adjust the silicate solutions to the desired properties for the wide variety of their applications. The hydrothermal production process is less common: here silicate solutions are directly obtained from fusion of sand and sodium or potassium hydroxide at temperatures around 200 °C and under high autoclave pressure (20 bar). Readily soluble silicate powders are usually produced by spray- or drum-drying processes from solutions (Kuhr 1998).

The uses of alkali metal silicates are manifold and can only be illustrated by selected important examples (Minihan and Lovell 2000; Kuhr 1998):

- **Raw materials** for industrial products (colloidal silica, silica gel, precipitated silica, zeolites, aluminosilicates, magnesium silicates, synthetic clays, ceramics, and catalysts).
- **Detergents** (fabric washing powders, dishwasher detergents, industrial cleansing agents).
- **Adhesives and binders** (paperboard and cardboard, coal dust briquettes, roofing tiles, bricks and ceramics, refractory cements, plasters and mortars, foundry molds and cores, welding rods).
- **Surface Coatings** (TiO_2 production, concrete, paints for masonry and glass surfaces, fire-proof glass and surface coatings, spray-coating in tunnel construction and mining).
- **Pulp and paper manufacture** (deinking and bleaching).
- **Water Treatment** (corrosion protection).
- **Civil Engineering** (soil sealing and stabilisation in drilling, tunnelling, and mining, sealing of landfills, building pits, and coastline stabilisation).
- **Enhanced Oil Recovery** (oil flow improvers).
- **Textile processing** (bleach and dye stabiliser).
- **Ceramic products** (liquefying agent in porcelain slips).

Approximately 50 % of soluble silicates are further processed to derivatives; the remaining 50 % are used directly with detergents and pulp and paper as the predominant application areas. Table 1 gives a more detailed breakdown of the various applications.

Table 1: Soluble silicate usage by industry application in Western Europe for 2000 (derived from Lauriente and Sakuma 2002)

	Applications	**SiO_2 in metric kilotons**	**% of total usage**
Direct uses:	Detergents, soaps and cleaners	188	21
	Pulp and paper	136	15
	Soil stabilizers	32	3.5
	TiO_2	29	3
	Refractories	20	2
	Ceramic binders	19	2
	Miscellaneous (incl. water treatment)	15	2
	Building industry	10	1
	Welding rods	4	0.5
Derivatives:	Precipitated silica, silica gel, colloidal silica, detergent zeolites, alumino silicates, potassium silicates, molecular sieves	460	50

See appendix 1 for national information on use and quantities.

2.2 Environmental Exposure and Fate

2.2.1 Anthropogenic and natural input

Based on the data from Lauriente and Sakuma (2002) for Western Europe, the soluble silicates and their emissions into the environment can be broken down into the different application areas. About 50 % of the combined sodium and potassium silicates production (460 ktons SiO_2/year) is further processed to derivatives. Emissions to the environment may take place during production and processing, but no quantitative information is available. Another 10 % (ca. 80 ktons SiO_2/year) go into direct uses which result in inclusion into or onto a matrix (e.g. refractories, TiO_2, ceramic binders, welding rods, building industry). There is potential for release to the aqueous and terrestrial environment during production, processing and use, but no emission data are available. The remaining soluble silicates (ca. 40 % or 360 ktons SiO_2/year)) are used in applications with likely emissions into the hydro- and/or geosphere (e.g. detergents, pulp and paper, water/wastewater treatment and soil stabilization). Detergents (188 ktons SiO_2/year) and pulp and paper (136 ktons SiO_2/year) are the most important water-relevant applications and together make up about 90 % of the soluble silicates used in these application areas. Once they reach the hydrosphere, they are diluted and depolymerize rapidly to give molecular species indistinguishable from natural dissolved silica (H_4SiO_4 or SiO_2 [aq.]) in the hydrosphere. A fraction is physically removed in the sewer system or sewage treatment plant or is retained in the process or product (e.g. pulp and paper applications). The removal of soluble silicates in several sewage treatment plants was measured and an average removal of 10 % determined (van Dokkum et al. 2004). The authors assume another 10 % removal from losses through sedimentation and adsorption in the sewer system before the sewage plant. Furthermore, to determine the amount of emissions from pulp and paper applications,

mass balances of three paper mills were made and an overall removal of 60 % was determined. This comprises incorporation in the produced paper or pulp and removal in the subsequent sewage treatment. From these data emissions into surface waters of 151 ktons SiO_2/year from detergent uses and 54 ktons SiO_2/year for pulp and paper applications can be calculated.

The amount of soluble silicate introduced into the environment must be seen in the context of the background input due to geochemical weathering processes of silicate minerals. For example, the total flux of dissolved silicate transported by rivers to the sea in Western Europe is estimated to be 5 Mtons SiO_2/year (van Dokkum et al. 2004). The anthropogenic contribution to this total flux is only 4 %. However, in a local situation, the contribution of anthropogenic sources may be significantly higher: when four paper plants were analysed for their contribution to the SiO_2 background concentration of the receiving waters, a local increase of ca. 10 - 40 % was estimated (van Dokkum et al. 2004).

2.2.2 Background concentrations of silicate

Of the elemental composition of the earth's crust, SiO_2 makes up 59 % and similar percentages are present in many sediments and soils (Jackson 1964). Silica is found in all natural waters, the concentration in surface waters fluctuating markedly. The median values in the US were reported to be 17 mg SiO_2/l for ground waters and 14 mg SiO_2/l for streams (Davis 1964). The worldwide mean concentration in rivers is 13 mg SiO_2/l (Edwards and Liss 1973). The surface layers of seawater and lakes are very low in silica (commonly < 1 mg/l) apparently due to incorporation of Si into the skeletons of diatoms (Hem, 1985). The biomass, including protozoans, sponges, animals and plants, also contains soluble silica, which is an essential constituent of many biochemical processes. Diatoms and lower plants, such as grasses, are particularly rich in silica (Schleyer and Blumberg 1982). Large deposits of diatoms sedimented over geological times (diatomaceous earth or kieselguhr) are found on every continent.

2.2.3 Photo- and biodegradation

Soluble silicates are inorganic substances and therefore not amenable to biodegradation. In view of their chemical structure and inorganic nature, they are also not expected to be photodegraded. The substances have no COD or BOD impact on effluents (CEES 2003). In a simulation test following the OECD confirmatory test procedure, the elimination and influence of spray-dried sodium silicate (MR 2.1) on the biological activity of a model sewage treatment plant was determined (see chapter 4.1.4). Elimination of sodium silicate in the model sewage treatment plant was only marginal; 90 - 100 % was detected in the effluent (Richterich 1994).

Silica is continuously removed from water by biochemical processes: diatoms, radiolarians, silicoflagellates, and certain sponges serve as a sink for silicon by incorporating it into their shells and skeletons as amorphous biogenic silica, frequently referred to as opal ($SiO_2 \cdot nH_2O$). They can deplete dissolved silica in surface waters to less than 1 mg/l during blooms (Edwards 1973).

2.3 Human exposure

2.3.1 Occupational exposure

Exposure during Manufacturing

During manufacturing, workers may potentially be exposed to soluble silicates by the dermal and respiratory routes. The fusion of sand and alkali carbonate takes place in a closed furnace. After the fusion process the silicate lumps pass through alternative processing steps. They are either ground

to powders or granules in a grinder, dissolved in rotating dissolvers or the solutions may be converted to a powder by spray- or drum-drying. All these operations are performed in closed systems. In granular products 96 -98 % of the particles are between 200 µm and 1250 µm, in powdered products 80 - 90 % are greater than 50 µm, i.e. well above the respirable range (Minihan and Lovell 2000; Rhodia 2003 and 2001; Cognis 2003). Particles (too large or too small) which are rejected at the sieving step are recycled back into the system. This process is under containment. Although silicate powders contain mostly particles in the non-respirable range, mucosal damage due to the inhalation of alkaline dust particles must be prevented by wearing dust masks or by operating appropriate exhaust ventilation systems. In the EU, Japan and the USA, there are no exposure limits for sodium or potassium silicates. According to its composition, dust exposure should be limited to 2 mg/m^3, the limit concentration foreseen for caustic soda (NaOH) and potash (KOH). Dust measurements at a typical manufacturing site yielded maximum concentrations of 0.8 mg/m^3 (Henkel 2003).

Both preparation and packaging of solutions and solids are automated and performed in closed systems or with local exhaust ventilation systems in place.

For quality control, sampling is performed using a trap door. Negative pressure kept within the reactor prevents spreading of particles to the outside.

Based on the industrial hygiene assessment, for tasks where a short-term exposure greater than 2 mg/m^3 cannot be excluded, workers have to wear a portable respiratory device in addition to standard protective equipment (overalls, goggles, and gloves).

Exposure of Downstream Users

Professional downstream users may be exposed to liquid and/or aerosol (liquid silicates) or dust (silicate powders). Since the primary hazard of soluble silicates is their alkalinity, the usual precautions must be observed in handling to prevent contact with clothes, skin and in particular with the eyes. Workers are recommended to wear protective equipment (safety gloves and glasses, protective clothes, and a respiratory mask with particle filter when handling fine powders). Information is provided to the professional users through the safety data sheets.

2.3.2 Consumer exposure

Consumer exposure may occur primarily by contact with laundry or automatic dishwashing detergents. The concentrations of soluble silicates typically range from 0.1 - 10 % in laundry and from 2 - 25 % in dishwashing detergents with maximum concentrations of 25 % and 45 %, respectively (HERA, in preparation). Information from national product registers (see Appendix 1) indicates that higher concentrations may be present in some consumer products. However, the very broad concentration ranges and descriptions of product groups in conjunction with missing indications whether the data refer to consumer or industrial products make it difficult to evaluate the information. Short-term exposure to dust may occur by the use of products in powder form only, other application forms, like tablets or liquids being of no concern for the inhalation route. Generally, the average particle size in powder detergents is far in excess of respirability, since the silicates in powder form used in consumer products are sieved to retain only non-respirable particles. In addition consumer detergents are specifically formulated to form non-dusting powders: in a process called agglomeration the various dry ingredients are combined into single granular particles through the binding power of liquid silicate leading to particle sizes from 230 to 1500 microns or higher (PQ Corp. undated). Alternatively, they are provided in the form of tablets sealed by individual package allowing only limited short-term exposure. The hazard is addressed by appropriate labelling on the consumer product.

A risk assessment taking into account all possible routes of consumer exposure through the use of detergents and cleaners has been performed under the HERA project (HERA, in preparation). The cumulative systemic exposure through oral, dermal and inhalative contact was estimated to be 12.3 µg soluble silicates/kg bw/d, which is about 1 - 2 orders of magnitude lower than the estimated daily silica intake through ubiquitous natural occurrence in the diet (see below). Another route of exposure is ingestion of drinking water, as sodium silicate may be added to drinking water as a corrosion inhibitor and sequestering agent. According to European Standard EN 1209, the maximum permissible concentration is 15 mg/l (European Committee for Standardization 1997).

2.3.3 Indirect exposure via the environment

Background exposure via the environment can be expected, as compounds of silicon and oxygen are the primary constituents of earth's landmasses, and an important compound in the biomass. Dissolved silica is also a minor but widespread solute in the earth's surface waters. Silicon compounds are present in plants and animal or human organs, tissues, blood and serum (Carlisle 1986).

Silicon is a ubiquitous constituent of foods. The average daily intake of silicon is in the range of 20 - 50 mg total Si/d (corresponding to 43 - 107 mg SiO_2/d). The estimated adult silicon intake via diets in the United States of 0.32 mg Si/kg bw/d (corresponding to 0.68 mg SiO_2/kg bw/d) in females and 0.53 mg Si/kg bw/d (corresponding to 1.13 mg SiO_2/kg bw/d) in males can be viewed as representative for the intake in the Western world (Pennington 1991). While the highest concentrations of total silicon are found in seafood, eggs and dairy products; the main dietary sources are cereals and beverages.

3 HUMAN HEALTH HAZARDS

Exposure to silicate solutions means exposure to silica in the form of its various silicate anions on the one hand and alkalinity on the other hand. Both distribution of the various silicate anion species and alkalinity depend on the silica to alkali-oxide ratio and the concentration of a given solution. It is not possible to attribute any observed toxicity of a silicate solution to either silicate, alkalinity or a combination of both. However, the observed toxicological symptoms are indicative of effects due to high alkalinity. Toxicity tests executed with the dissolved pentahydrate or nonahydrate forms of the disodium salt of silicic acid (CAS no. 10213-79-3 and 13517-24-3, respectively) are directly applicable to the anhydrous form (CAS no. 6834-92-0) and vice versa, as they all have the same molar ratio. Furthermore, results obtained with sodium silicate can be extrapolated to potassium silicates of the same molar ratio, the nature of the alkali ion having no effect on the biological properties (Schleyer and Blumberg 1982; Falcone 1997; Kuhr 1998).

3.1 Toxicokinetics, metabolism and mechanism of action

Silicon is an essential trace element participating in the normal metabolism of higher animals. It is required in bone, cartilage and connective tissue formation as well as participating in other important metabolic processes. The silicon is present almost entirely as free soluble monosilicic acid (Carlisle 1986). No reliable toxicokinetic, metabolic or mechanistic studies are available for soluble silicates. Since concentrated silicate solutions are only stable at pH values above 11.5 and lowering the pH below 11.5 leads to the formation of an insoluble silica gel (cf. Figure 2), it can be reasonably assumed that after ingestion gel formation will be induced by the hydrochloric acid of the stomach. The degree of gel formation will depend on the amount of ingested silicate solution and the neutralising and buffering capacity of the gastrointestinal tract. Thus, a sodium silicate solution of molar ratio 3 would lead to precipitation of silica according to the following equation:

$3\ SiO_2 \cdot Na_2O + 2\ HCl \rightarrow 3\ SiO_2 + 2\ NaCl + H_2O$

Gastrointestinal absorption of insoluble silica will be insignificant as compared to the absorption of the soluble anions.

Ingested silicates are excreted via urine and to a lesser extent via the faeces. Markedly increased and rapid urinary excretion of silica was observed when soluble sodium silicates were administered by various routes to rats (oral, Benke and Osborn 1979), dogs (oral and intravenous, King et al. 1933), cats (oral, intraperitoneal and inhalative, King and McGeorge 1938) and guinea pigs (oral and intraperitoneal, Sauer et al. 1959). The urinary silicon excretion half-life after administration of sodium silicate to rats via stomach tube was 24 h (Benke and Osborn 1979). The excretion rate was independent of the doses applied indicating that the limiting factor is the rate of production of soluble or absorbable silicon in the gastrointestinal tract. The same observation was made with sodium metasilicate, pentahydrate in guinea pigs (Sauer et al. 1959).

3.2 Acute toxicity

3.2.1 Oral toxicity

Animal data

The results of the most relevant acute oral toxicity studies are summarised in Table 2. Only the studies by Spanjers and Til are performed under conditions comparable to OECD guidelines.

Sodium silicates and metasilicates

Sodium silicates of varying molar ratios from 0.5 to 3.38 have been tested in rats. Toxicity decreased with increasing molar ratio: from LD_{50} of 500 mg/kg bw for molar ratio 0.5 to 8650 mg/kg bw for 3.38. This shows the inverse correlation between MR and toxicity. The majority of the test results are cited as secondary literature only (Schleyer and Blumberg 1982), but several study reports are available, albeit in limited detail (Potokar 1982; Gloxhuber and Potokar 1971a and b; Gloxhuber et al. 1973; Saiwai 1980; Spanjers and Til 1981a, b). Clinical symptoms observed near to or exceeding the LD_{50} values (Saiwai 1980) consisted of apathy, staggering gait, dyspnoea, piloerection, abdominal discomfort, and unconsciousness. The results of autopsy revealed acute gastro-enteritis, vascular congestion, mottled livers, changes in pH of body fluids, shock, chemical irritation and/or corrosion of the viscera. All symptoms are indicative of effects due to high alkalinity.

Potassium silicates

One study with rats assesses the acute oral toxicity of a potassium silicate (molar ratio 2.25) (Spanjers and Til 1981c). The LD_{50}-value was 5700 mg/kg bw. All clinical effects: sedation, signs of abdominal discomfort, sluggishness and unconsciousness, were reversible. No treatment-related gross alterations were found at autopsy.

Human data

Ingestion of 200 ml of sodium silicate egg preserving solution (they have typically a molar ratio of 3.2 and concentrations in the range of 5 - 36 %) caused severe vomiting, diarrhea and bleeding, elevated blood pressure, and renal damage, but was not fatal (Schleyer and Blumberg 1982). Ingestion of 500 ml of an egg-preserving solution containing sodium silicate in suicidal intention led to the death of a 68 year old woman within 1 hour by suffocation. Aspiration of the vomited silicate solution caused obstruction of the lungs by precipitation of amorphous silica. The

transformation of sodium silicate from liquid to solid occurred in the lungs by means of the carbonic acid of expiration air (Sigrist and Flury 1985).

Conclusion

The acute oral toxicity of soluble silicates is generally inversely correlated to the molar ratio SiO_2/Na_2O. Toxicity decreases in rats with increasing molar ratio from LD_{50} of 500 mg/kg bw for molar ratio 0.5 to 8650 mg/kg bw for 3.38. The one solitary study on potassium silicate fits well into the toxicity pattern of the sodium silicates.

Table 2: Results of acute oral toxicity studies

Silicate (molar ratio SiO_2/M_2O)	Na/K	Concentration (wt. %)	LD_{50} (mg/kg bw)	Species	Reference
2.25[e]	K	-	5700	Rat	Spanjers and Til 1981c *
3.38[c]	Na	35[c]	8650	Rat	Gloxhuber and Potokar 1971b
3.35[a]	Na	-	6600	Mouse	Gloxhuber 1973
3.3	Na	36	3200	Rat	Schleyer and Blumberg 1982
3.3	Na	-	> 2000	Rat	Potokar 1982
3.27[d]	Na	-	5150	Rat	Spanjers and Til 1981a *
3.1	Na	-	1600, 8600	Rat	Schleyer and Blumberg 1982
2.1	Na	-	1300, 2100	Rat	Schleyer and Blumberg, 1982
2.1	Na	81	1500 - 2200	Rat	Schleyer and Blumberg 1982
2.0[f]	Na	-	3400	Rat	Spanjers and Til 1981b *
1.7	Na	51	2000, 2500	Rat	Schleyer and Blumberg 1982
1.0[b]	Na	98[b]	1750	Rat	Gloxhuber and Potokar 1971a
1.0	Na	99	600	Rat	Schleyer and Blumberg 1982
1.0	Na	50	800	Rat	Schleyer and Blumberg 1982
1.0	Na	20	1152 - 1349	Rat	Saiwai 1980 *
1.0	Na	10	770 - 820	Mouse	Saiwai 1980 *
0.7	Na	61	1000, 1500	Rat	Schleyer and Blumberg 1982
0.5	Na	90	500	Rat	Schleyer and Blumberg 1982

* critical study for SIDS endpoint
\- not specified
a not specified in report whether it concerns a weight or molar ratio
b calculated on the basis of 51 % Na_2O and 47 % SiO_2
c calculated on the basis of 8 % Na_2O and 27 % SiO_2
d natron waterglass 38/40 (3.27), no further specification in study (density 1.37)
e kali waterglass 35.5/36.5 (2.25), no further specification in study (density 1.32)
f natron wasserglas 40/42 (2.0), no further specification in study (density 1.39)

3.2.2 Inhalation and dermal toxicity

No data are available on acute inhalation and dermal toxicity of soluble silicates. In view of the irritating or corrosive properties of undiluted, concentrated soluble silicates (cf. Section 3.3) which would result in severe local effects, studies on inhalation or dermal toxicity are neither feasible nor justifiable as far as animal welfare considerations are concerned. In addition, as outlined in Section

3.6.2, physico-chemical properties would cause technical problems preventing the generation of precise and appropriate doses in inhalation studies.

3.3 Skin irritation

Animal data

Several primary skin irritation studies have been performed in rabbits (presented in Table 3), including studies by Cuthbert and Carr (1985), ECETOC (1995), Heisler (1990a, b), Heisler (1993a, b), Karlsson and Loden (1984) and Mercier (1990a, b) performed in compliance with or under similar conditions as the relevant OECD guidelines.

Sodium silicates and metasilicates

The degree of irritation caused in the studies, indicate that the irritation response is inversely correlated with the molar ratio of the silicates; a lower molar ratio SiO_2 : Na_2O leads to a higher irritation score and vice versa. This correlation is superimposed by the concentration effect: lower concentrations will exhibit lower irritancy as compared to higher concentrations of the same molar ratio. The inverse correlation with molar ratio is demonstrated by the studies of Cuthbert and Carr (1985) where sodium silicates of comparable concentrations (38 - 41 %) but different molar ratios were tested. Whereas ratios of 2.0 and 2.4 exhibited irritating properties, ratios of 2.8 and 3.3 were not irritating. The concentration effect becomes evident when the irritancy of identical molar ratios but different concentrations are compared. A sodium silicate of MR 2.4 is irritating at 40 % and corrosive at 82 % (Cuthbert and Carr 1985; Karlsson and Loden 1984); sodium metasilicate is irritating at 10 % and corrosive at 50 % (ECETOC 1995). Sodium silicates of molar ratios 1.6 and below and concentrations greater than 50 % are corrosive. Sodium metasilicate, when tested as an anhydrous powder was not irritating to the skin; when moistened with water it was found to be corrosive (Mercier 1990a, b).

Potassium silicates

The limited studies available for potassium silicates are in line with the inverse correlation of skin effects and molar ratio that is observed for sodium silicates. Likewise, higher concentrations of the same molar ratio are expected to exhibit higher irritating potential. As observed with sodium silicates, potassium silicates of comparable concentrations and different molar ratios show the same inverse correlation to irritancy. Molar ratios of 2.0 and 3.0 and 33 - 36 % concentrations were irritating to the skin (Cuthbert and Carr 1985), whereas MR 3.4 and 3.9 (29 - 35 %) showed no irritation (Heisler 1990a, b; Heisler 1993a, b). The results indicate that the counterions of soluble silicates have no influence on skin irritation.

Human data

In an open epicutaneous test performed according to COLIPA, volunteers were exposed to 5, 10 or 50 % aqueous solutions or undiluted sodium silicate solution (MR 3.45) for 30 minutes (Kremer, 1997a). The light redness experienced by 2 - 3 of the 20 volunteers in each group tested with an aqueous solution disappeared within 20 minutes. The wax-like undiluted solution did not cause adverse effects. Under semi-occlusive (but otherwise identical) conditions, both a 50 % aqueous solution and undiluted solution resulted in peeling of the skin in a third of the subjects after 4 hrs exposure (Kremer 1997b). The study corresponded to OECD 404, with adjustments for human subjects. Both studies were performed under Good Clinical Practice.

Conclusion

Sodium and potassium silicates can be irritating to corrosive to the skin of rabbits, depending on their molar ratio and concentration. The nature of the counterion (Na^+ or K^+) has no influence as sodium and potassium silicates behave similarly with respect to skin irritation. Any effects on the skin decrease with increasing molar ratio, superimposed by increasing irritancy with increasing concentrations.

Table 3: Results of acute skin irritation studies

Silicate (MR SiO_2 / M_2O)	Na / K	Concentration (wt. %)	Result / PII [1]	Conclusion	Method	Reference
3.3	Na	38.3	0.33	-	OECD 404, 1981	Cuthbert and Carr 1985
2.8	Na	39	0	-		
2.4	Na	39.9	3	I		
2.0	Na	40.9	3	I		
1.0	Na	NR[2]	8	C		
1.0 (5 aq)	Na	NR[2]	8	C		
1.0 (9 aq)	Na	NR[2]	8	C		
3.4	Na	34.5	0.4	-	OECD 404, 1981	Karlsson and Loden 1984
2.4	Na	82[3]	4.6	C		
1.6	Na	53.5	8	C		
1.0 (5 aq)	Na	57.5[3]	7.8	C		
1.0	Na	97[3]	5.1	C		
1.0	Na	83[4]	4.67	C	OECD 404, 1981	Mercier 1990a
1.0	Na	100[3]	0.17	-		Mercier 1990b
1.0	Na	50	3.67	I-C	OECD 404	ECETOC 1995
1.0		10	1.22	I		
3.0	K	33	3	I	OECD 404, 1981	Cuthbert and Carr 1985
2.0		36	1	I		
3.9	K	29	0.25	-	OECD 404	Heisler 1990b
3.9		7	0	-		Heisler 1990a
3.4		35	0.17	-		Heisler 1993b
3.4		8.8	0	-		Heisler 1993a

- Not irritating
C Corrosive
I Irritating
NR Not reported
1 Primary Irritation Index
2 Sodium silicate powder, moistened before application to the skin. Application of dry powder did not cause irritation.
3 Sodium metasilicate powder was applied dry to the skin.
4 Sodium silicate powder, applied as an 83 % aqueous paste

3.4 Ocular irritation

Several *in vivo* and *in vitro* eye irritation studies have been performed in rabbits, of which only the studies by Heisler (1990c, d; 1993c, d) with potassium silicates were performed according to OECD guidelines. The results are presented in Table 4.

Sodium silicates and metasilicates

A series of non-validated *in vitro* studies indicate the same inverse correlation between molar ratio and irritation that has been observed for skin irritation (York et al. 1994; Wilson and Hartop 1993; Wilson and Lea 1994). The powders of varying molar ratios exhibited effects in enucleated rabbit eyes ranging from corrosive (MR 1.0) to severely irritating (MR 2.0, 2.4 and 2.6) to slightly irritating (MR 2.8, 3.0 and 3.3). As these results originate from non-validated test systems, their reliability is uncertain.

Potassium silicates

Potassium silicates have been tested on the rabbit eye at molar ratios of 3.4 and 3.9. At concentrations of 35 % or lower they are not or only slightly irritating (Heisler 1990c, d; Heisler 1993c, d).

Conclusion

At concentrations of 35 % and 29 % (highest tested concentrations) potassium silicates with molar ratios of 3.4 and 3.9 were only slightly, and not irritating to the eyes of rabbits, respectively. Results from non-validated *in vitro* assays indicate that the severity of eye effects is inversely correlated with the molar ratio, with corrosive effects found in the enucleated rabbit eye test after exposure to disodium silicate powder with a molar ratio of 1.0.

Table 4: Results of acute eye irritation studies

Silicate (MR SiO_2 / M_2O)	Na / K	Concentration (wt.%)	Result	Method	Reference
3.3[1]	Na	Powder[3]	Slightly irritating	*In vitro* enucleated rabbit eye irritation study[2] (non-validated test system)	York et al. 1994; Wilson and Hartop 1993; Wilson and Lea 1994
3.0[1]			Slightly irritating		
2.8[1]			Moderately irritating		
2.6[1]			Moderately/ severely irritating		
2.4[1]			Severely irritating		
2.0[1]			Severely irritating		
1.0			corrosive		
3.9	K	29	Not irritating	OECD 405	Heisler, 1990d
3.9		7	Not irritating		Heisler, 1990c
3.4		35	Slightly irritating		Heisler, 1993d
3.4		8.8	Not irritating		Heisler,1993c

- not reported

1 not specified in report whether it is a molar or weight ratio

2 1 minute exposure to the test substance, except for MR 1.0 where exposure was only for 10 sec.

3 50 mg water-soluble powder of dried silicate solution applied. Dried silicate solutions usually contain about 20 % residual water.

3.5 Sensitization

Skin

Sodium silicates and metasilicates

Karrow et al. (2002) tested the sensitisation potential in the local lymph node assay. Sodium metasilicate did not exhibit a significant effect on cell proliferation in the auricular lymph nodes of mice after sensitisation with 2, 4, and 6 % metasilicate for 3 consecutive days.

Human data

Tanaka et al. (1982) describe a 57-year-old worker, who had suffered recurrent ulcerative lesions on his left hand for two years, after repeated occupational exposure to 20 % aqueous sodium silicate. In a 24-hour patch test with 20 % sodium silicate (MR unspecified) ulcer formation could be elicited in the patient, but not in 30 healthy volunteers. An immediate wheal formation was observed in the patient 15 minutes after a scratch test was performed with 20 % metasilicate, whereas 30 control subjects did not show wheal formation.

Potassium silicates

No data available.

Respiratory Tract

Sodium metasilicate is nominated to the National Toxicology Program for Respiratory Sensitisation Testing (Federal Register, 2002). The technical limitations of the realisation of such an experiment are discussed in chapter 3.6.2.

Conclusion

Sodium metasilicate was not sensitising in the local lymph node assay. In a case study contact urticaria induced by sodium silicate was observed.

3.6 Repeated dose toxicity

3.6.1 Oral toxicity

Sodium silicates and metasilicates

Newberne and Wilson (1970) fed 2400 mg sodium silicate/kg bw/day of unspecified molar ratio, to Beagle dogs (8/sex) and rats (15/sex) via the diet for a period of four weeks. The study design was similar to OECD guideline 407. Significant clinical observations were polydipsia, polyuria and soft stools in an unspecified number of dogs and rats. Body weight, food intake, and urinary and blood measurements were essentially normal in all animals. All chemical clinical tests were within normal limits. Gross cortical lesions of the kidney were observed in all male and 7/8 female dogs fed sodium silicate, but not in rats. Histopathological examination revealed irritation of the renal tubular epithelium followed by degenerative and regenerative changes and inflammatory cell infiltration into the interstitium.

Smith et al. (1973) exposed male and female rats (6/sex/group) to sodium silicate (MR 3.2) in drinking water for a period of 180 days. The animals were administered the equivalent of 600 and 1200 mg SiO_2/l, corresponding to 78.9 and 158.7 mg sodium silicate/kg bw/d with a diet containing 0.1 to 1.0 % of SiO_2 (based on dry weight). Body weight and mortality were the only parameters monitored. Statistically significant differences in body weight between experimental groups and

controls were registered, but these were small (6 % or less), not consistent and not dose related. No mortalities were observed. After 180 days exposure, the male rats were used in a nitrogen and phosphorous retention study during a total of 17 days. Phosphorus retention was somewhat increased in the high dose group (approximately 12 %), while in the low dose group no effect of treatment was seen. Nitrogen retention was 50 % of controls in the lower dose group only.

Ito et al. (1975) conducted a 3-month toxicity study in rats (5/sex/group) with sodium metasilicate, administered via drinking water in concentrations of 200, 600 and 1800 mg/l (corresponding to approximately 26.4, 76.2 and 227.1 mg/kg bw/d for males and approximately 32.1, 97.6 and 237.2 mg/kg bw/d for females.). The study conditions were similar to OECD guideline 408. No clearly treatment related effects were found.

In a 3-month feeding study reported by Saiwai *et al.* (1980), 10 mice/sex/dose were exposed to sodium metasilicate in the drinking water at concentrations of 300, 900 and 2700 ppm (males) and 333, 1000 and 3000 (females). This corresponds to 96 - 100, 264 - 280 and 776 - 832 mg/kg bwl/d for males and 88 - 104, 260 - 284 and 716 - 892 mg/kg bw/d for females. Parameters examined were body weight, urinalysis, clinical chemistry, haematology, organ weights, and histopathology. No fatalities occurred. In females a significant decrease in pituitary glands weight was observed in the highest dose group. Other effects occasionally observed were single incidences and not dose-related.

Kayongo-Male and Jia (1999) studied the effect of various Silicon sources added to diets of rats and turkeys. Rats were exposed for 8 weeks to sodium metasilicate, pentahydrate at 500 ppm Si (corresponding to 1259 mg metasilicate/kg bw/d). Parameters examined were body weight, organ weight (liver and heart), hemoglobin, hematocrit, and mineral concentrations in blood plasma and organ tissues (liver and heart). No effects on body and organ weights were observed, whereas plasma Ca and Mg and liver Zn were reduced significantly. Turkeys exposed to 270 ppm Si (corresponding to 2039 ppm sodium metasilicate, pentahydrate,) for 4 weeks in a similar experiment did not exhibit significant effects on body and organ weights. Plasma P was increased and Cu was decreased. Minerals in heart and liver tissue were unaffected.

Potassium silicates

No studies are available for potassium silicates.

Table 5: Repeated dose toxicity of soluble silicates

Species	Exposure Period	Test Substance / Dosage	Effects	Reference
Rat	4 weeks	Sodium silicate (MR unspecified) 2400 mg/kg bw/d via diet	Polydipsia, polyuria and soft stools in an unspecified number of animals.	Newberne and Wilson (1970)
Rat	180 days	Sodium silicate (MR 3.2) 79 and 159 mg/kg bw/d via drinking water	No treatment-related effects[1].	Smith et al. (1973)
Rat	3 months	Sodium metasilicate 26.4, 76.2 and 227.1 mg/kg bw/d (males) and 32.1; 97.6 and 237.2 mg/kg bw/d (females) via drinking water	No treatment-related effects.	Ito et al. (1975)
Rat	8 weeks	Sodium metasilicate, pentahydrate 1259 mg/kg bw/d via the diet	Reduction of blood plasma Ca and Mg and liver Zn concentrations. No other effects[2].	Kayongo-Male and Jia (1999)

Table 5 (cont.): Repeated dose toxicity of soluble silicates

Species	Exposure Period	Test Substance / Dosage	Effects	Reference
Mouse	3 months	Sodium metasilicate 96-100, 264 - 280 and 776 - 832 mg/kg bw/d (males) and 88 - 104, 260 - 284 and 716 - 892 mg/kg bw/d (females) via drinking water	Females showed reduced pituitary glands weight at 716 - 892 mg/kg bw/d. No other dose-related effects.	Saiwai et al. (1980)
Dog	4 weeks	Sodium silicate (MR unspecified) 2400 mg/kg bw/d via diet	Gross cortical lesions of kidneys in all males and 7/8 females. Polydipsia, polyuria and soft discoloured feces in an unspecified number of animals.	Newberne and Wilson (1970)
Turkey	4 weeks	Sodium metasilicate, pentahydrate 2039 ppm in the diet	Increased blood plasma P and decreased Cu. No other effects[2].	Kayongo-Male and Jia (1999)

[1] body weight , mortality and nitrogen/phosphorus excretion were only parameters monitored.

[2] a limited number of parameters was monitored: body, liver and heart weight, hemoglobin, hematocrit and mineral concentrations in blood plasma and livers and hearts.

Conclusion

Repeated dose toxicity studies with sodium silicate or sodium metasilicate ranging from 4 weeks to 180 days have been conducted with rats, mice, dogs and turkeys. The only treatment-related effects observed in rats were:

- polydipsia, polyuria and soft stools at 2400 mg/kg bw/d (sodium silicate of unspecified MR; 4 weeks exposure).
- Reduction of blood plasma Ca and Mg and liver Zn concentrations at 1259 mg/kg bw/d (sodium metasilicate, pentahydrate; 8 weeks exposure).

In female mice, a reduced pituitary glands weight was observed at 716 - 892 mg/kg bw/d (sodium metasilicate; 3 months exposure). Dogs exhibited gross cortical lesions of the kidneys, polydipsia, polyuria and soft feces at 2400 mg/kg bw/d (sodium silicate of unspecified MR; 4 weeks exposure). In turkeys, blood plasma P was increased and Cu decreased at 2039 mg/kg diet (sodium metasilicate, pentahydrate; 8 weeks exposure).

From these studies a NOAEL (90 d) of 227 - 237 mg/kg bw/d can be derived for rats. The NOAEL (90 d) for mice is 260 - 284 mg/kg bw/d.

3.6.2 Inhalation and dermal toxicity

No repeated dose animal studies on the inhalation and dermal toxicity of silicates are available. Sodium metasilicate has been nominated to the National Toxicology Program (NTP) for Toxicological Studies in the United States. A subchronic inhalation study was recommended by the National Institute for Occupational Safety and Health (Federal Register 2002). At present, the technical feasibility and practical relevance of such a study is under discussion with the following points to consider:

First, commercial sodium metasilicates are sieved to contain only large non-respirable particles of > 200 µm in granular products, or > 50 µm in powders (Minihan and Lovell 2000; Rhodia 2003 and

2001; Cognis 2003), i.e. the commercial products are non-respirable. For the inhalation assay grinding to a fine and respirable powder would be required, representing a test substance which is not existing under real life conditions.

Second, due to the hygroscopic properties and the ready solubility in water, the majority of particles, if inhaled, will be retained and dissolved by mucus in the upper respiratory tract. Thus, effects would be restricted to local corrosive/irritant effects, due to the intrinsic alkalinity of sodium metasilicate. Furthermore, acidification to pH below 11 or 12 leads to precipitation of sodium metasilicate and transformation into amorphous silica. Amorphous silica has already been investigated and toxicological properties, including inhalation toxicity, are available on this compound.

Third, because of its hygroscopic properties, anhydrous sodium metasilicate tends to aggregate in the presence of moisture, and this limits further the technical realisation of such a study without specific conditions to maintain a dry atmosphere.

3.7 Genetic toxicity

3.7.1 Genetic toxicity in vitro

Sodium silicates and metasilicates

Sodium metasilicate was tested for DNA-damaging capacity and mutagenicity in the *Bacillus subtilis* strains H17 (Rec-, arg-, try-) and M45 (Rec+, arg-, try-). The result was negative for concentrations 0.005 - 0.5 M, however the test did not comply with an approved guideline (Kanematsu et al. 1980). An Ames test with sodium metasilicate, performed according to current guidelines using *Salmonella typhimurium* TA98, TA100, TA1535 and TA1537 with and without metabolic activation did not reveal a mutagenic activity for concentrations 0.1 - 10 mg/plate (Saiwai et al. 1980; Ito et al. 1986).

Sodium silicate of unspecified MR and concentration was investigated in the streptomycin-dependent strains *Escherichia coli* B/Sd-4/1,3,4,5 and B/Sd-4/3,4 in a non-guideline study. No evidence of mutagenicity was observed at concentrations of 0.025 - 0.3 % (Demerec et al. 1951). Of the 31 chemicals tested in this study, 19 were found to be mutagenic, indicating in the absence of positive control data that the test was sensitive and could detect a mutagenic activity.

An aqueous sodium silicate solution (36 % active ingredient; WR = 3.3) was tested in a chromosomal aberration study according to OECD TG 473 (Schulz, 2006). Chinese hamster V79 lung fibroblast cells were treated with sodium silicate solutions containing 19.5, 39.1, 78.1 or 156.3 µg active ingredient/ml for 4, 18 or 28 hours (without metabolic activation) or for 4 hours (with metabolic activation by rat liver S-9 mix). Concentrations of 156.3 µg/ml or greater caused the precipitation of the test substance, and were cytotoxic in the experiments without metabolic activation. No biologically relevant increases in chromosomal aberrations and in the frequencies of polyploid metaphases were found both in the experiments with and without metabolic activation.

Potassium silicates

No studies are available for potassium silicates.

Conclusion

The available *in vitro* genotoxicity tests with bacteria were all negative. In a modern guideline study that was performed in accordance with OECD TG 473, sodium silicate solution (36 % active

ingredient) induced no chromosomal aberrations in V79 cells, both in the absence and in the presence of metabolic activation.

3.7.2 Genetic toxicity *in vivo*

Sodium silicates and metasilicates

Sodium metasilicate was tested in a cytogenetic test for chromosome aberrations in bone marrow cells of male mice in a study similar to OECD TG 475 with the restriction that no information on the use of positive controls was available. Groups of 4 - 6 animals were administered single oral doses of sodium metasilicate at dose levels between 740 and 1340 mg/kg bw (in total, seven dose levels were used in this study). Animals were sacrificed 24 hours after the last administration of the test substance; 2 hours before sacrifice a metaphase arresting agent (colchicine; 4 mg/kg bw) was injected intraperitoneally. Slides from femur bone marrow cells were prepared according to standard methods, and 100 metaphases per animal analyzed for chromosomal aberrations (including gaps, breaks, deletions, and exchanges). No indication of chromosomal aberrations was detected. In a range-finding study, no mortality occurred within 4 days after administration in animals dosed up to 940 mg/kg bw. Mortality occurred at higher doses (Saiwai et al. 1980).

Potassium silicates

No studies are available for potassium silicates.

Conclusion

Sodium metasilicate was not mutagenic in an *in vivo* chromosomal aberration study performed similarly to OECD TG 475, with the restriction that no information on the use of positive controls was available for this study. Although the reliability of this study can therefore not be fully evaluated, the negative result is corroborated by the fact that the chemical structure does not contain elements that raise concern for a genotoxic activity, and by the negative results of genotoxicity tests with sodium silicate.

3.8 Carcinogenicity

No valid data are available for sodium or potassium silicates.

3.9 Reproduction / developmental toxicity

3.9.1 Effects on fertility

Sodium silicates and metasilicates

In a limited 4-generation study, Smith et al. (1973) assessed the effect of sodium silicate (MR 3.2) administered via drinking water to rats. The exposure concentration was 600 and 1200 mg SiO_2/l, corresponding to 79 and 159 mg sodium silicate/kg bw/d from weaning until mating. Control groups received no sodium silicate in their drinking water. For 4 consecutive generations, the rats were mated and the total number of offspring analysed. The average litter sizes were 9.6, 6.8 and 8.4 animals/litter for the 0, 600 and 1200 mg/l groups, respectively. Survival of offspring until weaning was poor, even in the controls (35, 24, and 11% at 0, 79, 150 mg/kg bw/d, respectively). The total number of offspring born was reduced to 67 % of the controls at 79 mg/kg bw/d and to 80 % at 159 mg/kg bw/d. Litters born to females receiving silicate were frequently stillborn or small and weak, with survival limited to only a few days. In addition, cannibalism was prevalent and necrosis of the tail and occasionally the feet was observed in offspring of silicate-treated animals.

Severe limitations of the study and intercurrent deaths, including controls, make it difficult to draw any firm conclusions from this study.

Potassium silicates

No data are available.

3.9.2 Developmental toxicity

Sodium silicates and metasilicates

In a developmental toxicity study by Saiwai *et al*. (1980), pregnant mice were administered 12.5, 50 or 200 mg/kg bw/d sodium metasilicate in aqueous solution from day 0 until 17/18 of gestation by daily gavage. Among the mother animals 2 fatalities occurred both in the 50 and 200 mg/kg group (total number of animals: 33 and 27, respectively); body and organ weights and dissection findings were not affected. On day 18 of gestation fetuses were delivered by hysterectomy and examined. No differences to controls were observed for the following parameters: number of pregnancies and living or dead fetuses, body weight and malformations of inner organs and the skeleton. 10 mother animals were allowed to deliver their young naturally. The neonates were observed for 30 days. Litter size and fertility index were not significantly affected up to and including 200 mg/kg bw/d. Body weight gain, organ weights and behavioral development did not reveal any differences to the control. Skeletal malformations did not exhibit a correlation with dosage. A dose-related decrease in the number of neonates was observed, however, this was not statistically significant.

Potassium silicates

No data are available.

3.9.3 Other studies

In a study by Kamboj and Kar (1964), male rats were injected subcutaneously and intratesticularly with doses of 0.08 mmole/kg sodium silicate (MR not specified). When the testes were examined 7 d after injection, no morphological or histological effects were seen in either application route nor was there any effect on residual spermatozoa in the ductus deferens. Testicular weight was slightly reduced as compared to controls injected with sterile water.

Some of the available subchronic/chronic repeat dose studies (cf. 3.6.1) shed also light on the effects of sodium silicates on the reproductive organs:

In the 3-month study performed by Sawai et al. (1980) with mice, exposure via drinking water to metasilicate concentrations up to and including 832 and 892 mg/kg bw/d for males and females, respectively, did not show treatment-related effects on the pathohistology of testes and ovaries. The mean wet weight of these organs was also not affected (testes: 0.13 - 0.14 g for control; 0.12 - 0.14 g for dosage groups; ovaries: 7.3 - 8.4 g for control; 7.4 - 9.7 g for dosage groups).

No effects on the male and female reproductive organs were observed upon macroscopic and microscopic examination when rats were exposed to 200, 600 and 1800 ppm in drinking water (26, 76 and 227 mg/kg bw/d for males; 32, 98 and 237 mg/kg bw/d for females) for 3 months (Ito et al. 1975).

Rats and beagle dogs were exposed to sodium silicate of unknown molar ratio for 4 weeks at a single concentration of 2400 mg/kg bw/d via the diet. According to the authors, a complete necropsy and histopathological study was performed and no treatment-related effects except in the kidneys observed (Newberne and Wilson 1970).

Conclusion

The available data on toxicity to reproduction are limited. In a 4-generation study, the total number of offspring born at 79 mg/kg bw/d was reduced to 67 % and of offspring weaned to 46 % of the control, respectively. Severe limitations of the study and intercurrent deaths, including controls, make it however difficult to draw any firm conclusion from this study. In mice, litter size and fertility index were unaffected at sodium metasilicate concentrations up to and including 200 mg/kg bw/d. No developmental effects were observed in this study up to and including 200 mg/kg bw/d. In repeat dose toxicity studies with rats, mice and dogs the macroscopic and microscopic examination of reproductive organs did not reveal treatment-related effects. In view of the limited data on reproduction and developmental toxicity further studies would be desirable. However, the irritating or corrosive properties of undiluted, concentrated soluble silicates (cf. Section 3.3) would result in severe local effects and are therefore neither feasible nor justifiable with respect to animal welfare. Dilution of the test material to avoid corrosive effects would make it difficult to administer high doses whereas neutralisation would lead to precipitation of SiO_2 thus altering the chemical identity of the test substance.

3.10 Initial Assessment of Human Health

The limited toxicokinetic studies on rats, cats, dogs and guinea pigs all showed that the excretion of silicon with the urine was markedly increased after ingestion of silicates. The excretion rate was independent of the doses applied indicating that the limiting factor is the rate of production of soluble or absorbable silicon in the gastrointestinal tract.

The oral LD_{50} in rats was 1152 – 5700 mg/kg bw depending on the molar ratio of the silicate species, i.e. toxicity decreases with increasing molar SiO_2:MeO_2 ratio. Clinical signs included apathy, staggering gait, tonic cramps, dyspnoea, cyanosis, piloerection and signs of abdominal discomfort.

Sodium and potassium silicates can be irritating to corrosive to the skin of rabbits, depending on their molar ratio and concentration. The nature of the counterion (Na^+ or K^+) has no influence as sodium and potassium silicates behave similarly with respect to skin irritation. Any effects on the skin decrease with increasing molar ratio, superimposed by increasing irritancy with increasing concentrations. At concentrations of 35 % and 29 % (highest tested concentrations) potassium silicates with molar ratios of 3.4 and 3.9 were only slightly, and not irritating to the eyes of rabbits, respectively. Results from non-validated *in vitro* assays indicate that the severity of eye effects is inversely correlated with the molar ratio, with corrosive effects found in the enucleated rabbit eye test after exposure to disodium silicate powder with a molar ratio of 1.0.

In a mouse local lymph node assay, sodium metasilicate was not sensitising. In humans, a single case of contact urticaria elicited by sodium silicate is reported.

Soluble silicates have been tested in a number of repeated dose studies with exposures ranging from 28 to 180 days. The NOAELs (90 d) of sodium metasilicate were 227 - 237 mg/kg bw/d for rats and 260 - 284 mg/kg bw/d for mice (highest tested dose levels, respectively). Sodium silicate had a NOAEL (180 d) of 159 mg/kg bw/d for rats (highest tested dose). In mice the LOAEL (90 d) of sodium metasilicate was 716 - 892 mg/kg bw/d with reduction of pituitary glands weight in female mice as adverse effect. Adverse effects in rats, dogs and turkeys were polydipsia, polyuria and soft stools, reduction of blood plasma Ca and Mg levels, and of liver Zn concentrations, gross cortical lesions of the kidneys or increased blood plasma P and decreased Cu at doses above 1000 mg/kg bw/d.

In vitro, soluble silicates did not induce gene mutations in bacteria: sodium silicate was negative in an *E. coli* reverse mutation assay and sodium metasilicate exerted no mutagenic activity in *B. subtilis* and *S. typhimurium*. In a modern guideline study that was performed in accordance with OECD TG 473, sodium silicate solution (36 % active ingredient) induced no chromosomal aberrations in V79 cells, both in the absence and in the presence of metabolic activation. *In vivo*, sodium metasilicate did not induce chromosomal aberrations in bone marrow cells of mice in a study performed similar to OECD TG 475, with the restriction that no information on the use of positive controls was available for this study. Although the reliability of this study can therefore not be fully evaluated, the negative result is corroborated by the fact that the chemical structure does not contain elements that raise concern for a genotoxic activity and by the negative results of genotoxicity tests with sodium silicate. For the group of soluble silicates under review here, it is therefore concluded that there is no evidence of a genotoxic potential.

There were no valid carcinogenicity studies available.

The available data on toxicity to reproduction are limited. In a 4-generation study, the total number of offspring born at 79 mg/kg bw/d was reduced to 67 % and of offspring weaned to 46 % of the control, respectively. Severe limitations of the study and intercurrent deaths, including controls, make it however difficult to draw any firm conclusion from this study. In mice, litter size and fertility index were unaffected at sodium metasilicate concentrations up to and including 200 mg/kg bw/d. No developmental effects were observed in mice up to and including 200 mg/kg bw/d. In repeat dose toxicity studies with rats, mice and dogs the macroscopic and microscopic examination of reproductive organs did not reveal treatment-related effects.

4 HAZARDS TO THE ENVIRONMENT

4.1 Aquatic effects

The majority of tests was performed without analytical verification. In these cases, the effect data refer to the nominal concentrations.

4.1.1 Effects on fish

Sodium silicates and metasilicates

Two guideline studies with the freshwater Zebra-fish *Danio rerio* were performed. In the first study, sodium metasilicate (MR 1.0) had a 96 h LC_{50} of 210 mg/l at pH 9.1 - 9.8 (Richterich and Mühlberg 2001d). The study was performed following guideline ISO 7346/2, but not according to GLP. The second study, following OECD guideline 203 was performed under GLP: for a sodium silicate solution (MR 3.46, 34.8 wt%) the 96 h LC_{50} was 1108 mg active matter/l. The NOEC values for mortality and swimming behaviour were 348 and 1114 mg active matter/l, respectively (Adema 1988). The pH varied depending on the test substance concentration from 7.9 to 10.3.

In two non-guideline studies offering limited information on the test conditions, the following results were observed. The 96 h LC_{50} of sodium silicate (MR and concentration not indicated) to the freshwater mosquito-fish *Gambusia affinis* was established by Wallen *et al.* (1957) as 2320 mg/l at pH 8.9 - 10.1. Maruyama et al. (1989) examined the toxicity of a neutralised sodium silicate solution (MR 3.1, concentration not indicated) to rainbow trout (*Oncorhynchus mykiss*). In four replicates the 96 h LC_{50} varied from 260 mg/l (pH 6.8 - 7.5,) to 310 mg/l (pH 7.2 - 8.0). Necrosis of gill filaments as a result of the formation of colloidal silica was observed. However, this is considered a physical rather than toxic effect.

No studies are available for sodium metasilicate, penta- and nonahydrate.

Potassium silicates

A 48-hour toxicity test was performed with freshwater golden orfes (*Leuciscus idus*) according to DIN 38412/15, a German standard method that corresponds to OECD guideline 203. When exposed to 500 mg/l of a potassium silicate solution (MR 3.9 – 4.1, 29.1 wt%) at unknown pH no mortality or signs of toxicity were observed (Richterich and Mühlberg 2001b). The 48 h LC_{50} is therefore > 146 mg active matter/l.

4.1.2 Effects on invertebrates

Sodium silicates and metasilicates

In a GLP study following EU Guideline 92/69/EWG, which corresponds to OECD guideline 202, part 1, exposure of the freshwater cladoceran *Daphnia magna* to sodium silicate solutions (MR 3.2, 35 wt%) at pH 9 - 11 and a pH adjusted to 7.8 - 8.0 resulted in a 48 h EC_{50} of 1700 mg active matter/l in both cases (Kirch 1997).

Potassium silicates

In a 24-hr toxicity test performed essentially according to OECD guideline 202, part 1, *Daphnia magna* were exposed to 500 mg/l (= 146 mg active matter/l) of a potassium silicate solution (MR 3.9 – 4.1, 29.1 % active matter) at unknown pH: no mortality or signs of toxicity were observed (Richterich and Mühlberg 2001a). The 24 h LC_{50} is therefore >146 mg active matter/l.

No studies are available for sodium metasilicate (anhydrous, penta- and nonahydrate).

4.1.3 Effects on aquatic plants / algae

Sodium silicates and metasilicates

Sodium silicate (MR 3.0, 34.54 wt%) was tested on the algae *Scenedesmus subspicatus*, in a guideline, GLP study according to German standard method DIN 38412, part 9, which corresponds to OECD guideline 201 (Rieche 1995). The 72 h EC_{50} based on biomass was 207 mg active matter/l at pH 8.2 - 9.5. The EC_{50} for growth rate was determined as > 345.4 mg active matter/l, the highest concentration tested.

No studies are available for sodium metasilicate (anhydrous, penta- and nonahydrate).

Si is the primary constituent of the frustules of diatoms (Vymazal 1995). Silicates may therefore promote the growth of diatoms in cases were other factors like phosphorus or nitrogen are not limiting.

Potassium silicates

No studies are available for potassium silicates.

4.1.4 Effects on micro-organisms, e.g. bacteria

Sodium silicates and metasilicates

The toxicity of a sodium silicate solution (MR 3.46, 34.8 wt%) has been determined with a growth inhibition test in compliance with German standards and GLP using the bacterium *Pseudomonas putida* (Hanstveit 1989). The 18 h toxicity threshold (EC_{10}, 10 % inhibition) of a neutralised silicate solution of pH 7.6 - 7.8 was > 3480 mg active matter/l, the highest concentration tested, while for the unneutralised solution (pH 7.9 - 10.4) effects were found at concentrations above 348 mg active

matter/l. In two GLP guideline studies complying with German standards corresponding to OECD 209, the toxicity to *Pseudomonas putida* was tested in oxygen consumption inhibition tests. Concentrations of a sodium silicate solution (MR 3.0, 34.54 wt%) of up to 3454 mg active matter/l at pH 8.0 - 11.1 and a sodium metasilicate solution of 1000 mg active matter/l at unknown pH did not cause toxic effects (Kirch 1993; Richterich and Mühlberg 2001c).

No significant inhibition of respiration was registered at exposure concentrations up to 100 mg/l sodium metasilicate (MR 1.0, 100 % active matter) for microorganisms from active sludge (Calmels 1994). The 3 h EC_{50} was > 100 mg active matter/l. The pH of the test media at the start and at the end of the study was 6.56 - 8.95 and 5.96 - 8.07, respectively. The study was carried out in compliance with GLP, OECD Guideline 209 and EEC Directive 88/302.

No studies are available for sodium metasilicate, penta- and nonahydrate.

In a simulation test following the OECD confirmatory test procedure, the elimination and influence of spray-dried sodium silicate (MR 2.1) on the biological activity of a model sewage treatment plant was determined. At doses of 25 mg/l, sodium silicate had no adverse effect on the biodegradation of easily degradable nutrients fed simultaneously: DOC (Dissolved Organic Carbon), pH and dry weight of activated sludge was comparable to the untreated control model plants. Visual inspection of colour and settling behaviour of activated sludge also did not reveal any differences between treated and untreated test runs. Elimination of sodium silicate in the model sewage treatment plant was only marginal; 90 - 100 % was detected in the effluent. The study was carried out in compliance with GLP and EU guidelines 82/242/EEC and 82/243/EEC (Richterich 1994).

Potassium silicates

No studies are available for potassium silicates.

Summary of aquatic effects

Table 6: Aquatic toxicity of soluble silicates

Species	Test type	Exposure period	Test substance CAS-No.	Ion	MR	Effects [mg/l]	Reference / Reliability
Fish							
Danio rerio	semistatic	96 h	1344-09-8	Na	3.46	LC_{50} = 1108	Adema 1988 * / 1
Danio rerio	semistatic	96 h	6834-92-0	Na	1.0	LC_{50} = 210	Richterich and Mühlberg 2001d * / 2
Gambusia affinis	unknown	96 h	6834-92-0	Na	1.0	LC_{50} = 2320	Wallen et al. 1957 * / 2
Oncorhynchus mykiss	unknown	96 h	1344-09-8	Na	3.1	LC_{50} = 260 - 310[n]	Maruyama et al. 1989* / 2
Lepomis macrochirus	unknown	96 h	1344-09-8	Na	unknown	LC_{50} = 301 - 478	UK Department of the Environment 1991 / 4
Leuciscus idus	static	48 h	1312-76-1	K	3.9 - 4.1	LC_{50} = >146 (highest tested conc.)	Richterich and Mühlberg 2001b * / 2
Invertebrates							
Daphnia magna	static	48 h	1344-09-8	Na	3.2	EC_{50} = 1700	Kirch 1997 * / 2
Daphnia magna	unknown	96 h	1344-09-8	Na	unknown	EC_{50} = 216 - 247	Dowden and Bennett 1965 / 4
Daphnia magna	unknown	100 h	1344-09-8	Na	unknown	EC_{50} = 247	Freeman and Fowler 1953 / 4
Daphnia magna	static	24 h	1312-76-1	K	3.9 - 4.1	EC_{50} = >146 (highest tested conc.)	Richterich and Mühlberg 2001a * / 2
Amphipoda (probably *Hyallela sp.*)	unknown	96 h	1344-09-8	Na	unknown	EC_{50} = 160	Dowden and Bennett 1965 / 4
Lymnea sp. eggs	unknown	96 h	1344-09-8	Na	unknown	EC_{50} = 632	Dowden and Bennett 1965 / 4
Algae							
Scenedesmus subspicatus	static	72 h	1344-09-8	Na	3.0	ErC_{50} = >345 (highest tested conc.) EbC_{50} = 207	Rieche 1995 * / 2
Microorganisms							
Pseudomonas putida	static	18 h	1344-09-8	Na	3.46	EC_0 = 348 EC_0 = 3480[n]	Hanstveit 1989 * / 1
Pseudomonas putida	static	30 min	1344-09-8	Na	3.0	EC_0 = 3454[n]	Kirch 1993 * / 2
Pseudomonas putida	static	30 min	6834-92-0	Na	1.0	EC_0 = 1000	Richterich and Mühlberg 2001c * / 2
Activated sludge	static	3 h	6834-92-0	Na	1.0	EC_{50} = >100	Calmels 1994 * / 2

* critical study for SIDS endpoint
MR Molar ratio
[n] neutralized test solutions

Conclusion of aquatic effects

The available aquatic ecotoxicity tests with silicates of varying molar ratios and kation species all show toxicities in excess of 100 mg/l. As a result of the low molar ratio, sodium metasilicate and its hydrates (MR 1.0) exhibit a higher alkalinity than the silicates of higher molar ratio. With the assumption that the primary hazard of soluble silicates is their alkalinity, it is expected that sodium metasilicate generally exhibits a higher toxicity than silicates of molar ratios 3 - 4. This is confirmed by toxicity data available for fish. Concerning invertebrate and algal toxicity, studies are available only for silicates of molar ratios 3 - 4 or of unknown ratio. Because of their higher alkalinity, the sodium metasilicates are expected to exhibit a higher daphnid and algal toxicity. The extent to which this toxicity will be increased should be similar to that observed for fish toxicity in *Danio rerio* (cf. metasilicate and a MR 3.46 silicate). This would result in metasilicate toxicities in the same order of magnitude as observed for fish and bacteria.

A sodium silicate tested in a bacterial toxicity test as such and after neutralization shows a ten-fold lower toxicity in the neutralized state. Whenever the pH is lowered –in laboratory studies or under environmental conditions- two effects of neutralization superimpose each other and in combination result in reduced toxicity: i) reduced alkalinity and ii) reduced bioavailability due to increasing precipitation as amorphous silica at pH values below 11.

A significant difference in fish toxicities is observed depending on species and molar ratio tested. On the one hand, this can be explained by the lower alkalinity of MR 3 - 4 silicates (see above) and on the other hand by interspecies variation in sensitivity. In cases where no data are available for the penta- and nonahydrate of sodium metasilicate, they are not expected to have higher toxicities than anhydrous metasilicate, since they differ from the anhydrous form only by their water of hydration.

Sodium silicate (MR 2.1) at 25 mg/l did not affect the biological activity of a model sewage treatment plant.

The few existing data on potassium silicates fit well into the toxicity pattern of the sodium silicates.

4.1.5 PNEC considerations

When assessing the environmental effect of an anthropogenic discharge on aquatic ecosystems, the predicted no effect concentration (PNEC) is usually put into context with the predicted environmental concentration (PEC). However, in the case of soluble silicates the calculation of a PEC and consequently a PEC/PNEC ratio is not feasible. The primary hazard of commercial soluble silicates is their moderate-to-strong alkalinity, which can be harmful to aquatic life. Thus, the effect of soluble silicates on aquatic ecosystems depends to a large extent on the local environmental conditions:

- the natural pH of aquatic environments can vary significantly,
- the sensitivity of the aquatic ecosystems to a change of the pH can vary significantly between aquatic ecosystems and
- the change in pH due to an anthropogenic discharge is influenced significantly by the buffer capacity of the receiving water.

To assess the environmental effect of a discharge of soluble silicates, the pH of the receiving water after the discharge can be calculated based on the pH and buffer capacity of effluent and receiving water and the dilution factor of the effluent. The pH change can be measured via a laboratory experiment or by conducting field measurements. The change in pH should be compared with the

natural variation in pH of the receiving water and based on this comparison it should be assessed if the pH change is acceptable.

It is not expected that the growth of diatoms and their seasonal fluctuation (blooms) is significantly influenced by the additional anthropogenic silica input, taking into account that the input of silica from the use of commercial silicates is negligible as compared to geochemical weathering processes. The possible effects of anthropogenic silica on diatomaceous growth are discussed in detail by van Dokkum et al. (2004). They predict i) an extension of the spring (and fall) blooms of diatoms (which often ends when the dissolved silicate pool is depleted) and (ii) a possible reduction in summer green or bluegreen algae blooms (because a larger amount of phosphorus is used up in the spring bloom). This in turn could lead to (iii) a shift in biomass production from summer to spring and fall, and, possibly, (iv) an overall increase of phytoplankton biomass over the year (when the increase in summer and fall bloom is larger than the decrease in summer density). However, these speculations are not corroborated by experimental evidence.

Conclusion

Because the buffer capacity, pH and the fluctuation of the pH are very specific for a certain aquatic ecosystem and the anthropogenic input is insignificant compared to the natural silica flux it is not considered useful to derive a PNEC or a $PNEC_{added}$.

4.2 Terrestrial effects

No data available.

Conclusion

Since silicates are natural components of soil minerals, such tests would be of limited value. Significant (unintended) exposure of the terrestrial environment as a side effect of applications does not occur. However, in certain applications soluble silicates are intentionally introduced into the terrestrial compartment (soil treatment, like sealing around landfill sites, waste fixation, and coastline stabilisation). Silicates added to or injected into soil react with the acidic constituents and polyvalent metal ions in the soil to form an impermeable gel structure. Any effects on soil organisms are confined to the area of soil within which the gel has formed. Due to its impermeable structure, no leaching into ground water or transport and further spreading of silicate solutions into soil layers outside the area penetrated by the gel will take place. Terrestrial toxicity tests are therefore not needed.

4.3 Other environmental effects

No data available.

4.4 Initial Assessment for the Environment

Solid crystalline silicates have discrete melting points which depend on the content of crystallisation water: anhydrous sodium metasilicate melts at 1089 °C while sodium penta- and nonahydrate melt at 72 °C and 48 °C, respectively. Due to their glass nature, solid amorphous silicates do not have discrete melting points but rather flow points. Aqueous silicate solutions have a melting point only slightly lower than that of water.

The specific gravity or density of silicate solutions depends on the concentration (solids content), the temperature, and the silica to alkali ratio. Commercial silicate solutions have densities ranging from ca. 1.2 – 1.7 g/cm^3 at 20 °C. Soluble silicates are insoluble in n-octanol.

The vapour pressures that have been measured for three solid sodium silicates are extremely low: 0.0103 hPa at 1175 °C (MR 1.0, metasilicate), 0.0031 hPa at 1165 °C (MR 2.0) and 0.0016 hPa at 1172 °C (MR 3.0). This indicates that the respective pressures at ambient temperature will be unmeasurably small.

Crystalline silicates like sodium metasilicate are readily soluble in water. Amorphous silicate glasses are only slightly attacked by water at ambient temperatures. They can be solubilised only at elevated temperature and pressure (ca. 150 °C and > 5 bar). The solutions are infinitely dilutable with water. Silicate powders obtained by water evaporation from silicate solutions are readily soluble in water. The water solubility depends on the pH. Above a pH of 11 - 12 stable solutions of monomeric and polymeric silicate ions exist. The soluble content rapidly decreases when the pH is lowered to 9. Below pH 9 only a small proportion is present as soluble monomeric silicate ions, the majority existing as insoluble amorphous silica gel.

As inorganic substances, soluble silicates are not amenable to photo- or biodegradation. Respiration of activated sludge is not inhibited at sodium metasilicate concentrations ≥ 100 mg/l. Continuous dosing of 25 mg sodium silicate/l has no adverse effects on the operation of a model sewage treatment plant simultaneously fed with easily degradable nutrients; no significant elimination occurred with > 90 % detected in the effluent.

Acute toxicity testing in fish, invertebrates, and algae indicate a low order of toxicity with effect concentrations between 210 and 1700 mg/l. The following results were obtained in acute tests:

Danio rerio	LC_{50} (96 h) = 210 mg/l (Na, MR 1.0)
Danio rerio	LC_{50} (96 h) = 1108 mg/l (Na, MR 3.46)
Oncorhynchus mykiss	LC_{50} (96 h) = 260 - 310 mg/l (Na, MR 3.1)
Leuciscus idus	LC_{50} (48 h) > 146 mg/l (K, MR 3.9 - 4.1)
Daphnia magna	EC_{50} (48 h) = 1700 mg/l (Na, MR 3.2)
Daphnia magna	EC_{50} (24 h) > 146 mg/l (K, MR 3.9 - 4.1)
Scenedesmus subspicatus	EbC50 (72 h) = 207 mg/l
	ErC50 (72 h) > 345 mg/l (Na, MR 3.0)

No long-term tests are available for fish, invertebrates or algae.

As a result of the low molar ratio, sodium metasilicate and its hydrates (MR 1.0) exhibit a higher alkalinity than the silicates of higher molar ratio. With the assumption that the primary hazard of soluble silicates is their alkalinity, it is expected that sodium metasilicate generally exhibits a higher toxicity than silicates of molar ratios 3 - 4. This is confirmed by toxicity data available for fish. Concerning invertebrate and algal toxicity, studies are available only for silicates of molar ratios 3 - 4 or of unknown ratio. Because of their higher alkalinity, the sodium metasilicates are expected to exhibit a higher daphnid and algal toxicity. The extent to which this toxicity will be increased should be similar to that observed for fish toxicity in *Danio rerio*. This would result in metasilicate toxicities in the same order of magnitude as observed for fish.

5 RECOMMENDATIONS

The chemicals of the soluble silicates category are currently of low priority for further work.

Environment: Soluble silicates are currently of low priority for further work because of their low hazard profile.

Human Health: Soluble silicates possess properties indicating a hazard for human health (irritancy/ corrosivity). In the Sponsor country, adequate risk reduction measures are in place (classification and labelling). No further work is recommended. In situations where this is not the case, risk assessment and, if necessary, risk reduction measures are recommended.

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APPENDIX 1: USES OF SOLUBLE SILICATES RECORDED BY 4 EUROPEAN PRODUCT REGISTERS (SWEDEN, FINLAND, DENMARK AND SWITZERLAND)

Sweden						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
Silicic acid, potassium salt	1312-76-1	0-2%	29 / 10	14	Cleaning agents, paints and varnishes, degreasing agents, binders.	National Chemicals Inspectorate, Sweden Year of data collection: 2001 Updated yearly
		2-20%	97 / 25	287		
		20-80%	22 / 3	449		
		80-100%	4 / 0	425		
		total	152 / 38	1,176		
Silicic acid, sodium salt	1344-09-8	0-2%	52 / 23	27	Detergents, dishwashing agents, binders, cleaning agents, degreasing agents, sealing compounds.	
		2-20%	260 / 120	1,884		
		20-80%	91 / 30	8,956		
		80-100%	17 / 2	17,016		
		total	420 / 175	27,883		
Sodium metasilicate, anhydrous	6834-92-0	0-2%	199 / 56	87	Cleaning agents, degreasing agents, High-pressure cleaning agents, dishwashing agents, detergents	
		2-20%	295 / 38	549		
		20-80%	133 / 22	853		
		80-100%	8 / 0	20,194		
		total	635 / 116	21,683		
Sodium metasilicate, pentahydrate	10213-79-3	0-2%	85 / 13	23	Cleaning agents, degreasing agents, High-pressure cleaning agents, dishwashing agents, car care product	
		2-20%	178 / 17	204		
		20-80%	54 / 8	374		
		80-100%	3 / 0	410		
		total	320 / 38	1,010		
Sodium metasilicate, nonahydrate	13517-24-3	0-80%	4 / 1	3	Various	

Finland						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products [1]**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
Silicic acid, potassium salt	1312-76-1	1-10%	16		Cleaning/washing agents, Paints, lacquers and varnishes, Photo chemicals in: Manufacture of basic metals, Manufacture of textiles, Printing and service activities related to printing	Product Control Agency for Welfare and Health in Finland, Product Register Unit Year of data collection: 2001 Updated yearly
		10-30%	17			
		total	33	277		
Silicic acid, sodium salt	1344-09-8	0-5%	16		Adhesives, binding agents, Cleaning /washing agents, Construction materials in: Manufacture of pulp, paper and paperboard, Casting of metals, Forging, pressing, stamping and roll forming of metal; powder metallurgy, Building and repairing of ships and boats, Construction	
		5-10%	15			
		10-30%	31			
		30-60%	16			
		60-100%	6			
		total	85	4,971		
Sodiummetasilicate, anhydrous	6834-92-0	0-1%	8		Cleaning/washing agents in: Industrial cleaning	
		1-5%	125			
		5-10%	54			
		10-30%	127			
		30-60%	21			
		60-100%	4			
		total	339	2,550		
Sodiummetasilicate, pentahydrate	10213-79-3	0-5%	80		Cleaning/washing agents in: Industrial cleaning	
		5-10%	10			
		10-30%	16			
		30-60%	4			

		60-100%	4			
		total	117	765		
Sodiummetasilicate, nonahydrate	13517-24-3	1-5%	5		Cleaning/washing agents in: Manufacture of soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations, Manufacture of other fabricated metal products, Industrial cleaning	
		5-10%	4			
		10-100%	1			
		total	10	17		

[1] The number of consumer products is not reported, only the total number of products is given.

Denmark						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
Potassium silicate *total number*	1312-76-1	0-2%	16 / NR[1]	2	See footnote for the 10 most frequent industry groups[2]	The Danish Product Register, Denmark Year of data collection: ? Information received: 26.02.2002 Frequency of update: ?
		2-20%	65 / NR	75		
		20-50%	10 / NR	11		
		50-100%	4 / NR	2,010		
Potassium silicate *by product group*	1312-76-1	total	3 / NR	2,000	Impregnation materials	
		2-20%	3 / NR	2	Photochemicals	
		total	3 / NR	2		
		2-20%	3 / NR	<1	Reprographic agents	
		total	3 / NR	<1		
		0-2%	13 / NR	2	Cleaning / washing agents	
		2-20%	46 / NR	70		
		total	61 / NR	76		
		2-20%	3 / NR	4	Non-agricultural pesticides and preservatives	
		total	4 / NR	5		
		2-20%	8 / NR	3	Paints, laquers and varnishes	
		20-50%	5 / NR	8		
		total	13 / NR	10		
		total	3 / NR	<1	Surface treatment	
Sodium silicates *total number*	1344-09-8	0-2%	58 / NR	36	See footnote for the 10 most frequent industry groups[3]	
		2-20%	161 / NR	1,844		

NR = not reported

[2] Manufacture of food, beverages and tobacco / Dairies and manufacture of condensed milk / Manufacture of beer / Painting and glazing / Hotels / Restaurants / cafeterias and community centres / Industrial cleaning / Hospital activities / Social work activities including residential institutions / Laundries and dry cleaners

Denmark						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
		20-50%	37 / NR	661		
		50-100%	14 / NR	2,378		
Sodium silicates *by product group*	1344-09-8	2-20%	3 / NR	2	Adhesives, binding agents	
		50-100%	6 / NR	2,144		
		total	12 / NR	2,217		
		20-50%	3 / NR	3	Process regulators	
		total	4 / NR	3		
		0-2%	6 / NR	2	Anti-freezing agents	
		total	6 / NR	2		
		0-2%	3 / NR	<1	Corrosion inhibitors	
		total	5 / NR	5		
		total	3 / NR	2,005	Cosmetics	
		0-2%	3 / NR	<1	Fillers	
		2-20%	3 / NR	1		
		20-50%	7 / NR	42		
		50-100%	4 / NR	9		
		total	17 / NR	53		
		total	3 / NR	<1	Insulating materials	
		2-20%	5 / NR	1	Reprographic agents	
		total	6 / NR	1		

[3] Manufacture of food, beverages and tobacco / Manufacture of fabricated metal products, except machinery and equipment / Maintenance and repair of motor vehicles / Hotels and restaurants / Restaurants, cafeterias and community centres / Industrial cleaning / Hospital activities / Laundries and dry cleaners / Private households with employed persons / Other activities.

Denmark						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
		0-2%	37 / NR	29	Cleaning / washing agents	
		2-20%	132 / NR	1,797		
		20-50%	15 / NR	413		
		total	185 / NR	2,247		
		0-2%	4 / NR	<1	Construction materials	
		total	8 / NR	5		
		2-20%	6 / NR	6	Non-agricultural pesticides and preservatives	
		total	8 / NR	6		
		total	3 / NR	8	Surface treatment	
		2-20%	4 / NR	4	Others	
		20-50%	3 / NR	162		
		total	7 / NR	166		
Disodium metasilicate *total number*	6834-92-0	0-2%	156 / NR	30	See footnote for the 10 most frequent industry groups[4]	
		2-20%	319 / NR	303		
		20-50%	72 / NR	345		
		50-100%	44 / NR	417		
Disodium metasilicate *by product group*	6834-92-0	0-2%	3 / NR	<1	Pesticides, agricultural	
		total	3 / NR	<1		
		total	3 / NR	3	Process regulators	
		0-2%	31 / NR	18	Anti-freezing agents	

[4] Manufacture of food, beverages and tobacco / Manufacture of iron and metal products / Manufacture of fabricated metal products, except machinery and equipment / Manufacture of machinery and equipment / Maintenance and repair of motor vehicles / Restaurants, cafeterias and community centres / Industrial cleaning / Hospital activities / Laundries and dry cleaners / Private households with employed persons

Denmark						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
		total	31 / NR	18		
		2-20%	3 / NR	1	Bleaching agents	
		total	4 / NR	1		
		0-2%	4 / NR	<1	Corrosion inhibitors	
		2-20%	5 / NR	1		
		total	10 / NR	181		
		total	5 / NR	6	Fillers	
		2-20%	6 / NR	6	Photochemicals	
		total	7 / NR	6		
		2-20%	12 / NR	14	Reprographic agents	
		total	15 / NR	15		
		2-20%	3 / NR	2	Surface-active agents	
		total	6 / NR	2		
		0-2%	99 / NR	12	Cleaning / washing agents	
		2-20%	271 / NR	302		
		20-50%	64 / NR	336		
		50-100%	37 / NR	416		
		total	471 / NR	1,066		
		0-2%	8 / NR	2	Non-agricultural pesticides and preservatives	
		2-20%	8 / NR	8		
		total	20 / NR	22		
		0-2%	3 / NR	<1	Cutting fluids	
		total	3 / NR	<1		

Denmark						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
		total	3 / NR	<1	Paints, laquers and varnishes	
		0-2%	3 / NR	<1	Surface treatment	
		2-20%	4 / NR	1		
		total	7 / NR	2		
		2-20%	3 / NR	<1	Others	
		total	3 / NR	<1		

Switzerland						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
Sodium silicates (3:2)	1344-09-8	0.1-1%	1 / 0		Lubricants, propulsion and heat transfer agents	Swiss Federal Office of Public Health, Chemical Products Division Year of data collection: 2001 Frequency of update: ?
		0.1-1%	1 / 0		Auxiliary agents	
		10-50%	2 / 2		Adhesives, putties, fillers and sealants	
		1-10%	1 / 0		Metal-care products	
		1-10%	2 / 2		Cleaning agents	
		10-50%	1 / 0			
		1-10%	1 / 1		Detergents, detergent auxiliaries and soaps	
		0.1-1%	1 / 0		Antirust agents	
		1-10%	2 / 1		Dishwashing agents	
		1-10%	7 / 7		Photochemicals	
		10-50%	2 / 2			
		0-0.1%	1 / 0		Anti-freezing agents	
		0-1%	7 / 7			
		0.1-1%	11 / 0			
		0-1%	1 / 0		Special applications in general	
		0.1-1%	1 / 0		Fuel, fuel additives	
Sodium silicates (1:2 to 1:4)	1344-09-8	0-0.1%	3 / 0		Paints, lacquers and varnishes	
		0.1-1%	4 / 0			
		1-10%	2 / 1			
		10-50%	3 / 0			

Switzerland						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
		0.1-1%	3 / 0		Lubricants, propulsion and heat transfer agents	
		1-10%	1 / 0			
		10-50%	1 / 0			
		0-0.1%	3 / 0		Auxiliary agents	
		0.1-1%	6 / 0			
		1-10%	17 / 0			
		10-50%	23 / 3			
		50-100%	8 / 1			
		0-0.1%	2 / 1		Adhesives, putties, fillers and sealants	
		0.1-1%	2 / 1			
		1-10%	5 / 0			
		10-50%	42 / 14			
		50-100%	18 / 8			
		50-100%	1 / 1		Teaching aids, drawing and writing materials	
		0-0.1%	1 / 1		Metal-care products	
		0.1-1%	2 / 0			
		1-10%	1 / 0			
		10-50%	5 / 4			
		50-100%	1 / 0			
		0-0.1%	1 / 0		Surface treatment in general	
		1-10%	2 / 0			
		10-50%	1 / 1			
		50-100%	1 / 0			

Switzerland						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
		0-0.1%	4 / 1		Cleaning agents	
		0.1-1%	23 / 5			
		1-10%	76 / 13			
		10-50%	24 / 3			
		50-100%	3 / 1			
		0-0.1%	5 / 2		Detergents, detergent auxiliaries and soaps	
		0.1-1%	7 / 4			
		1-10%	76 / 46			
		10-50%	8 / 3			
		50-100%	1 / 0			
		1-10%	8 / 0		Solvents, degreasing agents, diluents and paint strippers	
		10-50%	1 / 0			
		1-10%	1 / 0		Ceramic colours, glazes and enamel products	
		50-100%	1 / 0			
		0.1-1%	4 / 0		Car care agents	
		1-10%	3 / 0			
		10-50%	6 / 1			
		50-100%	1 / 0			
		10-50%	1 / 0		Soldering and welding agents	
		1-10%	7 / 6		Water treatment agents	
		10-50%	43 / 16			
		50-100%	7 / 4			
		10-50%	2 / 0		Antirust agents	
		10-50%	2 / 0		Various	

Switzerland						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
		50-100%	1 / 1			
		0.1-1%	7 / 1		Dishwashing agents	
		1-10%	24 / 5			
		10-50%	6 / 1			
		1-10%	6 / 0		Photochemicals	
		10-50%	6 / 0			
		50-100%	1 / 0			
		0-0.1%	1 / 0		Disinfectants, biostatics	
		1-10%	1 / 0			
		10-50%	2 / 2			
		0.1-1%	3 / 3		Swimming pool chemicals	
		1-10%	2 / 2			
		0.1-1%	1 / 0		Electroplating auxiliary	
		1-10%	2 / 0			
		10-50%	4 / 0			
		0.1-1%	1 / 0		Anti-freezing agents	
		0.1-1%	1 / 0		Laboratory chemicals	
		1-10%	1 / 1		Drain and toilet cleaners	
		0-0.1%	1 / 1		Stain remover	
		0.1-1%	1 / 1			
		10-50%	1 / 1			
		50-100%	3 / 0		Fire-extinguishing agents	
Silicic acid, potassium salt (1:2 to 1:4)	1312-76-1	0-0.1%	9 / 5		Paints, lacquers and varnishes	
		0.1-1%	3 / 1			

Switzerland						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
		1-10%	100 / 11			
		10-50%	70 / 11			
		50-100%	8 / 1			
		0.1-1%	2 / 0		Auxiliary agents	
		1-10%	15 / 1			
		10-50%	32 / 1			
		50-100%	5 / 0			
		0.1-1%	1 / 1		Adhesives, putties, fillers and sealants	
		1-10%	23 / 2			
		10-50%	12 / 0			
		50-100%	5 / 2			
		0.1-1%	2 / 1		Metal-care products	
		0.1-1%	1 / 1		Surface treatment in general	
		1-10%	2 / 0			
		0-0.1%	1 / 0		Cleaning agents	
		0.1-1%	8 / 1			
		1-10%	34 / 7			
		10-50%	27 / 4			
		50-100%	1 / 0			
		0.1-1%	1 / 0		Detergents, detergent auxiliaries and soaps	
		1-10%	4 / 2			
		10-50%	10 / 2			
		50-100%	1 / 0			
		1-10%	1 / 1		Herbicides	

Switzerland						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
		1-10%	3 / 1		Solvents, degreasing agents, diluents and paint strippers	
		10-50%	3 / 0			
		1-10%	1 / 0		Ceramic colours, glazes and enamel products	
		10-50%	1 / 0			
		50-100%	1 / 0			
		10-50%	1 / 0		Car care agents	
		10-50%	1 / 0		Soldering and welding agents	
		50-100%	2 / 0			
		1-10%	2 / 0		Impregnation agents	
		10-50%	1 / 0			
		0.1-1%	1 / 1		Antirust agents	
		50-100%	2 / 0			
		10-50%	1 / 1		Fungicides	
		0-0.1%	1 / 0		Various	
		10-50%	2 / 1			
		1-10%	10 / 0		Dishwashing agents	
		10-50%	11 / 4			
		10-50%	1 / 1		Antistatic agent	
		0.1-1%	1 / 0		Photochemicals	
		1-10%	18 / 0			
		10-50%	6 / 0			
		1-10%	1 / 1		Disinfectants, biostatics	
		10-50%	1 / 0			
		1-10%	2 / 2		Swimming pool chemicals	

Switzerland						
Substance	**CAS no.**	**Total amount of substance in product**	**No. of products in total / no. of consumer products (incl. in total)**	**Quantity in tons / year**	**Use, product group**	**Information on Product Register**
		1-10%	1 / 0		Electroplating auxiliary	
		10-50%	1 / 0			
		0-0.1%	1 / 1		Agricultural fertilizers	
		0-0.1%	1 / 1		Fertilizers for ornamental plants	

I U C L I D

D a t a S e t

Existing Chemical	ID: 1344-09-8
CAS No.	1344-09-8
EINECS Name	Silicic acid, sodium salt
EC No.	215-687-4
TSCA Name	Silicic acid, sodium salt

Producer Related Part	
Company:	Cognis Deutschland GmbH
Creation date:	03-FEB-2003
Substance Related Part	
Company:	Cognis Deutschland GmbH
Creation date:	03-FEB-2003
Memo:	Dataset of CEES Soluble Silicates Consortium

Printing date:	05-APR-2006
Revision date:	
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Number of Pages:	138

Chapter (profile):	Chapter: 1, 2, 3, 4, 5
Reliability (profile):	Reliability: without reliability, 1, 2, 3, 4
Flags (profile):	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 Applicant and Company Information

Type:	lead organisation
Name:	Centre Europeen d'Etude des Silicates (CEES)
Contact Person:	Joël Wilmot Date: 28-FEB-2003
Street:	Av. E van Nieuwenhuyse, 4
Town:	B-1160 Bruxelles
Country:	Belgium
Phone:	+32 26767288
Telefax:	+32 26767347
Email:	
Homepage:	http://www.cees-silicates.org

Remark: CEES, the Centre Europeen d'Etude des Silicates is a sector group of CEFIC and unites the Western European producers of silicates.
The Soluble Silicates Consortium is represented by the following companies:

Asahi Glass Co., Ltd. (JP)
Chimibase (IT)
Cognis Deutschland GmbH (DE)
FMC Foret SA (ES)
Industria Chimica Vera (IT)
Industrias Químicas del Ebro SA (ES)
Ineos Silicas Ltd (UK)
Ingessil (IT)
PQ Europe (NL)
Rhodia SA (FR)
Sasol Italy SpA (IT)
Silmaco NV (BE)
Solvay S.A. (BE)
Tokuyama Corp. (JP)
van Baerle & Cie (CH)
van Baerle GmbH (DE)
Woellner Silikat GmbH (DE)

28-FEB-2003

1.0.2 Location of Production Site, Importer or Formulator

1.0.3 Identity of Recipients

1.0.4 Details on Category/Template

1.1.0 Substance Identification

IUPAC Name:	Silicic acid, sodium salt
Smiles Code:	not applicable
Mol. Formula:	Na2O · nO2Si
Mol. Weight:	184.04 (tetrasodium orthosilicate)

Remark: Soluble silicates are generally not distinct stoichiometric chemical substances (with a specific chemical formula and molecular weight), but rather glasses or aqueous solutions of glasses.
For common silicates structural formulae are complex: monomer, linear or planar cyclic oligo-, and three-dimensional

polysilicate anions with potassium cations as counterions.
04-DEC-2003

1.1.1 General Substance Information

Purity type: typical for marketed substance
Substance type: inorganic
Physical status: solid
Purity: >= 99 - % w/w
Colour: Translucent, blue-greenish or yellow-brownish

Remark: Sodium silicate (sodium waterglass) is commercially provided as lumps, powders, and concentrated or diluted solutions. The purity given refers to the dry matter.

Solutions, which are the predominantly used form of waterglass, are prepared by solubilization of waterglass lumps in water at elevated temperature and pressure. Their water content lies mainly between 45% and 80%.

Powders are prepared by spray- or drum-drying of waterglass solutions. The residual water content can be between 0 - 25%.
Soluble silicates are characterized by the ratio of SiO2 versus Na2O (sodium silicates) or versus K2O (potassium silicates). For example, a sodium silicate solution, containing 26.6% SiO2 and 8% Na2O would be said to have a weight ratio of 3.3. Weight ratios can be converted to molar ratios by multiplication with 1.032.
The colour depends on the presence of iron ions: Fe 2+ will cause a blue-greenish colour, whereas Fe 3+ or Fe sulfides leads to a yellow-brownish colour of the silicate lumps.
The index x, equivalent to the quotient

$$\frac{\text{moles (SiO2)}}{\text{moles (Na2O)}}$$

is generally defined as the molar ratio (silica/alkali).

Sodium waterglass is either made by high temperature fusion of silica sand (SiO2) and soda (Na2CO3) at about 1300 °C, or by a hydro-thermal process using silica sand and sodium hydroxide as starting materials.
12-DEC-2003 (6) (14) (18)

1.1.2 Spectra

1.2 Synonyms and Tradenames

Silicic acid, sodium salt

09-JAN-2002

Silicon sodium oxide

13-NOV-1995

Sodium .beta.-silicate

13-NOV-1995

Sodium sesquisilicate

13-NOV-1995

Sodium silicate

21-MAR-1994

Sodium silicate glass

24-MAR-1994

Sodium water glass

24-MAR-1994

Soluble glass

24-MAR-1994

Waterglass

11-NOV-2002

1.3 Impurities

Purity type: typical for marketed substance

Remark: Impurities stem from the quartz sand used rather than from soda. Therefore, impurities of potassium silicates are similar to sodium silicates of comparable molar ratios. The following impurities were reported for sodium silicate lumps of weight ratio 3.35 (molar ratio 3.46):

Na2SO4: 0.06%
NaCl: 0.06%
Fe2O3: 0.033%
Al2O3: 0.097%
CaO: 0.03%
MgO: 0.02%
TiO2: 0.019%

Reliability: (4) not assignable
Review article only
Flag: Critical study for SIDS endpoint
03-DEC-2003 (14)

Purity type: typical for marketed substance

Remark: Soluble silicates are very pure substances with impurities less than 1%. The impurities stem from the quartz sand used rather than from the potash or soda components of the fusion mixture. Therefore, impurities of potassium silicates are similar to sodium silicates of comparable molar ratios.
Result: Composition range of a typical sodium silicate solution of weight ratio 3.3 (molar ratio 3.4):

Li 0.2-0.5

K	20-50	
Mg	5-20	
Ca	1-80	
Sr	1-5	
Ba	<1-5	
Al	50-200	
P	<1-10	
S	10-30	
Ti	30-80	
V	0.1-0.8	
Cr	<1	
Mn	<0.5-1	
Fe	25-100	
Co	<1	
Ni	<0.5	
Cu	<0.1-0.2	
Zn	<0.2-1	
La	0.2-1	
Ce	<0.3-2	
Zr	5-20	
W	<1-25	all contents in ppm

Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
29-MAR-2005 (15)

1.4 Additives

1.5 Total Quantity

Quantity: ca. 696000 tonnes produced in 2000

Remark: Quantity expressed in metric tonnes of SiO2
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
29-MAR-2005 (35)

1.6.1 Labelling

Labelling: provisionally by manufacturer/importer

Remark: The labelling of soluble silicates is governed by their molar ratio and concentration. Irritation is inversely correlated with the molar ratio (MR); it decreases with increasing MR. This inverse correlation is superimposed by the effect of concentration: higher concentrations cause higher irritation. However, there is a concentration limit above which silicate solutions become too viscous to be handled and turn into an intractable elastic mass. Typically, commercial silicate solutions have a solids content as high as can be conveniently handled at ordinary temperatures. This maximum concentration depends critically on the molar ratio of the silicate solution. By way of example, the typical marketed concentrations for some sodium silicate solutions of different molar ratios are as follows:

MR	Mean total solids [%]
1.65	47-53
2.1	42-54
2.6	44
2.8	46
3.3	36-40
3.5	36
4	28

Having in mind the maximum marketable concentrations of silicate solutions, the labelling of silicates is primarily dictated by the molar ratio.
There are numerous soluble silicate brands of varying molar ratios and concentrations from many different producers on the market. For specific labelling of a given product, the respective safety data sheet should be consulted. Generally, silicates with molar ratios 1.6 or lower are labelled as corrosive (R 34). Above MR 1.6 the labelling varies depending on the molar ratio and concentration from R 38, 41 to R 36/38. Solutions of MR > 3.2 and concentrations below 40% are not classified as dangerous. In addition, spray-dried powders should be labelled with R 37 (irritating to respiratory system) in combination with the above-mentioned R-phrases.

23-JAN-2004

1.6.2 Classification

1.6.3 Packaging

1.7 Use Pattern

Type: type
Category: Non dispersive use

06-FEB-2003

Type: type
Category: Use resulting in inclusion into or onto matrix

06-FEB-2003

Type: type
Category: Wide dispersive use

06-FEB-2003

Type: industrial
Category: Chemical industry: used in synthesis

06-FEB-2003

Type: industrial
Category: Paints, lacquers and varnishes industry

06-FEB-2003

Type: industrial

Category: Paper, pulp and board industry

06-FEB-2003

Type: industrial
Category: Personal and domestic use

06-FEB-2003

Type: industrial
Category: Textile processing industry

06-FEB-2003

Type: industrial
Category: other: civil engineering

06-FEB-2003

Type: industrial
Category: other: foundry industry

06-FEB-2003

Type: industrial
Category: other: tertiary oil recovery

15-DEC-2003

Type: use
Category: Adhesive, binding agents

Remark: Used in spiral tube winding, fibre drums, corrugated boxboard, foil lamination.
15-DEC-2003 (5) (9) (16) (34) (38) (57) (58)

Type: use
Category: Cleaning/washing agents and disinfectants

Remark: Fabric washing powders, dishwasher detergents, industrial cleansing agents.
15-DEC-2003 (5) (9) (16) (34) (38) (57) (58)

Type: use
Category: Construction materials additives

Remark: Refractive cements, plasters and mortars, roofing tiles, bricks, wet-gunned concrete in tunnel construction and mining.
15-DEC-2003 (5) (9) (16) (34) (38) (57)

Type: use
Category: Corrosive inhibitors

Remark: In water treatment and detergents
15-DEC-2003 (5) (58)

Type: use
Category: Cosmetics

15-DEC-2003 (9)

Type: use
Category: Fillers

Remark: Liquefying agent in porcelain slips.
15-DEC-2003 (9) (34)

Type: use
Category: Flame retardants and fire preventing agents

Remark: Fireproof glass and surface coatings; fire-extinguishing agents.
15-DEC-2003 (34) (58)

Type: use
Category: Flotation agents

15-DEC-2003 (5)

Type: use
Category: Intermediates

Remark: Production of silica gel, precipitated silica, zeolites.
15-DEC-2003 (5) (34)

Type: use
Category: Non agricultural pesticides

15-DEC-2003 (9)

Type: use
Category: Photochemicals

15-DEC-2003 (58)

Type: use
Category: Welding and soldering agents

Remark: Carrier in welding rods
15-DEC-2003 (5) (38) (58)

Type: use
Category: other: Anti-freezing agents

15-DEC-2003 (58)

Type: use
Category: other: Titanium dioxide production

Remark: Used in coating of TiO2.
15-DEC-2003 (38)

Type: use
Category: other: additive in paper production

Remark: Promotes deinking and bleaching of recycled paper.
15-DEC-2003 (5) (34) (38)

Type: use
Category: other: binder in foundry sand

Remark: Binds together sand molds and cores prior to pouring the molten metal.
15-DEC-2003 (5) (34) (38)

Type: use
Category: other: car-care product

15-DEC-2003 (58)

Type: use
Category: other: cleaning agent in food and beverage industry

15-DEC-2003 (9)

Type: use
Category: other: oil flow improver

Remark: Used in tertiary oil recovery to improve oil flow from porous rock.
15-DEC-2003 (5) (38)

Type: use
Category: other: paint additive

Remark: Component in paints for masonry.
15-DEC-2003 (38) (58)

Type: use
Category: other: sealing agent in soil

Remark: Soluble silicates react with the acidic constituents and polyvalent metal ions in the soil to form an an impermeable, stable gel structure.
Tunnels, mines, boreholes, landfills, building pits, dikes and embankments.
08-JAN-2004 (5) (34) (38)

Type: use
Category: other: textile treatment additive

Remark: Bleach stabilizer, facilitator in substrate dyeing.
15-DEC-2003 (5) (34)

1.7.1 Detailed Use Pattern

1.7.2 Methods of Manufacture

1.8 Regulatory Measures

1.8.1 Occupational Exposure Limit Values

Remark: No specific exposure limits have been established for alkali silicates.
For liquids the creation of aerosols should be avoided. For powders, general dust exposure limits according to national regulations, (typically from 6 to 10 mg/m3) will apply. For

corrosive alkali silicates (MR </=1.6) the exposure limits set for sodium hydroxide NaOH (2 mg/m3) should be considered as a guideline.
Sodium silicates have not been given an Occupational Exposure Limit value.

16-DEC-2003 (5)

1.8.2 Acceptable Residues Levels

1.8.3 Water Pollution

Classified by: KBwS (DE)
Class of danger: 1 (weakly water polluting)

Remark: Differing from the general classification, sodium silicates in the form of solid lumps and with a molar ratio SiO2 : Na2O of >= 3.2 are classified as "not water endangering" (nwg).
Reliability: (2) valid with restrictions
Official german classification

08-JAN-2004 (23)

1.8.4 Major Accident Hazards

1.8.5 Air Pollution

1.8.6 Listings e.g. Chemical Inventories

1.9.1 Degradation/Transformation Products

1.9.2 Components

1.10 Source of Exposure

Source of exposure: Human: exposure by production
Exposure to the: Substance

Remark: Accidental human exposure may occur during production and processing of silicates. No measured data are available.

21-OCT-2004

Source of exposure: Human: exposure through intended use
Exposure to the: Substance

Remark: Applications were exposure is possible: soil stabilization (in construction of tunnels, mines, boreholes, landfills, building pits, dikes and embankments) and construction materials additive (wet-gunned concrete).
From the use patterns listed in chapter 1.7 it can be inferred that accidental human exposure may occur during professional downstream use of silicates. No measured data are available.

21-OCT-2004

Source of exposure: Human: exposure of the consumer/bystander
Exposure to the: Substance

Remark: Applications were exposure is possible: detergents, soaps and cleaners, water treatment (corrosion inhibition). From the use patterns listed in chapter 1.7 it can be inferred that human exposure may occur during consumer use of washing and cleaning agents and drinking water containing silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure from production
Exposure to the: Substance

Remark: Accidental environmental exposure may occur during production of silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure from formulation
Exposure to the: Substance

Remark: Accidental environmental exposure may occur during formulation of products containing silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure from processing
Exposure to the: Substance

Remark: Accidental environmental exposure may occur during processing of silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure from intended use
Exposure to the: Substance

Remark: Applications were exposure is possible: soil stabilization (in construction of tunnels, mines, boreholes, landfills, building pits, dikes and embankments) and construction materials additive (wet-gunned concrete). Paper, pulp and board production (additive for deinking and bleaching of recycled paper), water treatment (corrosion inhibition). From the use patterns listed in chapter 1.7 it can be inferred that environmental exposure will occur during professional downstream use of silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure through private use
Exposure to the: Substance

Remark: Applications were exposure is possible: detergents, soaps and cleaners.
From the use patterns listed in chapter 1.7 it can be inferred that environmental exposure will occur during the use of consumer products containing silicates. No measured data are available.
21-OCT-2004

1.11 Additional Remarks

1.12 Last Literature Search

1.13 Reviews

2.1 Melting Point

Value: 730 - 870 degree C

Remark: Due to their glass nature, solid amorphous silicates do not have discrete melting points but rather flow points. They reversibly solidify and soften within a broad temperature range depending on their molar ratio. Sodium silicate lumps start to soften at 550 - 670°C and reach the flow point at 730 - 870°C. Aqueous silicate solutions have a melting point only slightly lower than that of water.
Reliability: (4) not assignable
Collection of data
Flag: Critical study for SIDS endpoint
16-DEC-2003 (14)

Value: 760 degree C
Decomposition: no at degree C

Remark: Due to their glass nature, solid amorphous silicates do not have discrete melting points but rather flow points. They reversibly solidify and soften within a broad temperature range depending on their molar ratio. The given value relates to the flow point. The softening point is 590°C.
Test substance: Sodium silicate anhydrous glass of molar ratio 2.06
Reliability: (4) not assignable
Handbook data
20-OCT-2004 (15)

Value: 840 degree C
Decomposition: no at degree C

Remark: Due to their glass nature, solid amorphous silicates do not have discrete melting points but rather flow points. They reversibly solidify and soften within a broad temperature range depending on their molar ratio. The given value relates to the flow point. The softening point is 655°C.
Test substance: Sodium silicate anhydrous glass of molar ratio 3.33
Reliability: (4) not assignable
Handbook data
20-OCT-2004 (15)

2.2 Boiling Point

Value:

Remark: The determination of a boiling point is not practical for solid anhydrous silicates as they are glasses with high melting points. The boiling point of silicate solutions on the other hand will be primarily determined by the water present and thus will not differ significantly from the boiling point of water.
30-SEP-2004

2.3 Density

Type: density
Value: 1.26 - 1.5 g/cm³ at 20 degree C

Test substance: Sodium silicate solutions; molar ratios between 3.97 and 2.06
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
20-OCT-2004 (38)

Type: density
Value: ca. 1.26 - 1.71 g/cm³ at 20 degree C

Remark: Density depends on solids content and molar ratio of sodium silicate solutions.
Test substance: Sodium silicate solutions
Reliability: (4) not assignable
Manufacturers data without proof.
Flag: Critical study for SIDS endpoint
20-OCT-2004 (18) (22)

Type: density
Value: 1.32 - 1.68 g/cm³ at 20 degree C

Test substance: Sodium silicate solutions; molar ratios between 3.86 and 1.65
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
20-OCT-2004 (15)

Type: bulk density
Value: ca. 700 kg/m3 at 20 degree C

Test substance: Spray-dried sodium silicate powder of molar ratio 2.1
Reliability: (4) not assignable
Manufacturers data without proof.
Flag: Critical study for SIDS endpoint
20-OCT-2004 (47)

Type: bulk density
Value: ca. 800 kg/m3 at 20 degree C

Test substance: Spray-dried sodium silicate powder of molar ratio 3.4.
Reliability: (4) not assignable
Manufacturers data without proof.
Flag: Critical study for SIDS endpoint
20-OCT-2004 (48)

2.3.1 Granulometry

2.4 Vapour Pressure

Value: .0031 hPa at 1165 degree C

Method: other (measured): Kroeger and Soerstroem

GLP: no data

Remark: The vapour pressure at environmental temperatures is negligibly low and thus not relevant.
Test substance: Sodium silicate (Na2O x 2 SiO2) of molar ratio 2.0
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
08-JAN-2004 (33)

Value: .0016 hPa at 1172 degree C

Method: other (measured): Kroeger and Soerstroem
GLP: no data

Remark: The vapour pressure at environmental temperatures is negligibly low and thus not relevant.
Test substance: Sodium silicate (Na2O x 3 SiO2) of molar ratio 3.0
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
08-JAN-2004 (33)

2.5 Partition Coefficient

Remark: Alkali silicates are totally insoluble in n-octanol (as for most other organic solvents). The oil/water partition coefficient of these substances (as normally determined with n-octanol/water) is therefore not applicable or relevant.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
Flag: Critical study for SIDS endpoint
20-OCT-2004 (5)

2.6.1 Solubility in different media

pH value: 11 - 13

Remark: Alkaline silicates are completely insoluble in n-octanol. The pH in alkaline silicates is dependant on the silica to alkali ratio and the concentrations of the individual solutions. Concentrated solutions usually have a pH between 10 and 13.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
Flag: Critical study for SIDS endpoint
19-OCT-2004 (5)

Remark: Solid sodium silicate (lumps or ground glass) is practically insoluble in water at ambient temperature and pressure. Solutions containing up to 55% solids in water can be achieved at elevated temperature and pressure. They are stable at room temperature.
Reliability: (4) not assignable
Manufacturers data without proof.

19-OCT-2004 (22)

Solubility in: Water
Value: 115 mg/l at 25 degree C

Remark: Amorphous silica which precipitates when alkaline silicate solutions are neutralized has a water solubility of 115 mg/l at 25°C and neutral pH.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
03-DEC-2003 (39)

Remark: Powders obtained by water evaporation from solutions are readily soluble in water at room temperature due to their residual water content of about 20%.
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
21-OCT-2004 (15) (38)

Remark: Soluble silicates are incompatible with most organic compounds.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (38)

Solubility in: Water

Remark: Solid sodium silicates are very slightly soluble or almost insoluble in cold water. They are best brought into solution by heating with with water under pressure. They are less readily soluble in large amounts of water than in small amounts and the anhydrous silicates dissolve with more difficulty than the hydrated silicates. Silicates containing more sodium dissolve more readily.
Reliability: (2) valid with restrictions
Peer-reviewed handbook data.
Flag: Critical study for SIDS endpoint
19-OCT-2004 (4)

2.6.2 Surface Tension

2.7 Flash Point

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (5) (38)

2.8 Auto Flammability

Value:

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (5) (38)

2.9 Flammability

Result: non flammable

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (5) (38)

2.10 Explosive Properties

Result: not explosive

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (5) (38)

2.11 Oxidizing Properties

Result: no oxidizing properties

Remark: Soluble silicates have no oxidizing properties.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
21-OCT-2004 (5)

2.12 Dissociation Constant

2.13 Viscosity

Value: 25 - 100000 mPa s (dynamic) at 20 degree C

Remark: In addition to the temperature, the viscosity of a sodium silicate solution depends to a large degree on the concentration and the molar ratio SiO2/Na2O.

For typical commercial silicate solutions the following viscosities are observed:

Solids content %	Molar ratio SiO2/Na2O	Viscosity mPa.s at 20°C

28.1	3.97	25
34.4	3.40	45
34.9	3.46	80
36.4	3.44	180
38.0	3.42	550
41.4	3.17	1100
43.3	2.69	400
45.0	2.84	2000
47.0	2.48	1750
54.5	2.09	ca. 100 000

Reliability: (4) not assignable
Collection of data
17-DEC-2003 (18)

Value: 20 - 500 mPa s (dynamic) at 20 degree C

Remark: In addition to the temperature, the viscosity of a sodium silicate solution depends to a large degree on the concentration and the molar ratio SiO2/Na2O.

Viscosities reported for typical commercial silicate solutions:

Total solids wt %	Molar ratio SiO2/Na2O	Viscosity mPa.s at 20°C
28.0	3.97	20
38.1	3.41	250-500
42.1	2.06	200
43.6	2.58	400

Reliability: (4) not assignable
Handbook data
21-OCT-2004 (38)

2.14 Additional Remarks

3.1.1 Photodegradation

Remark: The basic structural unit of soluble silicates is a tetrahedral arrangement of four oxygen atoms surrounding a central silicon atom. Tetrahedra are linked with each other via Si-O-Si bonds resulting in an infinite three-dimensional network where the oxygen atoms at the corners of a given tetrahedron are shared with neighbouring tetrahedra. Not all corners in the tetrahedra are shared; the negative charge of unshared oxygen atoms is balanced by the presence of sodium or potassium cations which are randomly spaced in the interstices of the silicate structure.
Based on these structural considerations a significant breakdown of soluble silicates via photodegradation is not expected.
Reliability: (2) valid with restrictions
Expert judgement
26-JAN-2004 (7)

3.1.2 Stability in Water

Type: abiotic

Remark: The basic consideration is that silica dissolves according to : $SiO_2 + H_2O = Si(OH)_4$. At low concentrations most species are present as monomers, at higher concentrations polymerisation will occur.
Most soluble silicates are in the form:
$M_2O . mSiO_2 . nH_2O$
where M = alkali metal, predominantly Na, but also K. The index m (molar ratio) ranges between 0.5 - 4, most commonly m = 3.3. Stability depends to a large extent on pH, above pH 10.6 the solutions are chemically stable. The increase of ionic strength accelerates nucleation and deposition and decreases the SiO_2 solubility. Coating of surfaces by organic matter may hamper dissolution, but at the same time $Si(OH)_4$ may form complexes with organic matter, a process which favours dissolution.
Reliability: (4) not assignable
Handbook data
29-MAR-2005 (15)

Remark: Polymerisation-Depolymerisation:
Upon dilution of concentrated commercial silicate solutions with water, the highly cross-linked polysilicate ions depolymerize rapidly to monosilicate ions, the extent of depolymerisation depending on the dilution factor.
Reliability: (2) valid with restrictions
Acceptable procedure and publication
18-DEC-2003 (41)

3.1.3 Stability in Soil

3.2.1 Monitoring Data (Environment)

Type of measurement: background concentration

Medium: other: surface-, ground- or drinking water

Remark: Dissolved silica from commercial soluble silicates is indistinguishable from natural dissolved silica since depolymerisation of polysilicate anions to monomeric dissolved silica occurs very rapidly when commercial soluble silicate solutions are diluted with water. Therefore any soluble silica input to the natural silica cycle as a result of the production or use of commercial soluble silicates will be insignificant in view of the size and high flux of the natural silica cycle.
Reliability: (2) valid with restrictions
Acceptable procedure and publication
Flag: Critical study for SIDS endpoint
18-DEC-2003 (15) (41) (50)

Type of measurement: background concentration
Medium: ground water
Concentration: ca. 17 mg/l

Remark: The median value in the US was reported to be 17 mg SiO2/l for ground waters.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (10)

Type of measurement: background concentration
Medium: surface water
Concentration: ca. 14 mg/l

Remark: The median value in the US was reported to be 17 mg SiO2/l for streams.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (10)

Type of measurement: background concentration
Medium: surface water
Concentration: ca. 13 mg/l

Remark: The worldwide mean concentration in rivers is 13 mg SiO2/l.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (13)

Remark: Natural occurrence:
Compounds of silicon comprise ca. 59% of the earth's crust, constituted by minerals, soils and sediments, dissolved silica, amorphous silica in the solid phase and silica bound to organic matter.

Dissolved silica is a minor but ubiquitous constituent of the hydrosphere. Dissolved silica is supplied to the environment by chemical and biochemical weathering processes.
Reliability: (4) not assignable
Handbook data

Flag: Critical study for SIDS endpoint
29-MAR-2005 (15) (24)

Remark: SiO2 enters surface waters via the four main application areas where emissions to water systems might occur (household detergents, pulp-and paper production, water treatment, and soil stabilisation).
Seen in the context of the natural silica cycle, and natural loading of water systems with silicates due to weathering of soil and rocks, weathering of sediments and atmospheric deposition, this amount is small.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (50) (61)

3.2.2 Field Studies

3.3.1 Transport between Environmental Compartments

Remark: Due to a strong dependance on pH and concentration which leads to a complex dynamic polymerisation-depolymerisation equilibrium with speciation into a variety of mono-, oligo-, and polymeric anions and amorphous silica, calculations on the distribution in various environmental compartments are not feasible.
The contribution of anthropogenic inputs to the occurrence in the various compartments will be negligible compared to the concentrations contributed to by the natural silica flux.
Reliability: (4) not assignable
Handbook data
29-MAR-2005 (15)

3.3.2 Distribution

Remark: See remark in 3.3.1
18-DEC-2003

3.4 Mode of Degradation in Actual Use

3.5 Biodegradation

Type: aerobic
Inoculum: other: activated sludge of a predominantly domestic sewage
Concentration: 25 mg/l related to Test substance

Method: other: OECD Confirmatory Test
Year: 1994
GLP: yes

Method: METHOD FOLLOWED: OECD Confirmatory test, conforming with 82/242/EEC
and 82/243/EEC

DEVIATIONS FROM GUIDELINE: Not reported
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Silica concentration measured by ICP-method.

Result: RESULTS: EXPOSED
- Biodegradation: >90% of added sodium silicate was detected in the effluent. No significant elimination was observed. The test substance had no adverse effects on the model sewage plant.
RESULTS CONTROL: There were no significant differences in DOC, pH or dry mass of sludge between the control and silicate-dosed biodegradation unit.
STATISTICAL RESULTS: Not reported.

Test condition: TEST ORGANISMS
- Strain: a mixture of different strains of micro-organisms present in sludge from a predominantly domestic sewage treatment plant.
- Source/supplier: A sewage treatment plant in Hochdahl, Germany.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
- Method: Sodium silicate was mixed with sludge to measure the biodegradability
- Vehicle, solvent: none
- Concentration of vehicle/ solvent: 25 mg Portil A/l test matrix.
- Other procedures: pH, Dissolved Organic Carbon (DOC) and dry mass content was measured to register differences in control and test sludge.
- Control: two model systems with sludge without the test substance.
TEST PARAMETER: Detection of continuously added sodium silicate in model sewage treatment plant effluent and effect on plant parameters (pH, DOC, dry mass of sludge).

Test substance: SOURCE: Henkel KGaA
PURITY: 90.8%
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium disilicate "Portil A", molar ratio 2.1. Water soluble, white powder.

Reliability: (2) valid with restrictions
Well-documented study designed to evaluate the influence of silicate on functioning of model sewage treatment plant rather than the toxicity towards microorganisms.

Flag: Critical study for SIDS endpoint

18-DEC-2003 (45)

Remark: Not applicable (inorganic substance).

Reliability: (4) not assignable
Product brochure of producers association; data without proof.

29-MAR-2005 (5)

3.6 BOD5, COD or BOD5/COD Ratio

Method:
Year:
Method:

Remark: Not applicable (inorganic compound).

Reliability: (4) not assignable

Product brochure of producers association; data without proof.
29-MAR-2005 (5)

3.7 Bioaccumulation

Remark: Ingested silicates are excreted via urine and to a lesser extent via the faeces. Markedly increased and rapid urinary excretion of silica was observed when soluble sodium silicates were administered to rats (Benke & Osborn, 1979), dogs (King et al., 1933), cats (King & McGeorge, 1938) and guinea pigs (Sauer et al., 1959). The urinary silicon excretion half-life after administration of sodium silicate to rats via stomach tube was 24 h (Benke & Osborn, 1979).

Based on these metabolic considerations no bioaccumulation is to be expected.
Reliability: (2) valid with restrictions
Well documented publications giving sufficient detail for evaluation.
19-DEC-2003 (2) (27) (28) (49)

Remark: Soluble silicates have no bioaccumulation potential. There are no structural alerts to suspect such a hazard.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
29-MAR-2005 (5)

3.8 Additional Remarks

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type:	semistatic
Species:	other: Brachydanio rerio (now Danio rerio)
Exposure period:	96 hour(s)
Unit:	mg/l Analytical monitoring: no
NOEC:	= 348
LC50:	= 1108
LC100:	= 1949
Method:	OECD Guide-line 203 "Fish, Acute Toxicity Test"
Year:	1988
GLP:	yes
Test substance:	other TS

Method: METHOD FOLLOWED: OECD 203
DEVIATIONS FROM GUIDELINE: in the final test a range of concentrations with 5600 mg/l as the highest concentration was tested instead of 1000 mg/l.
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: parametric model developed by Kooijman (Water Res. 15, 1981, 107-119)
ANALYTICAL METHODS: not reported

Result: RESULTS: EXPOSED
- Nominal/measured concentrations: 24h, 48h, 72h and 96h LC50: 3710, 3360, 3269 and 3185 mg/l respectively. 96h LC100: 5600 mg/l, 96 h NOEC (mortality): 1000 mg/l and 96 h NOEC (swimming behaviour): 3200 mg/l
- Effect data (Mortality): at 96 hours all fish had died at 5600 mg/l (1949 mg active matter/l)
It is suggested that mortality at concentration >= 1800 mg/l may have been caused by the high pH value.
- Concentration / response curve: the slope was 0.24 (95% confidence interval 0.14-0.33)
- Effect concentration vs. test substance solubility: not reported
- Other effects: the fish did not show any abnormal behaviour
RESULTS: CONTROL
- Number/percentage of animals showing adverse effects: surviving fish did not show abnormal swimming behaviour
- Nature of adverse effects: not applicable
RESULTS: TEST WITH REFERENCE SUBSTANCE
No tests were performed with reference substance

Test condition: TEST ORGANISMS
- Strain: Brachydanio rerio
- Supplier: M.B. Ruysbroek B.V. (Noordvliet 159, Maassluis)
- Age/size/weight/loading: size 2.5±0.2 cm long, weight 0.14±0.03 g
- Feeding: not reported
- Pretreatment: not reported
- Feeding during test: no
STOCK AND TEST SOLUTION AND THEIR PREPARATION
- Dispersion: not reported
- Vehicle: water
- Concentration of vehicle/ solvent: not reported
- Other procedures: not reported
STABILITY OF THE TEST CHEMICAL SOLUTIONS: not reported

REFERENCE SUBSTANCE: none
DILUTION WATER
- Source: groundwater from a locality near Linschoten, several (not defined) salts were added to give DSWL
- Aeration: not reported
- Alkalinity: not reported
- Hardness: 210 mg/l CaCO3
- Salinity: (trace elements << 1 mg/l)
- TOC: not reported
- TSS: not reported
- pH: 8.0-8.2 after aeration
- Oxygen content: > 6 mg/l
- Conductance: not reported
- Holding water: not reported
TEST SYSTEM
- Test type: determination of the acute toxicity to Zebra fish according to OECD Guideline no. 203
- Concentrations: 100, 180, 320, 560, 1000, 1800, 3200 and 5600 mg silicate solution/l corresponding to 35, 63, 111, 195, 348, 626, 1114 and 1949 mg active matter/l
- Dosing rate: not reported
- Renewal of test solution: daily
- Exposure vessel type: 2000 ml all-glass beakers
- Number of replicates, fish per replicate: 2 replicates with 10 fish for each test or control solution
- Test temperature: 25±1 °C
- Dissolved oxygen: > 6.0 mg/l
- pH: 8.0 (conc.: 100 mg/l) - 10.3 (conc.: 5600 mg/l)
7.9 - 8.2 (control). pH dropped 0.0-1.0 during the 24 hrs before renewal.
- Intensity of irradiation: not reported
- Photoperiod: 16 h light- 8 h dark regime
DURATION OF THE TEST: 96 h
TEST PARAMETER: mortality
SAMPLING: pH and oxygen concentration (daily)
MONITORING OF TEST SUBSTANCE CONCENTRATION: no

Test substance: SOURCE: Degussa AG Werk Wesseling
PURITY: 26.8% SiO2, 8% Na2O
IMPURITY/ADDITIVE/ETC.:
- Concentration in test substance:
280 ppm Al2O3
90 ppm Fe2O3
1 ppm V
70 ppm TiO2
60 ppm CaO
370 ppm NaCl
ANY OTHER INFORMATION:
Sodium waterglass solution (Wasserglas 37/40), Molar ratio 3.46, 34.8 wt%, colourless liquid

Reliability: (1) valid without restriction
Guideline study

Flag: Critical study for SIDS endpoint

30-SEP-2004 (1)

Species: Lepomis macrochirus (Fish, fresh water)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no data
LC50: = 301 - 478

Method: other
GLP: no data

Test substance: other TS

Method: METHOD FOLLOWED: not reported
GLP: not reported
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported
Result: No further test results have been provided.
Test condition: No data on test conditions have been provided.
Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: not reported
Reliability: (4) not assignable
Only toxicological values available, no further test conditions have been described in the review document
06-FEB-2003 (60)

Species: other: Salmo gairdneri (now Oncorhynchus mykiss)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no data
LC50: = 260 - 310

Method: other: no method cited
Year: 1989
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: no data on test methods can be extracted from the article of which a large part is written in Japanese.
GLP: not reported
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported
Result: RESULTS: EXPOSED
- Nominal/measured concentrations: not reported
- Effect data (Mortality): LC50 (24 h): 352 mg/l (average of 4 replicates; range: 314-390 mg/l); LC50 (48 h): 302 mg/l (range: 266-340 mg/l); LC50(96h): 281 mg/l (range: 260-310 mg/l)
- Concentration / response curve: not reported
- Effect concentration vs. test substance solubility: Samples which have higher concentration than 300 mg/l decreased to 160 mg/l through polymerization at pH 7.2 - 7.8. At higher S. SiO2 concentration as 350 mg/l, the negative charge of colloidal silica increased with aging time at neutral zone.
- Other effects: The death of rainbow trout were considered to be caused by necrosis of the gill filaments with the colloidal silica.
RESULTS: CONTROL
- Number/percentage of animals showing adverse effects: not reported
- Nature of adverse effects: not reported
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: not reported
- Results: not reported
Test condition: TEST ORGANISMS
- Age/size/weight/loading: 4-7 cm body length, 0.7-4.0 g body weight, 4-5 months old.

There were 4 replicates with an unknown number of fish
STOCK AND TEST SOLUTION AND THEIR PREPARATION
Not reported.
TEST SYSTEM
- Test type: Adjustment of rearing water by pH control. 4 tests performed, 2 tests 2 hr aging followed by 1 hr aeration, 1 test, only pH control, 1 test 24 hr aging. Allowable concentration of soluble silicate (S. SiO2) in treated waste water containing water glass in rainbow trouts rearing was examined with acute toxicity tests and histopathological examinations. The polymerization rate of soluble silicate or water glass at pH 7,2 - 7,8 in a rearing water and the time course change of electric charge of colloidal silica were measured.
- Test temperature: water temperature 14-17 degrees Celsius
- pH: 6.8 - 8.0
TEST PARAMETER: The measurements make clear the states of silicate, the mechanism of acute toxicity occurence and the histopathological phenomena.

Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: Sodium waterglass, molar ratio 3.0 (NaO.3SiO2).

Conclusion: The authors state that the allowable S. SiO2 concentration of a treated waste water containing water glass would be 150 mg/l in order to avoid sol formation. Thence, 100 mg/l of S. SiO2 concentration could practically be set as an allowable concentration of the treated effluent.

Reliability: (2) valid with restrictions
Acceptable procedure and publication

Flag: Critical study for SIDS endpoint

30-SEP-2004 (36)

4.2 Acute Toxicity to Aquatic Invertebrates

Species: Daphnia magna (Crustacea)
Exposure period: 100 hour(s)
Unit: mg/l Analytical monitoring: no data
EC50: 247

Method: other
Year: 1953
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Anderson et al. 1948
GLP: study performed before existence of GLP
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: method of Anderson for calculation of 100h toxicity threshold
ANALYTICAL METHODS: not reported

Result: RESULTS: EXPOSED
- Nominal/measured concentrations: not reported
- Effect data (Immobilisation): EC50 247 ppm
- Concentration / response curve: not reported
- Cumulative immobilisation: not reported
- Effect concentration vs. test substance solubility: not reported
- Other effects: not reported

RESULTS CONTROL: not reported
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: not reported
- Results: not reported

Test condition: TEST ORGANISMS
- Strain: Daphnia magna
- Source/supplier: not reported
- Breeding method: Daphnids for use in toxicity tests were cultured in 4-oz. wide-mouth bottles. One mature female was placed in each of a series of bottles filled with the culture medium. After four or five days, 1 mg. of yeast was added every other day to each bottle. The yeast was prepared by mixing 1 mg. of dried yeast per milliliter of reference water, and then employing 1 ml. of the resulting suspension. Under these conditions, it was found that the females reproduced 30 young per brood, on the average, every two and one-half days. The young were removed every day to prevent depletion of the food supply, and were transferrred to a stock tank to which occasional amounts of yeast were added.
- Age: 12h
- Feeding: not reported
- Pretreatment: The daphnids were washed three times in reference water prior to being employed for the tests.
- Feeding during test: not reported
- Control group: not reported
STOCK AND TEST SOLUTION AND THEIR PREPARATION
- Dispersion: not reported
- Vehicle, solvent: not reported
- Concentration of vehicle/ solvent: not reported
- Other procedures: not reported
STABILITY OF THE TEST CHEMICAL SOLUTIONS: not reported
REFERENCE SUBSTANCE: not reported
DILUTION WATER
- Source: reference water
- Aeration: not reported
- Alkalinity: not reported
- Hardness: not reported
- Salinity: not reported
- TOC: not reported
- Ca/Mg ratio: not reported
- Na/K ratio: not reported
- TSS: not reported
- pH: not reported
- Oxygen content: not reported
- Conductance: not reported
- Holding water: double distilled, first in a Bamstead still, then in a Pyrox glass still
TEST SYSTEM
- Test type: acute toxicity to Daphnia magna
- Concentrations: not reported
- Renewal of test solution: not reported
- Exposure vessel type: 4-oz. bottles
- Number of replicates, individuals per replicate: 10
Daphnids per concentration, number of replicates unknown
- Test temperature: not reported
- Dissolved oxygen: not reported
- pH: 9.1 (threshold pH)
- Adjustment of pH: not reported
- Intensity of irradiation: not reported
- Photoperiod: not reported
DURATION OF THE TEST: 100 h

TEST PARAMETER: immobilization
SAMPLING: not reported
MONITORING OF TEST SUBSTANCE CONCENTRATION: not reported
Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: not reported
Reliability: (4) not assignable
Documentation insufficient for complete assessment.
30-SEP-2004 (17) (60)

Species: Daphnia magna (Crustacea)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no data
EC50: 216 - 247

Method: other: according to Anderson et al (1948)
Year: 1965
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: according to Anderson et al. (1948)
GLP: No, research performed before existence of GLP.
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result: RESULTS: EXPOSED
- Nominal/measured concentrations: Not reported.
- Effect data (Immobilisation): LC50 (24 h): 575 mg/l; LC50 (48 h): 494 mg/l; LC50 (72 h): 413 mg/l; LC50 (96 h) 216 mg/l (in glass-wool filtered University Lake Water), and 247 mg/l by exposure in standard reference water (SRW).
No other details reported.
RESULTS CONTROL: Not reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
No details reported.
Test condition: TEST ORGANISMS
- Strain: Not reported.
- Source/supplier: Cultured in laboratory, starting culture obtained from Put-In Bay, Ohio, USA
No further details reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No further details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: One test with University Lake Water filtered through glass-wool. Other test with Standard Reference Water which is prepared in a laboratory, free from organics, containing all the major ions in concentrations and proportions of a mean surface water of the United States.
No further details reported.
TEST SYSTEM
No details reported.
DURATION OF THE TEST: 96 hr
TEST PARAMETER: Immobilisation
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.
Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported

ANY OTHER INFORMATION: not reported
Reliability: (4) not assignable
Documentation insufficient for complete assessment.
06-FEB-2003 (12) (60)

Type: static
Species: Daphnia magna (Crustacea)
Exposure period: 48 hour(s)
Unit: mg/l Analytical monitoring: yes
EC0: 100
EC50: 1700
EC100: 10000

Method: Directive 92/69/EEC, C.2
Year: 1997
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: Directive 92/69/EEC, C.2. The method conforms with OECD 202, part 1
DEVIATIONS FROM GUIDELINE: no
GLP: yes
STATISTICAL METHODS: according to Stephan (squareroot of EC0 and EC100)
METHOD OF CALCULATION: linear regression analysis
ANALYTICAL METHODS: Not reported
Result: RESULTS: EXPOSED
- Nominal concentrations: 100, 300, 1000, 3000, 10000 mg active substance/l
- Effect data (Immobilisation): EC0 1000 mg/l, EC50 1700 mg/l and EC100 3000 mg/l (pH 9-11)
EC0 100 mg/l, EC50 1700 mg/l and EC100 10000 mg/l (pH 7.8-8)
- Concentration / response curve: not reported
- Cumulative immobilisation: not reported
- Effect concentration vs. test substance solubility: not reported
- Other effects: Not reported
RESULTS CONTROL: not reported
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: not reported
- Results: EC50 (24 hr) 0.9-1.9 mg/l for potassium dichromate
Test condition: TEST ORGANISMS
- Strain: Daphnia magna
- Source/supplier: BioInternational B.V. NJ Hoorn,The Netherlands
- Breeding method: incubation of ephipids at 4800 Lux and 19-22°C. The ephipids are grown on M4-Medium according to Elendt. Neonates are incubated at 900 Lux (16h light-8h dark cycle), 20°C and grown on M4-Medium according to Elendt.
- Age: not reported (neonates)
- Feeding: green algae Spirula (feeding terminated 3 hrs before start of the test)
- Pretreatment: Neonates are incubated at 900 Lux (16h light-8 h dark cycle), 20°C and grown on M4-Medium according to Elendt.
- Feeding during test: green algae Spirula (feeding terminated 3 hrs before start of the test)
- Control group: The two control groups were kept in water without test substance.
STOCK AND TEST SOLUTION AND THEIR PREPARATION

- Dispersion: not reported
- Vehicle, solvent: water
- Concentration of vehicle/ solvent: not reported
- Other procedures: not reported
STABILITY OF THE TEST CHEMICAL SOLUTIONS: The dilutions with pH 8 were slightly turbid at concentrations over 3000 mg active matter/l. The unadjusted dilutions were slightly turbid at 300 and 1000 mg active matter/l. The actual concentration was 95-100% of the nominal concentration.
REFERENCE SUBSTANCE: potassium dichromate
DILUTION WATER
- Source: M4-Medium
- Aeration: not reported
- Alkalinity: not reported
- Hardness: not reported
- Salinity: not reported
- TOC: not reported
- Ca/Mg ratio: not reported
- Na/K ratio: not reported
- TSS: not reported
- pH: Not reported
- Oxygen content: not reported
- Conductance: not reported
- Holding water: not reported
TEST SYSTEM
- Test type: Acute toxicity to Daphnia magna according to EU Guideline 92/69/EWG.
- Concentrations: 100-10000 mg/l
- Renewal of test solution: no
- Exposure vessel type: 100 ml glass beakers covered with glass plates
- Number of replicates, individuals per replicate: 20 daphnids per concentration in groups of 10, 2 replicates
- Test temperature: 20.3-20.5 °C
- Dissolved oxygen: not reported
- pH: 7.8-8.0 (adjusted) and 9-11 (not adjusted)
- Adjustment of pH: yes
- Intensity of irradiation: 900 Lux
- Photoperiod: 16h light-8h dark cycle
DURATION OF THE TEST: 48 h
TEST PARAMETER: mortality
SAMPLING: not reported
MONITORING OF TEST SUBSTANCE CONCENTRATION: not reported during test, but at the end of the test

Test substance: SOURCE: Henkel KGaA
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: 35% active matter, molar ratio 3.2, colourless liquid

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint
30-SEP-2004 (30)

Species: other aquatic crustacea: probably Hyallela sp. (Amphipoda)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no data
EC50: 160

Method: other: according to Anderson et al (1948)
Year: 1965
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: according to Anderson et al. (1948)
GLP: No, research performed before existence of GLP.
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result: RESULTS: EXPOSED
- Nominal/measured concentrations: Not reported.
- Effect data (Immobilisation): LC50 (24 h): 895 mg/l; LC50 (48 h): 263 mg/l; LC50 (72 h): 261 mg/l; LC50 (96 h): 160 mg/l
No other details reported.
RESULTS CONTROL: Not reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
No details reported.
Test condition: TEST ORGANISMS
- Strain: Not reported.
- Wild caught: Obtained from University Lake on the campus of the Louisiana State University.
No further details reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No further details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: University Lake Water filtered through glass-wool.

No further details reported.
TEST SYSTEM
No details reported.
DURATION OF THE TEST: 96 hr
TEST PARAMETER: Death
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.
Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: not reported
Reliability: (4) not assignable
Documentation insufficient for assessment.
06-FEB-2003 (12)

Species: other: Lymnaea sp. eggs
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no data
EC50: 632

Method: other: according to Anderson et al. (1948)
Year: 1965
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: according to Anderson et al. (1948)
GLP: No, research performed before existence of GLP.
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result: RESULTS: EXPOSED
- Nominal/measured concentrations: Not reported.
- Effect data (mortality): LC50 (24 h): 632 mg/l; LC50 (48 h): 630 mg/l; LC50 (72 h): 630 mg/l; LC50 (96 h): 632 mg/l
No other details reported.
RESULTS CONTROL: Not reported.
RESULTS: TEST WITH REFERENCE SUBSTANCE
No details reported.

Test condition: TEST ORGANISMS
- Strain: Not reported.
- Wild caught: The snails from which eggs were obtained, were found in a ditch near Fountainebleau State Park, Louisiana, USA.
No further details reported.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
No further details reported.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported.
REFERENCE SUBSTANCE: Not reported.
DILUTION WATER
- Source: University Lake Water filtered through glass-wool.

No further details reported.
TEST SYSTEM
No details reported.
DURATION OF THE TEST: 96 hr
TEST PARAMETER: Death
SAMPLING: Not reported.
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported.

Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: LCx = TLm (median tolerance limit)

Reliability: (4) not assignable
Documentation insufficient for assessment.

06-FEB-2003 (12)

4.3 Toxicity to Aquatic Plants e.g. Algae

Species: Scenedesmus subspicatus (Algae)
Endpoint: biomass
Exposure period: 72 hour(s)
Unit: mg/l Analytical monitoring:
EC0: 35
EC50: 207
EC10 :

Method: other: DIN 38412, Teil 9 (Algal growth inhibition test)
Year: 1994
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: DIN 38412, Teil 9, German National guidelines; the method conforms with OECD 201
GLP: yes
STATISTICAL METHODS: t-test
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: RESULTS: EXPOSED
- Nominal/measured concentrations: 1, 10, 100, 1000 mg product/l (nominal).

- Effect data/Element values:
EC0 (0-72 hrs, algal biomass): 100 mg product/l. Equivalent with 34,54 mg active matter/l.
EC50 (0-72 hrs, algal biomass): 600 mg product/l. Equivalent with 207 active matter/l.
EC0 (0-72 hrs, growth rate): > 1000 mg product/l. Equivalent with 345.4 mg active matter/l.
The test substance is slightly toxic to Scenedesmus subspicatus.
- Cell density data: Reduced cell density at 1000 mg product/l.
- Growth curves: Reduced growth rate at 1000 mg product/l.
RESULTS CONTROL: No growth inhibition was registered.
RESULTS TEST WITH REFERENCE SUBSTANCE: No tests were conducted with a reference substance.
STATISTICAL RESULTS: Not reported.

Test condition: TEST ORGANISMS
- Strain: Scenedesmus subspicatus SAG 8681
- Source/supplier: Institute of Plant Physiology, University of Göttingen.
- Laboratory culture: Not reported
- Method of cultivation: Not reported
- Pretreatment: 3-4 days incubation in the test medium without test substance.
- Controls: Scenedesmus subspicatus in the test medium alone.
- Initial cell concentration: 10E4 cells/ml
STOCK AND TEST SOLUTION AND THEIR PREPARATION
- Dispersion: Not reported
- Vehicle, solvent: deionised water
- Concentration of vehicle/ solvent: 100%
- Other procedures: 5 g of the test substance was dissolved in 500 ml deionised water, and a 1:10 dilution of the stock was made. The test solutions were made from both the stock and its dilution.
STABILITY OF THE TEST CHEMICAL SOLUTIONS: Not reported
REFERENCE SUBSTANCE: Not reported
DILUTION WATER
- Source: Not reported
- Aeration: Not reported
GROWTH/TEST MEDIUM CHEMISTRY
Test medium according to DIN 38412/9
- Alkalinity: Not reported
- Hardness: Not reported
- Salinity: Not reported
- TOC: Not reported
- EDTA: Not reported
- TSS: Not reported
- pH: Not reported
- Dissolved oxygen: Not reported
TEST SYSTEM
- Test type: Algal growth inhibition test. Incubation time 24, 48 and 72 hrs.
- Concentrations: 0, 1, 10, 100 and 1000 mg product/l test solution.
- Renewal of test solution: Not reported
- Exposure vessel type: 300 ml Erlenmeyer vessel
- Number of replicates: 3
- Test temperature: 22.5-24.0
- pH: 7.8-7.9 after 24 hrs, 8.2-10 after 72 hrs
- Intensity of irradiation: ca. 2000 Lux.

- Photoperiod: Continuous light
TEST PARAMETER: Inhibition of mitosis
MONITORING OF TEST SUBSTANCE CONCENTRATION: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 34.54% active matter (Wasserglas 3.0 with molar ratio 3.0), colourless liquid.

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (46)

4.4 Toxicity to Microorganisms e.g. Bacteria

Type: aquatic
Species: Pseudomonas putida (Bacteria)
Exposure period: 18 hour(s)
Unit: mg/l Analytical monitoring: no

Method: other: growth inhibition test; Umweltbundesamt, Berlin: Bewertung wassergefåhrdender Stoffe. Erarbeitet von der ad-hoc-Arbeitsgruppe 1 "Bewertung wassergefahrdender Stoffe"
Year: 1989
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: Growth inhibition test according to Umweltbudesamt Guideline "Bewertung Wassergefahrdender Stoffe" (4.1).
DEVIATIONS FROM GUIDELINE: The OD of the inoculum used in the tests was slightly higher than given in the protocol. 200 ml Erlenmeyer flasks were used instead of 250 ml flasks. Disposable plastic cuvettes were used for OD determinations instead of glass cuvettes.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: 10% growth inhibition was determined by taking the mean value of the optical density of 3 cultures at each concentration, together with the OD representing 10% inhibition of the growth defined as toxicity threshold by Bringmann and Kuhn (1980). A line was fitted through the values and the toxicity threshold was determined graphically.
ANALYTICAL METHODS: Optical density (Pye Unicam PU 8600 spectrometer at 436 nm)

Result: RESULTS EXPOSED:
- Nominal/measured concentrations: Not reported
- EC0 (toxicity threshold): > 10000 mg/l for neutralised concentrations (pH 7.6-7.8). Equivalent to >3480 mg active matter/l.
- EC0 (toxicity threshold): > 1000 mg/l for unneutralised concentrations (pH > 9). Equivalent to > 348 mg active matter/l.
RESULTS CONTROL: No effects
RESULTS TEST WITH REFERENCE SUBSTANCE: No reference substance was tested

Test condition: TEST ORGANISMS:
- Strain: Pseudomonas putida

- Supplier: Institut fur Wasser-, Bodem- und Lufthygiene des Bundesgesundheitsamtes, Berlin G.
Pretreatment: a pre-culture was prepared and from this culture a test culture was prepared by dilution with NaCl-solution (0.5 g/l) until the bacterial suspension had an optical density of 0.46
The bacterium was cultivated according to the method described in "III Bestimmung der akuten Bakterientoxizitat"
TEST SYSTEM:
- Test type: growth inhibition test
- Concentrations: 0, 100, 320, 1000, 3200 and 10000 Natronwaterglass mg/l. (neutralised and unneutralised).
The stock solution used for the neutrised dilutions was adjusted with NaCl to pH 6.88 prior to making the dilutions.
Number of replicates: 3 neutralised and 1 unneutralised test culture per dose level.
- Dissolved oxygen: Not reported
DURATION OF TEST: 18 hours
TEST PARAMETER: growth inhibition, measured by optical density

Test substance: SOURCE: Degussa AG Werk Wesseling
PURITY: 26.8% SiO_2, 8% Na_2O
IMPURITY/ADDITIVE/ETC.:
- Concentration in test substance:
280 ppm Al_2O_3
90 ppm Fe_2O_3
1 ppm V
70 ppm TiO_2
60 ppm CaO
370 ppm NaCl
ANY OTHER INFORMATION:
Sodium waterglass solution (Wasserglas 37/40), Molar ratio 3.46, 34.8 wt%, colourless liquid

Reliability: (1) valid without restriction
Guideline study

Flag: Critical study for SIDS endpoint

06-FEB-2003 (21)

Species: activated sludge of a predominantly domestic sewage
Exposure period: 28 day(s)
Unit: mg/l Analytical monitoring:
NOEC: >= 25

Method: other: OECD Confirmatory test
Year: 1994
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Confirmatory test, conforming with 82/242/EEC
and 82/243/EEC
DEVIATIONS FROM GUIDELINE: Not reported
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Silica concentration measured by ICP-method.

Result: RESULTS: EXPOSED
- Biodegradation: >90% of added sodium silicate was detected in the effluent. No significant elimination was observed. The test substance had no adverse effects on the model sewage

plant.
RESULTS CONTROL: There were no significant differences in DOC, pH or dry mass of sludge between the control and silicate-dosed biodegradation unit.
STATISTICAL RESULTS: Not reported.

Test condition: TEST ORGANISMS
- Strain: a mixture of different strains of micro-organisms present in sludge from a predominantly domestic sewage treatment plant.
- Source/supplier: A sewage treatment plant in Hochdahl, Germany.
STOCK AND TEST SOLUTION AND THEIR PREPARATION
- Method: Sodium silicate was mixed with sludge to measure the biodegradability
- Vehicle, solvent: none
- Concentration of vehicle/ solvent: 25 mg Portil A/l test matrix.
- Other procedures: pH, Dissolved Organic Carbon (DOC) and dry mass content was measured to register differences in control and test sludge.
- Control: two model systems with sludge without the test substance.
TEST PARAMETER: Detection of continuously added sodium silicate in model sewage treatment plant effluent and effect on plant parameters (pH, DOC, dry mass of sludge).

Test substance: SOURCE: Henkel KGaA
PURITY: 90.8%
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium disilicate "Portil A", molar ratio 2.1. Water soluble, white powder.

Reliability: (2) valid with restrictions
Well-documented study designed to evaluate the influence of silicate on functioning of model sewage treatment plant rather than the toxicity towards microorganisms.

18-DEC-2003 (45)

Species: Pseudomonas putida (Bacteria)
Exposure period: 30 minute(s)
Unit: mg/l Analytical monitoring:
EC0: 3454
EC10 :

Method: other: DIN 38412, Teil 27 (Bacterial oxygen consumption test)
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: DIN 38412, Teil 27, German National guidelines. The method conforms with OECD 209.
DEVIATIONS FROM GUIDELINE: no
GLP: yes
STATISTICAL METHODS: not reported.
METHOD OF CALCULATION: linear regression analysis

Result: RESULTS: EXPOSED
- Nominal concentrations: 10000 mg product/l
- Effect data (Immobilisation): EC0 10000 mg product/l (3454 mg active matter/l) (pH 11.1, at start 8.0), oxygen consumption was reduced by 8.13% i.e. < 10%
- Concentration / response curve: not reported
- Cumulative immobilisation: not reported

- Effect concentration vs. test substance solubility: not reported
- Other effects: not reported
RESULTS CONTROL: not reported
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: not reported
- Results: not reported

Test condition: TEST ORGANISMS
- Strain: Pseudomonas putida MIGULA, Stamm Berlin 33.2 (DSM 50026), 2 days old.
- Source/supplier: TFB-Mikrobiologie, Henkel KGaA
TEST SYSTEM:
According to DIN 38412

Test substance: SOURCE: Henkel KGaA
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: 34.54% active matter (Wasserglass 3.0 with molar ratio 3.0), colourless liquid.

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (29)

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

4.5.2 Chronic Toxicity to Aquatic Invertebrates

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Sediment Dwelling Organisms

4.6.2 Toxicity to Terrestrial Plants

4.6.3 Toxicity to Soil Dwelling Organisms

4.6.4 Toxicity to other Non-Mamm. Terrestrial Species

4.7 Biological Effects Monitoring

4.8 Biotransformation and Kinetics

4.9 Additional Remarks

5.0 Toxicokinetics, Metabolism and Distribution

Result: The silicon metabolism of rabbits after inhalation of a sodium silicate aerosol was studied. It was concluded that sodium silicate dissolves in the lungs and is rapidly eliminated via the urine.
Reliability: (3) invalid
Old literature without experimental details.
16-JUL-2003 (37)

Result: The rate and extent of urinary excretion of silicon in rats after oral administration of a single dose of sodium silicate of molar ratio 2.4 was investigated. Two trials were conducted: 40 mg/kg and 1000 mg/kg administration respectively.
At the 40 mg/kg level 18.9% of administered silicate was excreted in the urine, elevated levels of Si in the urine were observed only in the first 24 hrs after oral dosing.
At the 1000 mg/kg level 2.8% of the total administered silicate was excreted in the urine. The rate of sodium silicate excretion was obtained from data on urinary excretion (microgram Si) measured after 24, 48, 72 and 96 hrs of administration. The urinary excretion half-life for ingested sodium silicate was calculated to be 24 hours.
The excretion rate was independent of the doses applied indicating that the limiting factor is the rate of production of soluble or absorbable silicon in the gastrointestinal tract.
Reliability: (2) valid with restrictions
Well documented publication giving sufficient detail for evaluation.
21-NOV-2003 (2)

Result: The excretion of silicate administered to dogs orally or by intravenous injection was studied. A sodium silicate solution of unknown molar ratio was neutralized by hydrochloric acid and introduced into the stomachs of dogs by stomach tube. The output of silica (SiO2) in the urine markedly increased without corresponding increase in the blood and returned to normal after some hours. Moderate increases in the concentration of silica in the blood and enormous increases in the urine were observed following intravenous injection. As upon oral ingestion, silica levels in the urine returned to normal after the end of injection.
Reliability: (2) valid with restrictions
Well documented publication giving sufficient detail for evaluation.
21-NOV-2003 (28)

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Value: 3200 mg/kg bw

Method: other
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: Not reported
CLINICAL SIGNS: Changes in pH of the body fluids, shock, chemical irritation or corrosion of the viscera are reported as general acute effects of sodium silicate, with no further details.
NECROPSY FINDINGS: Acute gastroenteritis, vascular congestion, mottled livers
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
OTHER INFORMATION: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 36 wt% Sodium Silicate. Molar ratio of 3.3
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Type: LD50
Species: rat
Value: 1600 - 8600 mg/kg bw

Method: other
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: Not reported
CLINICAL SIGNS: Not reported
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported

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                  EXAMINATIONS: Not reported
Test substance:   SOURCE: Not reported
                  PURITY: Not reported
                  IMPURITY/ADDITIVE/ETC.: Not reported
                  ANY OTHER INFORMATION: Concentration not indicated. Molar
                  ratio 3.1
Reliability:      (4)  not assignable
                  Only secondary literature available (review).
06-FEB-2003                                                          (50)

Type:             LD50
Species:          rat
Value:            1500 - 2200 mg/kg bw

Method:           other
   GLP:           no
Test substance:   other TS

Method:           METHOD FOLLOWED: Not reported
                  GLP: No, study executed before existence of GLP
                  STATISTICAL METHODS: Not reported
                  METHOD OF CALCULATION: Not reported
                  ANALYTICAL METHODS: Not reported
Result:           MORTALITY: Not reported
                  CLINICAL SIGNS: Not reported
                  NECROPSY FINDINGS: Not reported
                  POTENTIAL TARGET ORGANS: Not reported
                  SEX-SPECIFIC DIFFERENCES: Not reported
Test condition:   TEST ORGANISMS: Not reported
                  ADMINISTRATION: Not reported
                  EXAMINATIONS: Not reported
Test substance:   SOURCE: Not reported
                  PURITY: Not reported
                  IMPURITY/ADDITIVE/ETC.: Not reported
                  ANY OTHER INFORMATION: 81 wt% Sodium Silicate. Molar ratio
                  2.1
Reliability:      (4)  not assignable
                  Only secondary literature available (review).
06-FEB-2003                                                          (50)

Type:             LD50
Species:          rat
Value:            1300 - 2100 mg/kg bw

Method:           other
   GLP:           no
Test substance:   other TS

Method:           METHOD FOLLOWED: Not reported
                  GLP: No, study executed before existence of GLP
                  STATISTICAL METHODS: Not reported
                  METHOD OF CALCULATION: Not reported
                  ANALYTICAL METHODS: Not reported
Result:           MORTALITY: Not reported
                  CLINICAL SIGNS: Not reported
                  NECROPSY FINDINGS: Not reported
                  POTENTIAL TARGET ORGANS: Not reported
                  SEX-SPECIFIC DIFFERENCES: Not reported
Test condition:   TEST ORGANISMS: Not reported
                  ADMINISTRATION: Not reported
                  EXAMINATIONS: Not reported
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Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Concentration not indicated. Molar ratio 2.1
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Type: LD50
Species: rat
Value: 1600 mg/kg bw

Method: other
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: Not reported
CLINICAL SIGNS: Not reported
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 81 wt% Sodium Silicate. Molar ratio 2.1
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Type: LD50
Species: rat
Strain: other: Cpb:Wu; Wistar random
Sex: male/female
No. of Animals: 50
Vehicle: no data
Doses: 3.30, 3.96, 4.75, 5.70, 6.86 g/kg bw
Value: = 3400 mg/kg bw

Method: other
Year: 1981
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Comparable to OECD Guideline 401
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Method of Weil (Biometrics 8, 1952, p. 249-263)
ANALYTICAL METHODS: Not reported
Result: MORTALITY:
- Time of death: Between 5 hours and 2 days after dosing

- Number of deaths at each dose:

Dose	male	female
3.30	0/5	1/5
3.96	0/5	2/5
4.75	1/5	1/5
5.70	2/5	1/5
6.86	5/5	5/5

CLINICAL SIGNS: Sedation, abdominal discomfort, sluggishness and unconsciousness
NECROPSY FINDINGS: No treatment related gross alterations
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported

Test condition: TEST ORGANISMS:
- Strain: Not reported
- Source: The Central Institute for the Breeding of Laboratory Animals TNO, Zeist, Netherlands
- Age: Young adult
- Weight at study initiation: 196-336 g (males), 142-195 (females)
- Number of animals: 50, 5/sex/dose
- Controls: Not reported
ADMINISTRATION:
- Doses: 3.30, 3.96, 4.75, 5.70, 6.86 g/kg bw
- Doses per time period: single doses administered (by gavage)
- Volume administered: 2.50, 3.00, 3.60, 4.32, 5.20 ml/kg
- Post dose observation: 14 days after treatment
EXAMINATIONS: Mortality, clinical signs and necropsy (microscopic and macroscopic)

Test substance: SOURCE: AKZO N.V.
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: The test substance Natron Waterglass 40/42 (ratio 2.0) is a clear colourless liquid. Density was 1.39. Concentration not indicated.

Reliability: (2) valid with restrictions
Test procedure according to national standards; report with limited detail.

Flag: Critical study for SIDS endpoint

06-FEB-2003 (56)

Type: LD50
Species: rat
Strain: other: Cpb:Wu; Wistar Random
Sex: male/female
No. of Animals: 60
Vehicle: no data
Doses: 3.43, 4.11, 4.93, 5.89, 7.12, 8.49 g/kg bw
Value: = 5150 mg/kg bw

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Comparable to OECD Guideline 401
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Method of Weil (Biometrics 8, 1952, p. 249-263)
ANALYTICAL METHODS: Not reported

Result: MORTALITY:
- Time of death: Between 3 hours and 3 days after dosing
- Number of deaths at each dose:

Dose	male	female
3.43	0/5	0/5
4.11	1/5	1/5
4.93	4/5	5/5
5.89	4/5	5/5
7.12	4/5	5/5
8.49	5/5	5/5

CLINICAL SIGNS: Sedation, abdominal discomfort, sluggishness and unconsciousness. Survivors recovered at the end of the 14-day observation period.
NECROPSY FINDINGS: No treatment related gross alterations
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported

Source: TNO Voeding AJ Zeist

Test condition: TEST ORGANISMS:
- Strain: Not reported
- Source: The Central Institute for Breeding of Laboratory Animals TNO, Zeist, The Netherlands.
- Age: Young adult
- Weight at study initiation: 225-300 g (males), 143-214 g (females)
- Number of animals: 60, 5/sex/dose
- Controls: Not reported

ADMINISTRATION:
- Doses: 3.43, 4.11, 4.93, 5.89, 7.12, 8.49 g/kg bw
- Doses per time period: single doses administered
- Volume administered: 2.5, 3.0, 3.6, 4.3, 5.2, 6.2 ml/kg
- Post dose observation: 14 days after treatment

EXAMINATIONS: Mortality, clinical signs and autopsy (microscopic and macroscopic).

Test substance: SOURCE: AKZO N.V.
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: The test substance Natron waterglass 38/40 (ratio 3.27) is a clear colourless liquid. The density was 1.37. Concentration not indicated.

Reliability: (2) valid with restrictions
Test procedure according to national standards; report with limited detail.

Flag: Critical study for SIDS endpoint

06-FEB-2003 (55)

Type: LD50
Species: rat
Value: 1000 mg/kg bw

Method: other
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: MORTALITY: Not reported
CLINICAL SIGNS: Not reported
NECROPSY FINDINGS: Not reported

POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 61 wt% Sodium SIlicate. Molar ratio 0.7
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Type: LD50
Species: rat
Value: 1500 mg/kg bw

Method: other
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: Not reported
CLINICAL SIGNS: Not reported
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 61 wt% Sodium Silicate. Molar ratio 0.7
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Type: LD50
Species: rat
Value: 500 mg/kg bw

Method: other
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: Not reported
CLINICAL SIGNS: Not reported
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported

SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 90 wt% Sodium Silicate. Molar ratio 0.5
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Type: LD50
Species: rat
Strain: Wistar
Sex: male
Vehicle: water
Value: 8650 mg/kg bw

Method: other
Year: 1971
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: after the method of Litchfield-Wilcoxon (J.Pharm. Exptl. Ther. 96, 99-108, 1949).
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY:
- Time of death: Between 3 hours and 3 days after treatment
- Number of deaths at each dose: Not reported
CLINICAL SIGNS: Affected well being, breathing difficulties, staggering gait and reduced motility
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS:
- Strain: Wistar
- Source: Not reported
- Age: Not reported
- Weight at study initiation: 175 g (male)
- Number of animals: 1 animal/dose
- Controls: Not reported
ADMINISTRATION:
Doses: Not reported
Doses per time period: Not reported
Volume administered or concentration: Not reported
- Postexposure period: 8 days
EXAMINATIONS: Mortality, clinical signs
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio 3.38. 35 wt% concentration calculated on the basis of 8% Na2O and 27% SiO2.
Reliability: (4) not assignable
Only short abstract available.
06-FEB-2003 (20)

Type: LD50
Species: rat
Value: 2000 - 2500 mg/kg bw

Method: other
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: Not reported
CLINICAL SIGNS: Not reported
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 51 wt% Sodium Silicate. Molar ratio 1.7
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Type: LD50
Species: rat
Vehicle: no data
Doses: no data
Value: > 2000 mg/kg bw

Method: other
Year: 1982
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: No deaths
CLINICAL SIGNS: None
NECROPSY FINDINGS: No remarkable findings
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Natron Wasserglas 37/40. Molar ratio 3.3. Concentration not indicated.
Reliability: (4) not assignable

Report has too limited information.
06-FEB-2003 (44)

Type: LD50
Species: mouse
Sex: male
Vehicle: no data
Doses: no data
Value: = 6600 mg/kg bw

Method: other
Year: 1973
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: Not reported
CLINICAL SIGNS: Not reported
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS:
- Strain: Not reported
- Source: Not reported
- Age: Not reported
- Weight at study initiation: 22 g (average)
- Controls: Not reported
ADMINISTRATION:
- Doses: Not reported
- Doses per time period: Not reported
- Volume administered or concentration: Not reported
- Postexposure period: 8 days
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Waterglass 37/40. Molar ratio 3.35.
Concentration not indicated.
Reliability: (4) not assignable
Only short abstract available.
06-FEB-2003 (19)

5.1.2 Acute Inhalation Toxicity

5.1.3 Acute Dermal Toxicity

5.1.4 Acute Toxicity, other Routes

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species: rabbit
Concentration: 38.3 other: wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 1
PDII: .33
Result: not irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1985
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: Yes (only 1 animal tested)
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Erythema: 0.33
- Edema: 0
REVERSIBILITY: At 48 hrs erythema was no longer observed.
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: male
- Source: Cheshire Rabbit Farms Ltd.
- Age: approx. 11 weeks
- Weight at study initiation: 2.3 - 3.0 kg
- Number of animals: 1
- Controls: not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area.
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: no
- Concentration in vehicle: not applicable
- Total volume applied: 0.5 ml
- Postexposure period: 5 days
- Removal of test substance: yes (washed away with water)
- Other: the exposure lasted 1 min, 1 hr or 4 hrs
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: according to Draize
- Examination time points: 1, 24, 48, 72 hours and 5 days
Test substance: SOURCE: Imperial Chemical Industries
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 38.25 wt% Sodium Silicate. Molar ratio 3.28, colourless liquid
Reliability: (2) valid with restrictions
Study according to OECD Guideline, but only 1 animal tested.
Flag: Critical study for SIDS endpoint
22-JAN-2004 (8)

Species: rabbit
Concentration: 39 other: wt%

Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 1
PDII: 0
Result: not irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1985
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: Yes (only 1 animal tested)
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Erythema: 0
- Edema: 0
REVERSIBILITY: After 24 hours no transient erythema was observed.
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: female
- Source: Cheshire Rabbit Farms Ltd.
- Age: approx. 11 weeks
- Weight at study initiation: 2.3 - 3.0 kg
- Number of animals: 1
- Controls: not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: no
- Concentration in vehicle: not applicable
- Total volume applied: 0.5 ml
- Postexposure period: 5 days
- Removal of test substance: yes (washed away with water)
- Other: the exposure lasted 1 min, 1 hr or 4 hrs
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: according to Draize
- Examination time points: 1, 24, 48, 72 hours and 5 days
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 39.01 wt% Sodium Silicate. Molar ratio of 2.80, clear colourless liquid.
Reliability: (2) valid with restrictions
Study according to OECD Guideline, but only 1 animal tested.
Flag: Critical study for SIDS endpoint
04-AUG-2003 (8)

Species: rabbit
Concentration: 39.9 other: wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 1

PDII: 3
Result: irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1985
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: Yes (only 1 animal tested)
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Erythema: 2
- Edema: 1
REVERSIBILITY: Effects persisted for at least 5 days.
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: male
- Source: Cheshire Rabbit Farms Ltd.
- Age: approx. 11 weeks
- Weight at study initiation: 2.3 - 3.0 kg
- Number of animals: 1
- Controls: not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: no
- Concentration in vehicle: not applicable
- Total volume applied: 0.5 ml
- Postexposure period: 5 days
- Removal of test substance: yes (washed away with water)
- Other: the exposure lasted 1 min, 1 hr or 4 hrs
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: according to Draize
- Examination time points: 1, 24, 48, 72 hours and 5 days
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 39.86 wt% Sodium Silicate. Molar ratio 2.40, clear colourless liquid.
Reliability: (2) valid with restrictions
Study according to OECD Guideline, but only 1 animal tested.
Flag: Critical study for SIDS endpoint
04-AUG-2003 (8)

Species: rabbit
Concentration: 40.9 other: wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 1
PDII: 3
Result: irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"

Year: 1985
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: Yes (only 1 animal tested)
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Erythema: 2
- Edema: 1
REVERSIBILITY: Effects persisted for at least 5 days.
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: female
- Source: Cheshire Rabbit Farms Ltd.
- Age: approx. 11 weeks
- Weight at study initiation: 2.3 - 3.0 kg
- Number of animals: 1
- Controls: not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: no
- Concentration in vehicle: not applicable
- Total volume applied: 0.5 ml
- Postexposure period: 5 days
- Removal of test substance: yes (washed away with water)
- Other: the exposure lasted 1 min, 1 hr or 4 hrs
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: according to Draize
- Examination time points: 1, 24, 48, 72 hours and 5 days
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 40.93 wt% Sodium Silicate. Molar ratio 2.00, clear colourless liquid.
Reliability: (2) valid with restrictions
Study according to OECD Guideline, but only 1 animal tested.
Flag: Critical study for SIDS endpoint
04-AUG-2003 (8)

Species: rabbit
Concentration: 53.5 other: wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 3
PDII: 8
Result: corrosive

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1984
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: Not reported
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Erythema: 4
- Edema: 4
REVERSIBILITY: The wounds caused by erythema and oedema were not healed after 14 days.
OTHER EFFECTS: All exposed animals showed an acute necrosis. The necrosis and an acute oedema outside the wound remained during the following examinations.
Test condition: TEST ANIMALS:
- Strain: White Landrace
- Sex: Not reported
- Source: Dörröds Djur -och Foderservice, Veberöd
- Age: Not reported
- Weight at study initiation: 2.7 kg (average)
- Number of animals: 3
- Controls: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area.
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusion
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml
- Postexposure period: one week for animals with no lesions and 14 days for animals with wounds
- Removal of test substance: removed with water after 4 hrs exposure
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: skin irritation index, according to OECD 404.
- Examination time points: 1, 24, 48 and 72 hours
Test substance: SOURCE: EKA AB
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 53.5 wt% Sodium Silicate in water. Molecular weight 158, pH 12.8, liquid, molar ratio 1.6. Classification "corrosive" according to Swedish standards
Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.
Flag: Critical study for SIDS endpoint
25-NOV-2003 (26)

Species: rabbit
Concentration: 34.5 other: wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 3
PDII: .4
Result: not irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1984

GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: Not reported
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Erythema: 0.3
- Edema: 0.1
REVERSIBILITY: 1 of 3 rabbits had redness that persisted until 72 hrs and oedema observed only 48 hrs after exposure ended.
OTHER EFFECTS: One rabbit had redness for 72 hrs, and oedema briefly at 48 hrs after exposure ended.
Test condition: TEST ANIMALS:
- Strain: White Landrace
- Sex: Not reported
- Source: Dörröds Djur -och Foderservice, Veberöd
- Age: Not reported
- Weight at study initiation: 2.7 kg (average)
- Number of animals: 3
- Controls: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area.
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusion
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml
- Postexposure period: one week for animals with no lesions and 14 days for animals with wounds
- Removal of test substance: removed with water after 4 hrs exposure
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: skin irritation index, according to OECD 404.
- Examination time points: 1, 24, 48 and 72 hours
Test substance: SOURCE: EKA AB
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 34.5 wt% Sodium Silicate in water. Molecular weight 268, pH 11.2, liquid, molar ratio 3.4. Classification "irritating" according to Swedish standard.
Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.
Flag: Critical study for SIDS endpoint
25-NOV-2003 (26)

Species: rabbit
Concentration: 99 other: wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 4
Result: irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R.

1500.41
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: not reported
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: not reported
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 99 wt% Sodium Silicate. Molar ratio 3.3. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 80 other: wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 0
Result: not irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.41
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported

ADMINISTRATION/EXPOSURE
- Preparation of test substance: Not reported
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 80 wt% Sodium Silicate. Molar ratio 3.3. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.

Reliability: (4) not assignable
Only secondary literature available (review).

06-FEB-2003 (50)

Species: rabbit
Concentration: 36 other: wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 3
Result: moderately irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.41
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported

Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: Not reported
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours

Test substance: SOURCE: Not reported

PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 36 wt% Sodium Silicate. Molar ratio 3.3. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 43 other: wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 3
Result: moderately irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.41
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: Not reported
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 43 wt% Sodium Silicate. Molar ratio 3.0. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 37 other: wt%
Exposure: Occlusive

Exposure Time: 24 hour(s)
PDII: 3
Result: moderately irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.41
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: Not reported
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 37 wt% Sodium Silicate. Molar ratio 2.6. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 24 other: wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 4
Result: irritating

Method: other: Federal Hazardous Substance Act), 16 C.F.R. 1500.41
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: Not reported
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 24 wt% Sodium Silicate. Molar ratio 2.5. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 99 other: wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 8
Result: corrosive

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.41
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: Not reported
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS

- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 99 wt% Sodium Silicate. Molar ratio 2.1. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.

Reliability: (4) not assignable
Only secondary literature available (review).

06-FEB-2003 (50)

Species: rabbit
Concentration: 54 other: wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 4
Result: irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.41
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported

Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: Not reported
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 54 wt% Sodium Silicate. Molar ratio 2.1. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.

Reliability: (4) not assignable
Only secondary literature available (review).

06-FEB-2003 (50)

```
Species:          rabbit
Concentration:    8 other: wt%
Exposure:         Occlusive
Exposure Time:    24 hour(s)
PDII:             4
Result:           irritating

Method:           other: FHSA (Federal Hazardous Substance Act), 16 C.F.R.
                  1500.41
   GLP:           no
Test substance:   other TS

Method:           METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act)
                  test specified in 16 C.F.R. 1500.41 et.seq.
                  GLP: No, study executed before existence of GLP
                  STATISTICAL METHODS: Not reported
                  METHOD OF CALCULATION: Draize method (1944)
                  ANALYTICAL METHODS: Not reported
Result:           AVERAGE SCORE: Not reported
                  REVERSIBILITY: Not reported
                  OTHER EFFECTS: PDII was > 4
Test condition:   TEST ANIMALS: Not reported
                  ADMINISTRATION/EXPOSURE
                  - Preparation of test substance: Not reported
                  - Area of exposure: intact and abraded skin
                  - Occlusion: yes
                  - Vehicle: Not reported
                  - Concentration in vehicle: not reported
                  - Total volume applied: 0.5 ml or 0.5 g, not specified
                  - Postexposure period: 72 hours
                  - Removal of test substance: after 24 hours
                  EXAMINATIONS
                  - Scoring system: Primary irritation indices from 1 to 4;
                  sum of intact and abraded scores included
                  - Examination time points: 24 and 72 hours
Test substance:   SOURCE: Not reported
                  PURITY: Not reported
                  IMPURITY/ADDITIVE/ETC.: Not reported
                  ANY OTHER INFORMATION: 8 wt% Sodium Silicate. Molar ratio
                  2.1. The article does not specify whether the substance was
                  a dry powder or a liquid. Powders were moistened with
                  physiological saline before application of 0.5 g, while
                  liquids were applied directly in 0.5 ml doses.
Reliability:      (4)  not assignable
                  Only secondary literature available (review).
06-FEB-2003                                                          (50)

Species:          rabbit
Concentration:    43 other: wt%
Exposure:         Occlusive
Exposure Time:    4 hour(s)
PDII:             3.3
Result:           moderately irritating

Method:           other: DOT skin contact test, Federal Hazardous Materials
                  Transportation Act (FHMTA) 49 C.F.R. 173.240
   GLP:           no
Test substance:   other TS

Method:           METHOD FOLLOWED: DOT Skin contact test, Federal Hazardous
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Materials Transportation Act (FHMTA) 49 C.F.R.173.240.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 4 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 43 wt% Sodium Silicate. Molar ratio 3.0. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 37 other: wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
PDII: 0
Result: not irritating

Method: other: DOT skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R.173.240
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: DOT Skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R.173.240.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact and abraded skin

- Occlusion: yes
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 4 hours

EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 37 wt% Sodium Silicate. Molar ratio 2.6. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.

Reliability: (4) not assignable
Only secondary literature available (review).

06-FEB-2003 (50)

Species: rabbit
Concentration: 47 other: wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
PDII: 4.2
Result: irritating

Method: other: DOT skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: DOT Skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported

Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 4 hours

EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported

ANY OTHER INFORMATION: 47 wt% Sodium Silicate. Molar ratio 2.5. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 44 other: wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
PDII: 4.2
Result: irritating

Method: other: DOT skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: DOT Skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 4 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 44 wt% Sodium Silicate. Molar ratio 2.1. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 54 other: wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)

PDII: 4.7
Result: irritating

Method: other: DOT skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R.173.240
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: DOT Skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 4 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 54 wt% Sodium Silicate. Molar ratio 2.1. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 38 other: wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
PDII: 3.2
Result: moderately irritating

Method: other: DOT skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: DOT Skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)

ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area.
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 4 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 38 wt% Sodium Silicate. Molar ratio 1.9. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 51 other: wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
Result: corrosive

Method: other: DOT skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: DOT Skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: the substance was reported to be corrosive, no irritation index was reported.
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area.
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml or 0.5 g, not specified

- Postexposure period: 72 hours
- Removal of test substance: after 4 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 51 wt% Sodium Silicate. Molar ratio 1.7. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.

Reliability: (4) not assignable
Only secondary literature available (review).

06-FEB-2003 (50)

Species: rabbit
Concentration: 61 other: wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)

Method: other: DOT skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: DOT Skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R.173.240
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: the substance was reported not to be corrosive, no irritation index was reported.

Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area.
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 4 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 61 wt% Sodium Silicate. Molar ratio 0.7. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.

Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 90 other: wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
Result: corrosive

Method: other: DOT skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: DOT Skin contact test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: the substance was reported to be corrosive, no irritation index was reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied diretly to the test area.
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Postexposure period: 72 hours
- Removal of test substance: after 4 hours
EXAMINATIONS
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 90 wt% Sodium Silicate. Molar ratio 0.5. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 82 %
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 3
PDII: 4.6
Result: corrosive

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"

Year: 1984
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: Not reported
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Erythema: 2.6
- Edema: 2.0
REVERSIBILITY: 1 animal had a wound that had not healed after 14 days. The skin on the other animal had healed after 14 days.
OTHER EFFECTS: 2 of 3 animals showed necrotic skin lesions. 1 animal had a local necrosis which remained together with an acute oedema during the whole examination period. The second animal had a pigmented wound with an acute oedema which decreased to a slight oedema after 72 hrs. The third animal showed no skin irritancy. The fur grew fast on this animal, which made it difficult to obtain close contact between the test substance and the exposed area.

Test condition: TEST ANIMALS:
- Strain: White Landrace
- Sex: Not reported
- Source: Dörröds Djur -och Foderservice, Veberöd
- Age: Not reported
- Weight at study initiation: 2.7 kg (average)
- Number of animals: 3
- Controls: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area.
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusion
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 g/ml
- Postexposure period: one week for animals with no lesions and 14 days for animals with wounds
- Removal of test substance: removed with water after 4 hrs exposure
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: skin irritation index, according to OECD 404.
- Examination time points: 1, 24, 48 and 72 hrs

Test substance: SOURCE: EKA AB
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 82 wt% Sodium Silicate in water. Molecular weight 204, solid, molar ratio of 2.4. Classification "corrosive" according to Swedish standards.

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (26)

Species: human

Concentration: 34.9 other: wt%
Exposure: Open
Exposure Time: 30 minute(s)
No. of Animals: 20
Vehicle: water
Result: not irritating

Method: other: COLIPA open cutaneous test
Year: 1997
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: COLIPA open cutaneous test.
GLP: The study was compliant with GCP guidelines.
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: FINDINGS
- Clinical signs: Exposure to undiluted sodium silicate solution did
not cause any irritation. It rapidly hardened on the skin, forming a wax-like coating. The 50% aqueous dilution caused slight redness (barely perceptible erythema) in 3/20 volunteers 21-25 minutes after the exposure started, and lasted 15-19 minutes. The 10% aqueous dilution caused slight redness (barely perceptible erythema) in 2/20 volunteers 21 and 25 minutes after the exposure started, and lasted 19 and 15 minutes, respectively. Exposure to 5% dilution resulted in slight redness (barely perceptible erythema) in 2/20 volunteers, which started 25 and 21 minutes after the first exposure and lasted 15 and 19 minutes in total, respectively. A third volunteer had a slight itch that started right after the exposure ended, and lasted 30 minutes. All the adverse effects were reversible.
Under non-occlusive conditions the 5, 10 and 50% aqueous dilutions of the sodium silicate solution caused slight irritation
(barely perceptible erythema). The undiluted sodium silicate solution
did not cause irritation.
Test condition: PERSONS EXPOSED: 10 male and 10 female volunteers.
EXPOSURE
- Reason of exposure: To assess the skin irritation potential of waterglas 37/40 in humans.
- Type of exposure: Dermal, non-occlusive.
- Duration of exposure: 30 minutes, the test substance was reapplied with a glass stick every 30 seconds. The test area on the inner lower arm was 3 cm2. After 30 minutes, the test area was rinsed with water and dried.
- Exposure concentrations / dose: 5, 10, 50% aqueous solutions and undiluted.
- Other information: The test was performed according to COLIPA.
EXAMINATIONS: The adverse skin effects were scored for erythema and oedema until 30 minutes after the last application. The range ran from 0 (no reaction) to 4 (very strong redness spreading outside the test site and/or very strong oedema >2 mm). In addition the subjects were questioned to assess the occurrence of burning sensation, itching, pain, heat, cold.
OTHER: Not reported.
Test substance: SOURCE: Henkel KGaA

PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: The test substance is a Natronwasserglas 37/40, a silicate solution of 34.9 wt% and a molar ratio 3.45.
Reliability: (2) valid with restrictions
Guideline study, adapted to human conditions. No information on purity of test substance.
25-NOV-2003 (32)

Species: human
Concentration: 34.9 other: wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 20
Vehicle: water
Result: not irritating

Method: other: in line with OECD Guide-line 404
Year: 1997
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: In line with OECD 404
DEVIATIONS FROM GUIDELINE: Adjusted to testing on human subjects.
GLP: According to GCP
STATISTICAL METHODS: Many-one comparison with the positive control SDS.
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: FINDINGS
- Clinical signs: The undiluted test substance caused slight scaling of the skin in 7/20 volunteers and strong scaling in 1/20. The total score was 0.45. Exposure to a 50% dilution caused slight scaling of the skin in 7/20 volunteers and strong scaling in 1/20, giving the total score 0.45.
- Outcome: Undiluted sodium silicate 37/40 caused scaling of the skin in 8/20 volunteers, but is not considered irritating to the skin. A 50% dilution of sodium silicate 37/40 resulted in scaling of the skin in 9/20 subjects, giving a total score of 0.50.
OTHER: Not reported.
Test condition: PERSONS EXPOSED: 10 male and 10 female volunteers.
EXPOSURE
- Reason of exposure: To assess the irritation potential of sodium silicate 37/40 on human skin.
- Type of exposure: 500 µl of the substance was applied to the inside of the lower arm and covered by a semi-occlusive patch, app. 1.5 cm2. 2 hrs after application, the site was examined for irritation, and removed if strong irritation was observed. The patch was removed after 4 hrs, and the test site rinsed.
- Duration of exposure: 4 hrs.
- Exposure concentrations / dose: 500 µl of undiluted sodium silicate or a 50% aqueous solution.
- Other information:
EXAMINATIONS: The test site was examined for irritation at 1, 24, 48 and 72 hrs after the exposure ended. The occurrence of erythema, oedema, flaking/dandruff and fissures in the skin was assessed according to Frosch'

scoring system (PJ Frosch, AM Kligman: J Am Acad Dermatol 1, 1979, 35-41.). The scores were summed and an irritation score derived from the results. Sodium dodecylsulfate 20% was used a positive control, if the results did not differ significantly (p greater than or equal to 0.05) from those of the positive control, it was considered irritating. The positive control caused erythema within 2 hrs, with a score of 21.8. The negative control, water, did not cause any adverse effects.

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC: Not reported
ANY OTHER INFORMATION: The test substance was Natronwasserglas 37/40, a silicate solution of 34.9 wt% and a molar ratio 3.45.

Reliability: (2) valid with restrictions
Guideline study, adapted to human conditions. No information on purity of test substance.

25-NOV-2003 (31)

Species: mouse
No. of Animals: 15
Result: not irritating

Method: other
Year: 1973
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: Not reported
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: The exposure did not cause any irritation of the skin.

Test condition: TEST ANIMALS:
- Strain: hairless
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: not reported
- Number of animals: 5 animals/dose
- Controls: Not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the skin area.
The test substance was applied once a day for one week.
- Area of exposure: Not reported
- Occlusion: Not reported
- Vehicle: Not reported
- Concentration in vehicle: Not reported
- Total volume applied: Not reported
- Postexposure period: Not reported
- Removal of test substance: Not reported
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium Silicate 37/40 was tested

undiluted in a 10% and in a 50% dilution. The molar ratio is 3.35.
Reliability: (3) invalid
Method not validated and insufficient documentation.
06-FEB-2003 (19)
Species: rat
Concentration: 52 other: wt%
Exposure: Open
Exposure Time: 4 hour(s)
Vehicle: water
Result: corrosive

Method: other: comparable to Directive 2000/33/EC, B.40
Year: 1988
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: comparable to the rat skin transcutaneous electrical resistance (TER) assay according to Directive 2000/33/EC, B.40. The study was a basis for elaborating this guideline.
DEVIATIONS FROM GUIDELINE: In comparison to the guideline, the following parts of the study were not in line.
- The skin was not washed in antibiotica before harvesting;
- The skin was clipped approximately 48 hrs before harvesting, instead of 3-7 days;
- Physiological saline was used to hydrate the skin during measurement of TER, instead of MgSO4 (154mM);
- The water used to rinse the skin discs was 40-45°C instead of 30°C;
- 70% ethanol was not used to rinse the skin disc after the test substance had been removed;
- No negative control was used;
- The threshold value was 4kOhm instead of 5 kOhm.
GLP: No, study performed before existence of GLP.
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: The substance is classified as corrosive if the electrical resistance value is reduced below the set threshold level of 4 kOhm.disc (3.2 kOhm.cm2)
ANALYTICAL METHODS: electrical resistance measurements and tritiated water permeability measurements
Result: AVERAGE SCORE:
- Erythema: not applicable
- Oedema: not applicable
REVERSIBILITY: not applicable
ELECTRICAL RESISTANCE VALUE (kOhm.disc): kOhm.disc (1hr): 1.1 (SD 0.3), kOhm.disc (4hrs): 0.9 (SD 0.1)
ANY OTHER INFORMATION: The substance is predicted to be corrosive.
Test condition: TEST ANIMALS:
- Strain: Alderley Park (Wistar)
- Sex: Male
- Age: 28 days
- Weight at study initiation: 60-80 grams
- Number of animals: Not reported
- Controls: Not reported
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: applied directly to the skin disc.
- Area of exposure: 18 mm x 80 mm
- Occlusion: No

- Vehicle: water
- Concentration in vehicle: Not applicable
- Total volume applied: 0.3 ml
- Removal of test substance: with warm water
- Number of discs: 3

IN VITRO TEST SYSTEM:
- Test conditions: Animals were anaesthesized (3% Fluothane) and the dorsal and flank hair carefully removed using fine clippers. Epidermal slices were not prepared from animals until at least 48 hrs after hair clipping. Animals were killed humanly and the dorsal skin was removed as a single pelt. Excess fat was cut away and the remaining skin was placed over a cork saddle. Epidermal slices (18 mm x 80 mm) were cut and placed , stratum corneum uppermost, over a rubber 'O' ring. The epidermal slice attached to the PTFE tube was suspended in physiological saline and maintained at ambient temperature (appr. 20°C).
Each test chemical was placed onto thestratum corneum. After required skin contact the chemical was removed with a jet of warm water (40-45°C) immediately prior to measuring electrical resistance across the skin slice.

EXAMINATIONS:
- Scoring system: Electrical resistance over the skin was measured. Resistance < 4 kOhm.disc (3.2 kOhm.cm2) was regarded as positive with respect to corrosive properties.
- Examination time points: 1 or 4 hrs.

Test substance: SOURCE: Imperial Chemical Industries
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium Silicate 52 wt%. pH 13.6, viscous liquid, molar ratio 1.6

Reliability: (2) valid with restrictions
Comparable to guideline study.

06-FEB-2003 (42)

Species: rat
Exposure: Open
Exposure Time: 4 hour(s)
Vehicle: water
Result: corrosive

Method: other: comparable to Directive 2000/33/EC, B.40
Year: 1992
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: comparable to rat skin electrical transcutaneous resistance (TER) assay according to Directive 2000/33/EC, B.40. The study was used as a basis for elaborating the guideline.
DEVIATIONS FROM GUIDELINE: The skin was not rinsed in antibiotica after clipping and 3 days later. Paraffin wax was used to seal the skin to the tube instead of jelly.
GLP: No
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result: AVERAGE SCORE
- Erythema: Not applicable.
- Edema: Not applicable.

REVERSIBILITY: Not applicable.

OTHER EFFECTS: Sodium silicate resulted in TER (24 hrs) values of 0.9, 1.4 and 1.1, at laboratory I, U and S, respectively. It was classified as predicted to be corrosive.

Test condition: TEST ANIMALS:
- Strain: Wistar
- Sex: male
- Source: Laboratory I: ICI Laboratory Animal Breeding Unit, Alderley Park; Laboratory U: Harlan-Olac Ltd., Bicester, Oxon.; Laboratory S: Charles River, Marston, Kent.
- Age: 28 days. In telogen phase of hair growth cycle.
- Weight at study initiation: Not reported.
- Number of animals: Not reported.
- Controls: Skin treated with deionised water. Positive control is an in vivo test on rabbit according to OECD guideline 404.

ADMINISTRATION/EXPOSURE
- Preparation of test substance: 100mg solid substance was mixed with 0.15 ml water to a paste.
- Area of exposure: Skin disc from dorsal side.
- Occlusion: No.
- Vehicle: Deionised water.
- Concentration in vehicle: Not reported.
- Total volume applied: 100 mg solid in 0.15 ml water.
- Postexposure period: No.
- Removal of test substance: After 1, 4 or 24 hrs.

IN VITRO TEST SYSTEM
- Cell type: Not applicable.
- Test conditions: Disc of skin was mounted epidermal side up on a polytetrafluoroethylene tube secured with an O-ring. Excess tissue and fat was removed. The O-ring/tube interface was sealed with soft paraffin wax. The tube was supported by a plastic coated spring glip inside a plastic tube containing electrolyte solution (154 mM $MgSO_4$ in deionised/distilled water). Chemical was applied to the epidermal surface, and removed with a jet of water after the exposure period. The stratum corneum was treated with 20 microliter 70% aqueous ethanol for 2 sec, before 3 ml electrolyte solution was added and the transcutaneous electrical resistance was measured.

EXAMINATIONS
- Scoring system: TER values < 5 kohm/skin disc are predicted to be skin corrosive. The in vivo positive control was scored according to Draize.
- Examination time points: 1, 4 or 24 hrs.

Test substance: SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: pH > 12.

Reliability: (3) invalid
Documentation insufficient for assessment.

06-FEB-2003 (3)

Species: rat
Concentration: 44 other: wt%
Exposure: Open
Exposure Time: 24 hour(s)
Vehicle: water
Result: corrosive

Method: other: comparable to Directive 2000/33/EC, B.40

Year:	1988
GLP:	no
Test substance:	other TS
Method:	METHOD FOLLOWED: comparable to the rat skin transcutaneous electrical resistance (TER) assay according to Directive 2000/33/EC, B.40. The study was used as a basis for elaborating the guideline. DEVIATIONS FROM GUIDELINE: In comparison to the guideline the following parts of the study were not in line. - The skin was not washed in antibiotica before harvesting; - The skin was clipped approximately 48 hrs before harvesting, instead of 3-7 days; - Physiological saline was used to hydrate the skin during measurement of TER, instead of MgSO4 (154 mM); - The water used to rinse the skin discs was 40-45°C instead of 30°C; - 70% ethanol was not used to rinse the skin disc after the test substance had been removed; - No negative control was used; - The threshold was 4 kOhm.disc instead of 5 kOhm.disc. GLP: No, study performed before existence of GLP. STATISTICAL METHODS: Not reported METHOD OF CALCULATION: The substance is classified as corrosive if the electrical resistance value is reduced below the set threshold level of 4 kOhm.disc (3.2 kOhm.cm2) ANALYTICAL METHODS: electrical resistance measurements and tritiated water permeability measurement
Result:	ELECTRICAL RESISTANCE VALUE (kOhm.disc): kOhm.disc (1 hr) : 4.6 (SD 1.3) kOhm.disc (4hrs) : 3.5 (SD 1.5) kOhm.disc (24 hrs): 1.1 (SD 0.6) ANY OTHER INFORMATION: 4 hr exposure: resistance measured at 24 hrs: 7.6 (SD 1.4) The substance is predicted to be corrosive.
Test condition:	TEST ANIMALS: - Strain: Alderley Park (Wistar) - Sex: Male - Age: 28 days - Weight at study initiation: 60-80 grams - Number of animals: Not reported - Controls: Not reported ADMINISTRATION/EXPOSURE: - Preparation of test substance: applied directly to the skin disc. - Area of exposure: 18 mm x 80 mm - Occlusion: No - Vehicle: water - Concentration in vehicle: Not applicable - Total volume applied: 0.3 ml - Removal of test substance: with warm water - Number of skin discs: 3 IN VITRO TEST SYSTEM: - Test conditions: Animals were anaesthesized (3% Fluothane) and the dorsal and flank hair carefully removed using fine clippers. Epidermal slices were not prepared from animals until at least 48 hrs after hair clipping. Animals were killed humanly and the dorsal skin was removed as a single pelt. Excess fat was cut away and the remaining skin was placed over a cork saddle. Epidermal slices (18 mm x 80 mm) were cut and placed , stratum corneum uppermost, over a

rubber 'O' ring. The epidermal slice attached to the PTFE tube was suspended in physiological saline and maintained at ambient temperature (appr. 20°C).
Each test chemical was placed onto thestratum corneum. After required skin contact the chemical was removed with a jet of warm water (40-45°C) immediately prior to measuring electrical resistance across the skin slice.
EXAMINATIONS:
- Scoring system: Electrical resistance over the skin was measured. Resistance < 4 kOhm.disc (3.2 kOhm.cm2) was regarded as positive with respect to corrosive properties.
- Examination time points: 1, 4 or 24 hrs

Test substance: SOURCE: Imperial Chemical Industries
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium Silicate 44 wt%. pH 12.3, viscous liquid, molar ratio 2.4

Reliability: (2) valid with restrictions
Comparable to guideline study.

06-FEB-2003 (42)

Species: rat
Concentration: 38 other: wt%
Exposure: Open
Exposure Time: 24 hour(s)
Vehicle: water
Result: corrosive

Method: other: comparable to Directive 2000/33/EC, B.40
Year: 1988
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: comparable to the rat skin transcutaneous electrical test (TER) assay according to Directive 2000/33/EC, B.40. The study was used as a basis for elaborating the guideline.
DEVIATIONS FROM GUIDELINE: In comparison to the guideline the following parts of the study were not in line.
- The skin was not washed in antibiotcs before harvesting;
- The skin was clipped approximately 48 hrs before harvesting, instead of 3-7 days;
- Physiological saline was used to hydrate the skin during measurement of TER, instead of MgSO4 (154 mM);
- The water used to rinse the skin discs was 40-45°C instead of 30°C;
- 70% ethanol was not used to rinse the skin disc after the test substance had been removed;
- No negative control was used;
- The threshold was 4 kOhm.disc instead of 5 kOhm.disc;
- The skin was not rinsed in antibiotics after clipping and 3 days later. Paraffin was used to seal the skin to the tube instead of jelly.

GLP: No, study performed before existence of GLP.
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: The substance is classified as corrosive if the electrical resistance value is reduced below the set threshold level of 4 kOhm.disc (3.2 kOhm.cm2)
ANALYTICAL METHODS: electrical resistance measurements and tritiated water permeability measurement.

Result: ELECTRICAL RESISTANCE VALUE (kOhm.disc):

kOhm.disc (1 hr) : 7.3 (SD 2.5)
kOhm.disc (4 hrs) : 2.8 (SD 0.3)
kOhm.disc (24 hrs): 1.6 (SD 0.1)
ANY OTHER INFORMATION: 4 hr exposure: resistance measured at 24 hrs: 7.5 (SD 0.2)
The substance is predicted to be corrosive.

Test condition: TEST ANIMALS:
- Strain: Alderley Park (Wistar)
- Sex: Male
- Age: 28 days
- Weight at study initiation: 60-80 grams
- Number of animals: Not reported
- Controls: Not reported
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: applied directly to the skin disc.
- Area of exposure: 18 mm x 80 mm
- Occlusion: No
- Vehicle: water
- Concentration in vehicle: Not applicable
- Total volume applied: 0.3 ml
- Removal of test substance: with warm water
- Number of skin discs: 3
IN VITRO TEST SYSTEM:
- Test conditions: Animals were anaesthesized (3% Fluothane) and the dorsal and flank hair carefully removed using fine clippers. Epidermal slices were not prepared from animals until at least 48 hrs after hair clipping. Animals were killed humanly and the dorsal skin was removed as a single pelt. Excess fat was cut away and the remaining skin was placed over a cork saddle. Two epidermal slices (18 mm x 80 mm) were cut and placed , stratum corneum uppermost, over a rubber 'O' ring. Epidermal slice attached to the PTFE tube was suspended in physiological saline and maintained at ambient temperature (appr. 20°C).
Each test chemical was placed onto thestratum corneum. After required skin contact the chemical was removed with a jet of warm water (40-45°C) immediately prior to measuring electrical resistance across the skin slice.
EXAMINATIONS:
- Scoring system: Electrical resistance over the skin was measured. Resistance < 4 kOhm.disc (3.2 kOhm.cm2) was regarded as positive with respect to corrosive properties.
- Examination time points: 1, 4 or 24 hrs

Test substance: SOURCE: Imperial Chemical Industries
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium Silicate 38 wt%. pH 11.6, liquid, molar ratio 3.2

Reliability: (2) valid with restrictions
Comparable to guideline study.

06-FEB-2003 (42)

5.2.2 Eye Irritation

Species: rabbit
Concentration: 36 other: wt%
Result: not irritating

Method: other: FHSA (Federal Hazardous Substance Act) 16 C.F.R.

1500.42
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substance Act) test specified in 16 C.F.R. 1500.42 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not applicable
EXAMINATIONS: Not described
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Concentration 36 wt% and molar ratio 3.3
Reliability: (4) not assignable
Only secondary literature (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: 1 minute(s)
Result: highly irritating

Method: other: in vitro rabbit eye irritation study
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies providing the test substance is shown to be skin irritating/corrosive. The test is described in several publications: Burton et al. (1981), York et al. (1982), York et al. (1994). In York et al. (1994) results of 10 seconds and 1 minute exposure to Sodium Silicate are presented, of which the study report for the 1 minute exposure is also available.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Maximum opacity score:
10 seconds: 1-2 ((1): scattered/diffuse areas of opacity or loss of corneal epithelium, iris clearly visible/ (2): easily discernable greyish transculant areas, details of iris slightly obscured)
60 seconds: 4 (complete corneal opacity, iris not discernable)
- Maximum mean swelling:
10 seconds: 23.26%

60 seconds: Not measurable
- Fluorescein staining:
10 seconds: distinct (pale continous staining of the epithelium with slow diffusion into stroma)
60 seconds: strong (intense staining of the epithelium and anterior stroma with very rapid diffusion into the remainder of the stroma)
- Loss of corneal cell layers:
10 seconds: 3-7
60 seconds: 1-7
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not applicable
OTHER EFFECTS: Opacities were detected macroscopically and microscopically. No corneal swelling measurements were taken because of the considerable damage to the corneal surface. The overall result after 60 seconds exposure was severe irritation (moderate/severe opacity and/or > 35% swelling and/or 7-8 corneal cell layer loss).

Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: Not reported
- Source: Laboratories of Industrial Toxicology, Huntingdon Research Centre Ltd. (HRC)
- Age: Not reported
- Weight at study initiation: Not reported
- Number of animal eyes: 3
- Controls: yes, 2 untreated eyes served as control
The eyes were from animals used by HRC in skin irritation tests or were the control eyes from eye irritation tests.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface.
- Amount of substance instilled: 50 mg
- Vehicle: None
- Postexposure period: No
IN VITRO TEST SYSTEM
- Test conditions: the eyes were wetted with saline and humidity maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. At the testing laboratory the eyes were placed in superfusion chambers. Immediately after the eyes were positioned in the chamber the eyes were stained with 1% Fluorescein for 10 seconds to establish if there was any damage. The corneal thickness of each eye was then measured and left for 60 minutes to allow the eyes to eliquibrate. Then the test sample was applied to the corneal surface of each eye for 1 minute and then rinsed with saline.
EXAMINATIONS
- Opacification of the cornea (macroscopic and microscopic [with a Zeiss slit lamp] appearance): after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Corneal thickness with a Zeiss lamp: prior to and after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Rate fluorescein diffusion into corneal stroma together with possible corneal damage using slit lamp.
- Histological assessment after dissection eyes.
- Scoring system: Unilever enucleated eye grading
- Observation period: after treatment, 30 minutes, 1, 2, 3, 4 hours after treatment
- Tool used to assess score: Not reported

Test substance: SOURCE: Not reported

PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio of 2.0, white powder
Reliability: (4) not assignable
The method is well-documented, but not yet validated. It is currently in use as an alternative to in vivo eye irritation studies for substances which are shown to be irritating in skin irritation tests.
Flag: Critical study for SIDS endpoint
26-JAN-2004 (62) (64)

Species: rabbit
Concentration: 43 other: wt%
Result: highly irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.42
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substance Act) test specified in 16 C.F.R. 1500.42 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not applicable
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Concentration 43 wt% and molar ratio 3.0
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 8 other: wt%
Result: irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.42
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substance Act) test specified in 16 C.F.R. 1500.42 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported

ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not applicable
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Concentration 8 wt% and molar ratio 2.1
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 44 other: wt%
Result: highly irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.42
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substance Act) test specified in 16 C.F.R. 1500.42 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not applicable
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Concentration 44 wt% and molar ratio 2.1
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 6 other: wt%
Result: irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.42
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substance Act) test specified in 16 C.F.R. 1500.42 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported

Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not applicable
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Concentration 6 wt% and molar ratio 0.7
Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: 3 other: wt%
Result: irritating

Method: other: FHSA (Federal Hazardous Substance Act), 16 C.F.R. 1500.42
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substance Act) test specified in 16 C.F.R. 1500.42 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not applicable
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Concentration 3 wt% and molar ratio 0.7
Reliability: (4) not assignable
Only secondary literature (review).
06-FEB-2003 (50)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: 1 minute(s)
Result: highly irritating

Method: other:in vitro rabbit eye irritation study
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies providing the test substance is shown to be skin irritating/corrosive. The test is described in several publications: Burton et al. (1981), York et al. (1982), York et al. (1994). In York et al.

(1994) results of 10 sec. and 1 min. exposure to Sodium Silicate are presented, of which the study report for the 1 min. exposure is also available.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Maximum opacity score:
10 seconds: 1 (scattered/diffuse areas of opacity or loss of corneal epithelium, iris clearly visible)
60 seconds: 4 (complete corneal opacity, iris not discernable)
- Maximum mean swelling:
10 seconds: 15.91%
60 seconds: Not measurable
- Fluorescein staining:
10 seconds: marginal (punctate staining across cornea with osme evidence of slight diffusion into cornea)
60 seconds: strong (intense staining of the epithelium and anterior stroma with very rapid diffusion into the remiander of the stroma)
- Loss of corneal cell layers:
10 seconds: 2-4
60 seconds: 4-7
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not applicable
OTHER EFFECTS: Opacities were detected macroscopically and microscopically. No corneal swelling measurements were taken because of the considerable damage to the corneal surface. The overall result after 60 seconds exposure was severe irritation (moderate/sever opacity and/or >35% swelling and/or 7-8 corneal cell layer loss)

Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: Not reported
- Source: Laboratories of Industrial Toxicology, Huntingdon Research Centre Ltd. (HRC)
- Age: Not reported
- Weight at study initiation: Not reported
- Number of animal eyes: 3
- Controls: yes, 2 untreated eyes served as control
The eyes were from animals used by HRC in skin irritation tests or were the control eyes from eye irritation tests.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface.
- Amount of substance instilled: 50 mg
- Vehicle: None
- Postexposure period: No
IN VITRO TEST SYSTEM
- Test conditions: the eyes were wetted with saline and humidity maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. At the testing laboratory the eyes were placed in superfusion chambers. Immediately after the eyes were positioned in the chamber the eyes were stained with 1% Fluorescein for 10 seconds to establish if there was any damage. The corneal thickness of each eye was then measured and left for 60 minutes to allow the eyes to eliquibrate. Then the test sample was applied to the corneal surface of each eye for 1 minute and then rinsed

with saline.
EXAMINATIONS
- Opacification of the cornea (macroscopic and microscopic [with a Zeiss slit lamp] appearance): after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Corneal thickness with a Zeiss lamp: prior to and after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Rate fluorescein diffusion into corneal stroma together with possible corneal damage using slit lamp.
- Histological assessment after dissection eyes.
- Scoring system: Unilever enucleated eye grading
- Observation period: after treatment, 30 minutes, 1, 2, 3, 4 hours after treatment
- Tool used to assess score: not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio of 2.4, white powder

Reliability: (4) not assignable
The method is well-documented, but not yet validated. It is currently in use as an alternative to in vivo eye irritation studies for substances which are shown to be irritating in skin irritation tests.

Flag: Critical study for SIDS endpoint

26-JAN-2004 (62) (64)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: 1 minute(s)
Result: irritating

Method: other: in vitro rabbit eye irritation study
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies providing the test substance is shown to be skin irritating/corrosive. The test is described in several publications: Burton et al. (1981), York et al. (1982), York et al. (1994). In York et al. (1994) results of 10 sec. and 1 min. exposure to Sodium Silicate are presented, of which the study report for the 1 min. exposure is also available.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Maximum opacity score:
10 seconds: 1 (scattered/diffuse areas of opacity or loss of corneal epithelium, iris clearly visible)
60 seconds: 2/3 (easily discernable greyish transculant areas, details of iris slightly obscured/grey-white areas, no details of iris visible, size of pupil barely discernable)
- Maximum mean swelling:
10 seconds: 16.28%
60 seconds: 46.56%

- Fluorescein staining:
10 seconds: marginal (punctate staining across cornea with some evidence of slight diffusion into cornea)
60 seconds: distinct (pale continuous staining of the epithelium with slow diffusion into the stroma).
- Loss of layers:
10 seconds: 1-3
60 seconds: 1-7
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not applicable
OTHER EFFECTS: The overall result after 60 seconds exposure was moderate/severe irritation (moderate/severe opacity and/or >35% swelling and/or 7-8 cell layers lost/ Slight/moderate opacity and/or > 25% swelling and/or 5-6 layers loss)

Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: Not reported
- Source: Laboratories of Industrial Toxicology, Huntingdon Research Centre Ltd. (HRC)
- Age: Not reported
- Weight at study initiation: Not reported
- Number of animal eyes: 3
- Controls: yes, 2 untreated eyes served as control
The eyes were from animals used by HRC in skin irritation tests or were the control eyes from eye irritation tests.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface.
- Amount of substance instilled: 50 mg
- Vehicle: None
- Postexposure period: No
IN VITRO TEST SYSTEM
- Test conditions: the eyes were wetted with saline and humidity maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. At the testing laboratory the eyes were placed in superfusion chambers. Immediately after the eyes were positioned in the chamber the eyes were stained with 1% Fluorescein for 10 seconds to establish if there was any damage. The corneal thickness of each eye was then measured and left for 60 minutes to allow the eyes to eliquibrate. Then the test sample was applied to the corneal surface of each eye for 1 minute and then rinsed with saline.
EXAMINATIONS
- Opacification of the cornea (macroscopic and microscopic appearance): after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Corneal thickness and appearance slit image of the corneal surface: after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Rate fluorescein diffusion into the corneal stroma using slit lamp
- Histological assessment after dissection eyes
- Scoring system: Unilever enucleated eye grading
- Observation period: after treatment, 30 minutes, 1, 2, 3, 4 hours after treatment
- Tool used to assess score: not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported

ANY OTHER INFORMATION: Molar ratio of 2.6, white powder
Reliability: (4) not assignable
The method is well-documented, but not yet validated. It is currently in use as an alternative to in vivo eye irritation studies for substances which are shown to be irritating in skin irritation tests.
Flag: Critical study for SIDS endpoint
26-JAN-2004 (62) (64)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: 1 minute(s)
Result: moderately irritating

Method: other: in vitro rabbit eye irritation study
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies providing the test substance is shown to be skin irritating/corrosive. The test is described in several publications: Burton et al. (1981), York et al. (1982), York et al. (1994). In York et al. (1994) results of 10 sec. and 1 min. exposure to Sodium Silicate are presented, of which the study report for the 1 min. exposure is also available.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Maximum opacity score:
10 seconds: 1 (scattered/diffuse areas of opacity or loss of corneal epithelium, iris clearly visible)
60 seconds: 2 (easily discernable greyish translucant areas, details of iris slightly obscured)
- Maximum mean swelling:
10 seconds: 9.30%
60 seconds: 28.25%
- Fluorescein staining:
10 seconds: marginal (punctate staining across cornea with some evidence of slight diffusion into cornea)
60 seconds: Distinct (pale continuous staining of the epithelium with slow diffucion into the stroma)
- Loss of corneal cell layers:
10 seconds: 0-2
60 seconds: 1-7
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: The overall result after 60 seconds was moderate irritation (slight/moderate opacity and/or > 25% swelling and/or 5-6 cell layers loss)
Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: Not reported
- Source: Laboratories of Industrial Toxicology, Huntingdon Research Centre Ltd. (HRC)
- Age: Not reported

- Weight at study initiation: Not reported
- Number of animal eyes: 3
- Controls: yes, 2 untreated eyes served as control
The eyes were from animals used by HRC in skin irritation tests or were the control eyes from eye irritation tests.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface.
- Amount of substance instilled: 50 mg
- Vehicle: None
- Postexposure period: No
IN VITRO TEST SYSTEM
- Test conditions: the eyes were wetted with saline and humidity maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. At the testing laboratory the eyes were placed in superfusion chambers. Immediately after the eyes were positioned in the chamber the eyes were stained with 1% Fluorescein for 10 seconds to establish if there was any damage. The corneal thickness of each eye was then measured and left for 60 minutes to allow the eyes to eliquibrate. Then the test sample was applied to the corneal surface of each eye for 1 minute and then rinsed with saline.
EXAMINATIONS
- Opacification of the cornea (macroscopic and microscopic appearance): after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Corneal thickness and appearance slit image of the corneal surface: after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Rate of fluorescein diffusion into stroma using slit lamp
- Histological assessment after dissection
- Scoring system: Unilever enucleated eye grading
- Observation period: after treatment, 30 minutes, 1, 2, 3, 4 hours after treatment
- Tool used to assess score: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio of 2.8, white powder

Reliability: (4) not assignable
The method is well-documented, but not yet validated. It is currently in use as an alternative to in vivo eye irritation studies for substances which are shown to be irritating in skin irritation tests.

Flag: Critical study for SIDS endpoint

26-JAN-2004 (62) (64)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: 1 minute(s)
Result: slightly irritating

Method: other: in vitro rabbit eye study
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies providing the test

substance is shown to be skin irritating/corrosive. The test is described in several publications: Burton et al. (1981), York et al. (1982), York et al. (1994). In York et al. (1994) results of 10 sec. and 1 min. exposure to Sodium Silicate are presented, of which the study report for the 1 min. exposure is also available.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Maximum opacity score:
10 seconds: 1 (scattered/diffuse areas of opacity or loss of corneal epithelium, iris clearly visible)
60 seconds: 1 (scattered/diffuse areas of opacity or loss of corneal epithelium, iris clearly visible)
- Maximum mean swelling:
10 seconds: 6.82%
60 seconds: 20.34%
- Fluorescein staining:
10 seconds: marginal (punctate staining across cornea with some evidence of slight diffusion into cornea)
60 seconds: marginal (punctate staining across cornea with some evidence of slight diffusion into cornea)
- Loss of corneal cell layers:
10 seconds: 1-3
60 seconds: 0-4
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: The overall result after 60 seconds exposure was slight irritation (any unusual effect or slight opacity, > 11% swelling and/or 3-4 corneal cell layers loss)

Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: Not reported
- Source: Laboratories of Industrial Toxicology, Huntingdon Research Centre Ltd. (HRC)
- Age: Not reported
- Weight at study initiation: Not reported
- Number of animal eyes: 3
- Controls: yes, 2 enucleated eyes served as control
The eyes were from animals used by HRC in skin irritation tests or were the control eyes from eye irritation tests.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface.
- Amount of substance instilled: 50 mg
- Vehicle: None
- Postexposure period: No
IN VITRO TEST SYSTEM
- Test conditions: the eyes were wetted with saline and humidity maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. At the testing laboratory the eyes were placed in superfusion chambers. Immediately after the eyes were positioned in the chamber the eyes were stained with 1% Fluorescein for 10 seconds to establish if there was any damage. The corneal thickness of each eye was then measured and left for 60 minutes to allow the eyes to eliquibrate. Then the test sample was applied to the corneal surface of each eye for 1 minute and then rinsed with saline.

EXAMINATIONS
- Opacification of the cornea (macroscopic and microscopic appearance): after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Corneal thickness and appearance slit image of the corneal surface: after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Rate fluorescein diffusion into the corneal stroma using slit lamp
- Histological assessment after dissection eyes
- Scoring system: Unilever enucleated eye grading
- Observation period: after treatment, 30 minutes, 1, 2, 3, 4 hours after treatment
- Tool used to assess score: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio of 3.0, white powder

Reliability: (4) not assignable
The method is well-documented, but not yet validated. It is currently in use as an alternative to in vivo eye irritation studies for substances which are shown to be irritating in skin irritation tests.

Flag: Critical study for SIDS endpoint

26-JAN-2004 (62) (64)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: 1 minute(s)
Result: slightly irritating

Method: other: in vitro rabbit eye study
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies providing the test substance is shown to be skin irritating/corrosive. The test is described in several publications: Burton et al. (1981), York et al. (1982), York et al. (1994).
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Maximum opacity score: 1/2 ((1)scattered/diffuse areas of opacity or loss of corneal epithelium, iris clearly visible/(2) early discernable greyish transculant areas, details of iris slightly obscured)
- Maximum mean swelling: 19.32%
- Fluorescein staining: Marginal (punctate staining across cornea with some evidence of slight diffusion into cornea)
- Loss of corneal cell layers: 0-4
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: The overall result after 60 seconds exposure was slight irritation (any unusual effect or slight opacity, > 11% swelling and/or 3-4 corneal cell layers loss)

Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: Not reported
- Source: Laboratories of Industrial Toxicology, Huntingdon Research Centre Ltd. (HRC)
- Age: Not reported
- Weight at study initiation: Not reported
- Number of animal eyes: 3
- Controls: yes, 2 enucleated eyes served as control
The eyes were from animals used by HRC in skin irritation tests or were the control eyes from eye irritation tests.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface.
- Amount of substance instilled: 50 mg
- Vehicle: None
- Postexposure period: No
IN VITRO TEST SYSTEM
- Test conditions: the eyes were wetted with saline and humidity maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. At the testing laboratory the eyes were placed in superfusion chambers. Immediately after the eyes were positioned in the chamber the eyes were stained with 1% Fluorescein for 10 seconds to establish if there was any damage. The corneal thickness of each eye was then measured and left for 60 minutes to allow the eyes to eliquibrate. Then the test sample was applied to the corneal surface of each eye for 1 minute and then rinsed with saline.
EXAMINATIONS
- Opacification of the cornea (macroscopic and microscopic appearance): after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Corneal thickness and appearance slit image of the corneal surface: after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Rate fluorescein diffusion into corneal stroma using slit lamp
- Histological assessment after dissection eyes
- Scoring system: Unilever enucleated eye grading
- Observation period: after treatment, 30 minutes, 1, 2, 3, 4 hours after treatment
- Tool used to assess score: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio of 3.3, white powder

Reliability: (4) not assignable
The method is well-documented, but not yet validated. It is currently in use as an alternative to in vivo eye irritation studies for substances which are shown to be irritating in skin irritation tests.

Flag: Critical study for SIDS endpoint

26-JAN-2004 (62) (64)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: .17 minute(s)
Result: irritating

Method: other: in vitro rabbit eye irritation study
Year: 1994
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies providing the test substance is shown to be skin irritating/corrosive. The method is described in several publications: Burton et al. (1981), York et al. (1982), York et al. (1994). Primarly, chicken eyes are used to assess the irritation potential, while rabbit eyes have been used in this study.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Maximum macroscopic and microscopic opacity score: 2 (early discernable greyish transculant areas, details of iris slightly obscured)
- Maximum mean swelling: 54.67%
- Fluorescein staining: Distinct (pale continous staining of the epithelium with slow diffusion into the stroma)
- Loss of corneal cell layers: 2-7
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not applicable
OTHER EFFECTS: The overall result after 60 seconds was moderate irritation (slight/moderate opacity and/or > 25% swelling and/or 5-6 corneal cell layers loss)

Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: Not reported
- Source: Laboratories of Industrial Toxicology, Huntingdon Research Centre Ltd. (HRC)
- Age: Not reported
- Weight at study initiation: Not reported
- Number of animal eyes: 3
- Controls: yes, 2 enucleated eyes served as control
The eyes were from animals used by HRC in skin irritation tests or were the control eyes from eye irritation tests.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface.
- Amount of substance instilled: 50 mg
- Vehicle: None
- Postexposure period: No
IN VITRO TEST SYSTEM
- Test conditions: the eyes were wetted with saline and humidity maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. At the testing laboratory the eyes were placed in superfusion chambers. Immediately after the eyes were positioned in the chamber the eyes were stained with 1% Fluorescein for 10 seconds to establish if there was any damage. The corneal thickness of each eye was then measured and left for 60 minutes to allow the eyes to eliquibrate. Then the test sample was applied to the corneal surface of each eye for 1 minute and then rinsed with saline.
EXAMINATIONS
- Opacification of the cornea (macroscopic and microscopic

appearance): after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Corneal thickness and appearance slit image of the corneal surface: after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Rate fluorescein diffusion into corneal stroma using slit lamp
- Histological assessment after dissection eyes
- Scoring system: Unilever enucleated eye grading
- Observation period: after treatment, 30 minutes, 1, 2, 3, 4 hours after treatment
- Tool used to assess score: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio of 1.5, white powder

Reliability: (4) not assignable
The method is well-documented, but not validated. There are no guidelines for this kind of study, but the protocol is in use as an alternative to in vivo eye irritation studies for substances which are shown to be skin irritating/corrosive in in vivo studies.

26-JAN-2004 (63)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: .17 minute(s)
Result: irritating

Method: other: in vitro rabbit eye irritation study
Year: 1994
GLP: yes

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies providing the test substance is shown to be skin irritating/corrosive. The method is described in several publications: Burton et al. (1981), York et al. (1982), York et al. (1994). Primarly, chicken eyes are used to assess the irritation potential, while rabbit eyes have been used in this study.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Maximum macroscopic and microscopic opacity score: 2 (early discernable greyish transculant areas, details of iris slightly obscured)
- Maximum mean swelling: 48.49%
- Fluorescein staining: Distinct (pale continous staining of the epithelium with slow diffusion into the stroma)
- Loss of corneal cell layers: 2-7
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not applicable
OTHER EFFECTS: The overall result was moderate/severe irritation (Moderate: slight/moderate opacity and/or > 25% swelling and/or 5-6 corneal cell layer/ Severe: moderate/severe
opacity and/or > 35% swelling and/or 7-8 corneal cell layers

loss)
Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: Not reported
- Source: Laboratories of Industrial Toxicology, Huntingdon Research Centre Ltd. (HRC)
- Age: Not reported
- Weight at study initiation: Not reported
- Number of animal eyes: 3
- Controls: yes, 2 enucleated eyes served as control
The eyes were from animals used by HRC in skin irritation tests or were the control eyes from eye irritation tests.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface.
- Amount of substance instilled: 50 mg
- Vehicle: None
- Postexposure period: No
IN VITRO TEST SYSTEM
- Test conditions: the eyes were wetted with saline and humidity maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. At the testing laboratory the eyes were placed in superfusion chambers. Immediately after the eyes were positioned in the chamber the eyes were stained with 1% Fluorescein for 10 seconds to establish if there was any damage. The corneal thickness of each eye was then measured and left for 60 minutes to allow the eyes to eliquibrate. Then the test sample was applied to the corneal surface of each eye for 1 minute and then rinsed with saline.
EXAMINATIONS
- Opacification of the cornea (macroscopic and microscopic appearance): after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Corneal thickness and appearance slit image of the corneal surface: after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Rate fluorescein diffusion into corneal stroma using slit lamp
- Histological assessment after dissection eyes
- Scoring system: Unilever enucleated eye grading
- Observation period: after treatment, 30 minutes, 1, 2, 3, 4 hours after treatment
- Tool used to assess score: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio of 1.6, white powder
Reliability: (4) not assignable
The method is well-documented, but not validated. There are no guidelines for this kind of study, but the protocol is in use as an alternative to in vivo eye irritation studies for substances which are shown to be skin irritating/corrosive in in vivo studies.
26-JAN-2004 (63)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: .17 minute(s)
Result: irritating

Method: other: in vitro rabbit eye irritation study
Year: 1994
GLP: yes

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies providing the test substance is shown to be skin irritating/corrosive. The method is described in several publications: Burton et al. (1981), York et al. (1982), York et al. (1994). Primarly, chicken eyes are used to assess the irritation potential, while rabbit eyes have been used in this study.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Maximum macroscopic and microscopic opacity score: 2 (early discernable greyish transculant areas, details of iris slightly obscured)
- Maximum mean swelling: 76.79%
- Fluorescein staining: Distinct (pale continous staining of the epithelium with slow diffusion into the stroma)
- Loss of corneal cell layers: 3-7
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not applicable
OTHER EFFECTS: The overall result after 60 seconds exposure was moderate/severe irritation (Moderate: slight/moderate opacity
and/or > 25% swelling and/or 5-6 corneal cell layer/ Severe: moderate/severe opacity and/or > 35% swelling and/or 7-8 corneal cell layers loss)

Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: Not reported
- Source: Laboratories of Industrial Toxicology, Huntingdon Research Centre Ltd. (HRC)
- Age: Not reported
- Weight at study initiation: Not reported
- Number of animal eyes: 3
- Controls: yes, 2 enucleated eyes served as control
The eyes were from animals used by HRC in skin irritation tests or were the control eyes from eye irritation tests.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface.
- Amount of substance instilled: 50 mg
- Vehicle: None
- Postexposure period: No
IN VITRO TEST SYSTEM
- Test conditions: the eyes were wetted with saline and humidity maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. At the testing laboratory the eyes were placed in superfusion chambers. Immediately after the eyes were positioned in the chamber the eyes were stained with 1% Fluorescein for 10 seconds to establish if there was any damage. The corneal thickness of each eye was then measured and left for 60 minutes to allow the eyes to eliquibrate. Then the test sample was applied to the corneal surface of each eye for 1 minute and then rinsed

with saline.
EXAMINATIONS
- Opacification of the cornea (macroscopic and microscopic appearance): after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Corneal thickness and appearance slit image of the corneal surface: after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Rate fluorescein diffusion into corneal stroma using slit lamp
- Histological assessment after dissection eyes
- Scoring system: Unilever enucleated eye grading
- Observation period: after treatment, 30 minutes, 1, 2, 3, 4 hours after treatment
- Tool used to assess score: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio of 1.8, white powder

Reliability: (4) not assignable
The method is well-documented, but not validated. There are no guidelines for this kind of study, but the protocol is in use as an alternative to in vivo eye irritation studies for substances which are shown to be skin irritating/corrosive in in vivo studies.

26-JAN-2004 (63)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: .17 minute(s)
Result: irritating

Method: other: in vitro rabbit eye irritation study
Year: 1994
GLP: yes

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies providing the test substance is shown to be skin irritating/corrosive. The method is described in several publications: Burton et al. (1981), York et al. (1982), York et al. (1994). Primarly, chicken eyes are used to assess the irritation potential, while rabbit eyes have been used in this study.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Maximum macroscopic and microscopic opacity score: 2 (easliy discernable greyish transculant areas, details of iris slightly obscured)
- Maximum mean swelling: 55.00%
- Fluorscein staining: distinct (pale continuous staining of the epithelium with slow diffusion into the stroma)
- Loss of layers: 3-7
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not applicable
OTHER EFFECTS: The overall result was moderate/severe irritation (Moderate: slight/moderate opacity and/or >25%

swelling
and/or 5-6 corneal cell layers loss/ Severe: moderate/severe opacity and/or > 35% swelling and/or 7-8 corneal cell layers loss)

Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: Not reported
- Source: Laboratories of Industrial Toxicology, Huntingdon Research Centre Ltd. (HRC)
- Age: Not reported
- Weight at study initiation: Not reported
- Number of animal eyes: 3
- Controls: yes, 1 untreated eye served as control
The eyes were from animals used by HRC in skin irritation tests or were the control eyes from eye irritation tests.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as awater-soluble powder to the corneal surface.
- Amount of substance instilled: 50 mg
- Vehicle: None
- Postexposure period: No
IN VITRO TEST SYSTEM
- Test conditions: the eyes were wetted with saline and humidity maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. At the testing laboratory the eyes were placed in superfusion chambers. Immediately after the eyes mounted in clamps and placed under saline drip in cells in the maintenance chamber, the eyes were stained with 1% Fluorescein for 10 seconds to establish if there was any damage. The corneal thickness of each eye was then measured and left for 60 minutes to allow the eyes to eliquibrate. Then the test sample was applied to the corneal surface of each eye for 10 seconds and then rinsed with saline.
EXAMINATIONS
- Opacification of the cornea (macroscopic [with a Zeiss slit lamp] after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment.
- Corneal thickness (with a Zeiss slit lamp) after treatment, 30 minutes, 1, 2, 3 and 4 hrs after treatment
- Rate fluorescein diffusion into corneal stroma using slit lamp
- Histological assessment after dissection eyes
- Scoring system: Unilever enucleated eye grading
- Observation period: after treatment, 30 minutes, 1, 2, 3, 4 hours after treatment
- Tool used to assess score: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio of 2.0, white powder

Reliability: (4) not assignable
The method is well-documented, but not validated. There are no guidelines for this kind of study, but the protocol is in use as an alternative to in vivo eye irritation studies for substances which are shown to be skin irritating/corrosive in in vivo studies.

26-JAN-2004 (63)

Species: rabbit
Exposure Time: unspecified

GLP: no
Test substance: other TS

Remark: Schleyer et al. (1982) reports on a series of esophageal tests (oral, rabbit) conducted under the auspicies of the Consumer Product Safety Commission.
Microscopic examination of the esophagus was used as the primary criterion for categorizing results as either "corrosive" or "negative".
The data are summarized below.

SiO2/Na2O wt ratio	Concentration	results + = corrosive
3.2	5 % w/v	-
3.2	10% w/v	-,-
2.9	10% w/v	-
2.9	15% w/v	+
2.9	neat liq (43%)	+
2.4	10% v/v	-
2.4	15% v/v	+
2.4	neat pwd.	+,-
2.0	5% v/v	-
2.0	10% v/v	+,+
2.0	neat pwd.	+,-
0.7	10% w	+

Reliability: (4) not assignable
Only secondary literature available (review).
06-FEB-2003 (50)

5.3 Sensitization

Remark: See section 5.10 Exposure Experience, for a case of human sensitization.
06-FEB-2003

5.4 Repeated Dose Toxicity

Type: Sub-acute
Species: rat Sex: male/female
Strain: other: Charles River Cesarean-Derived (CD)
Route of administration: oral feed
Exposure period: 4 weeks
Frequency of treatment: daily
Doses: 2400 mg/kg bw/d
Control Group: yes

Method: other: comparable to OECD guideline 407
Year: 1970
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Comparable to OECD 407
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: NOAEL: Polydipsia, polyuria and soft stools was observed in a few animals (number of animals and dosage groups not stated).
ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX:
- Time of death: no mortality
- Number of deaths at each dose: no mortality
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Mortality and time to death: None
- Clinical signs: Polydipsia, polyuria and soft stools was observed in a few animals (not quantified)
- Body weight gain: No effects
- Food/water consumption: No effects
- Ophthalmoscopic examination: Not reported
- Clinical chemistry: No effects
- Haematology: No effects
- Urinalysis: No effects
- Organ weights: No effects
- Gross pathology: No effects
- Histopathology: No effects
- Other: Not reported
STATISTICAL RESULTS: Not reported

Test condition: TEST ORGANISMS
- Age: Not reported
- Weight at study initiation: 80-100 g
- Number of animals: 15 animals/sex/dose
ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 4 weeks
- Type of exposure: oral
- Post exposure period: Not reported
- Vehicle: feed
- Concentration in vehicle: Not reported
- Doses: 2400 mg sodium siliate/kg/day, approximately equivalent to 800 mg SiO2/kg/day. It is assumed that mg/kg/day = mg/kg bw/day. (nominal dose)
SATELLITE GROUPS AND REASONS THEY WERE ADDED: Not reported
CLINICAL OBSERVATIONS AND FREQUENCY:
- Clinical signs: registered daily
- Mortality: registered daily
- Body weight: registered weekly
- Food consumption: registered with unknown frequency
- Water consumption: not reported
- Ophthalmoscopic examination: not reported
- Haematology: Total WBC count, differential WBC count, packed cell volume, prothrombine time and serum hemoglobin was registered weekly.
- Biochemistry: not reported
- Urinalysis: Urinary specific gravity protein concentration, glucose concentration and urea nitrogen was registered weekly.
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: the weight of not specified organs was registered.
- Microscopic: A set of tissues was preserved in formalin for histopathological examination. There are no further details.
OTHER EXAMINATIONS: Not reported
STATISTICAL RESULTS: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio not reported

Reliability: (2) valid with restrictions
Well-documented study, but test substance not clearly identified and background exposure through diet not stated.
Flag: Critical study for SIDS endpoint
08-MAY-2003 (40)

Type: Sub-chronic
Species: rat Sex: male/female
Strain: Sprague-Dawley
Route of administration: drinking water
Exposure period: 180 d
Frequency of treatment: daily
Post exposure period: no
Doses: 600 and 1200 mg SiO2/l
Control Group: yes
NOAEL: > 159 mg/kg bw

Year: 1973
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: The study was conducted to assess the influence of silica in the diet on growth and nutrient balance.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: NOAEL: No dose-related effects were observed. Therefore, the NOAEL is > 1200 mg SiO2/l, the highest concentration tested. This corresponds to 1578 mg Na-silicate/l or 157.8 mg/kg bw/d (calculation based on average body weight of 250 g and 25 ml water consumption/d).
ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX: not reported, drinking water was provided ad libitum.
- Time of death: no mortality
- Number of deaths at each dose: no mortality
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Mortality and time to death: None
_ Clinical signs: no effects
- Body weight gain: Some statistically significant differences in body weight between experimental groups and controls were registered, but these were small (6% or less), not consistent and not dose related.
- Food/water consumption: not reported
- Ophtalmoscopic examination: not reported
- Clinical chemistry: not reported
- Haematology: not reported
- Urinalysis: significant, but not dose-related effects on nitrogen and phosphorus retention ($p<0.05$)
- Organ weights: not reported
- Gross pathology: not reported
- Histopathology: not reported
- Other: In the male low dose group nitrogen retention was 50% lower that in the control group, while in the high dose group no such difference was observed. In a repeat experiment no clear and significant differences in nitrogen retention were found. In both experiments phosphorous retention seemed somewhat increased in the male high dose groups (approximately 12%), while in the low dose groups no effect of treatment was seen.

Test condition: TEST ORGANISMS
- Age: Weanling
- Weight at study initiation: Not reported
- Number of animals: 6/sex/dose
ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 180 (m-f) + 17 days (m)
- Type of exposure: oral via drinking water. All animals were maintained on a normal diet which contained 0.15 to 1.0% of SiO2 (based on dry weight).
- Post exposure period: no
- Vehicle: drinking water
- Concentration in vehicle: not reported
- Doses: 600 and 1200 mg SiO2/l corresponding to 789.5 and 1587 mg sodium silicate/l
SATELLITE GROUPS AND REASONS THEY WERE ADDED: None
CLINICAL OBSERVATIONS AND FREQUENCY:
- Clinical signs: Not reported
- Mortality: registered with unknown frequency
- Body weight: registered every week
- Food consumption: Not reported
- Water consumption: Not reported
- Ophthalmoscopic examination: Not reported
- Haematology: Not reported
- Biochemistry: Not reported
- Urinalysis: nitrogen and phosphorous registered daily from day 181-197 in males
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: Not reported
- Microscopic: Not reported
OTHER EXAMINATIONS: Analysis of faeces: nitrogen and phosphorous registered daily from day 181-197 in males
STATISTICAL METHODS: Not reported

Test substance: SOURCE: Diamond Alkali Company, Cleveland, Ohio, USA
PURITY: Not indicated
IMPURITY/ADDITIVE/ETC.: Not indicated
ANY OTHER INFORMATION: Molar ratio 3.2. Background concentration in the diet varied between 0.1 and 1.0% of SiO2 (w/w). Test substance Sodium Silicate was used.

Reliability: (2) valid with restrictions
Only two standard parameters were studied: body weight and survival. Background concentration in the diet varied between 0.1 and 1.0% of SiO2 (w/w). Nitrogen and phosphorous retention/excretion was measured only in the males at the end of the exposure period.

Flag: Critical study for SIDS endpoint

28-NOV-2003 (54)

Type: Sub-acute
Species: dog Sex: male/female
Strain: other: Beagle
Route of administration: oral feed
Exposure period: 4 weeks
Frequency of treatment: daily
Doses: 2400 mg/kg bw/d
Control Group: yes

Method: other: comparable to OECD guideline 407
Year: 1970
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Comparable to OECD 407

GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: LOAEL: Gross cortical lesions of the kidney were observed in 15/16 animals.
ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX:
- Time of death: no mortality
- Number of deaths of each dose: no mortality
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Mortality and time to death: None
- Clinical signs: Polydipsia, polyuria and soft stools observed in a few animals (not quantified). Most animals had soft discoloured faeces occasionally due to unabsorbed compound.
- Body weight gain: No effects
- Food/water consumption: No effects
- Ophthalmoscopic examination: Not reported
- Clinical chemistry: No effects
- Haematology: No effects
- Urinalysis: No effects
- Organ weights: No effects
- Gross pathology: Gross cortical lesions of the kidney were observed in 8/8 males and 7/8 females.
- Histopathology: Irritation of the renal tubular epithelium was followed by degenerative and regenerative changes, accompanied by inflammatory cell infiltration into the interstitium in all dogs exhibiting gross renal lesions. These phenomena were not observed in any of the control animals. Animals with renal lesions did not show any impairment of renal function.
- Other: Not reported
STATISTICAL RESULTS: Not reported

Test condition: TEST ORGANISMS
- Age: about 6 months (young adult)
- Weight at study initiation: 7-9 kg
- Number of animals: 8 animals/sex/dose
ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 4 weeks
- Type of exposure: oral
- Post exposure period: Not reported
- Vehicle: feed
- Concentration in vehicle: Not reported
- Doses: 2400 mg sodium silicate/kg/day (app. equivalent to 800 mg SiO2/kg/day. It is assumed that mg/kg/day = mg/kg bw/day nominal dose
SATELLITE GROUPS AND REASONS THEY WERE ADDED: Not reported
CLINICAL OBSERVATIONS AND FREQUENCY:
- Clinical signs: daily
- Mortality: examined daily
- Body weight: recorded weekly
- Food consumption: registered with unknown frequency
- Water consumption: not reported
- Ophthalmoscopic examination: not reported
- Haematology: registered weekly: total WBC count, differential WBC count, packed cell volume, prothrombine time, serum hemoglobin
- Biochemistry: not reported
- Urinalysis: urinary specific gravity, protein, glucose concentrations and urea nitrogen measured weekly
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):

- Macroscopic: the weight of not specified organs was registered.
- Microscopic: A set of tissues was preserved in formalin for histopathology examination. No further information.
OTHER EXAMINATIONS: Not reported
STATISTICAL METHODS: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio not reported

Reliability: (2) valid with restrictions
Well-documented study, but test substance not clearly identified and background exposure through diet not stated.

Flag: Critical study for SIDS endpoint

08-MAY-2003 (40)

5.5 Genetic Toxicity 'in Vitro'

Type: Escherichia coli reverse mutation assay
Concentration: 0.025 - 0.30%
Metabolic activation: without
Result: negative

Method: other
Year: 1951
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: according to Demerec (1951), Bertani (1951).
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: The mutant frequency (number of mutant per 10E6 bacteria) is calculated by dividing the total number of colonies scored in an experiment by the total number of bacteria. If the number of colonies increases more than twice as much as the spontaneous revertant colonies we can conclude that the chemical causes gene mutation
ANALYTICAL METHODS: Not reported

Remark: Of the 31 chemicals tested, 19 were found to be mutagenic, indicating in the absence of positive control data that the test was sensitive and could detect a mutagenic activity.

Result: mutant frequency (mutants per 10E6 bacteria):

conc. (%)	mut.freq.(treated)	mut.freq.(control)	survival (%)
0.025	5.9	6.3	66
0.100	2.4	5.3	33
0.050	8.7	6.3	27
0.100	6.6	6.1	16
0.100	11.4	6.2	4.6
0.150	2.0	6.2	3
0.300	0.0	7.0	0.11

It is concluded that sodium silicate is not mutagenic.

Test condition: SYSTEMS OF TESTING:
- Species/cell type: E.coli B/Sd-4/1,3,4,5 and B/Sd-4/3,4
- Deficiencies/Proficiencies: streptomycin -dependant strains
- Metabolic activation system: Not used
ADMINISTRATION
- Dosing: 0.025 - 0.300 wt%

- Number of replicates: 3 hrs exposure, 5-10 replicates/dose
- Application: Not reported
DMSO: Not reported
DESCRIPTION OF FOLLOW UP REPEAT STUDY: Not reported
CRITERIA FOR EVALUATING RESULTS: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Not reported

Reliability: (2) valid with restrictions
Well-documented study, but not according to established guidelines.

Flag: Critical study for SIDS endpoint

01-OCT-2004 (11)

Type: Chromosomal aberration test
Concentration: 19.5, 39.1, 78.1 & 156.3 µg active ingredient/ml
Cytotoxic Concentration: 156.3 - 312.5 µg active ingredient/ml
Metabolic activation: with and without
Result: negative

Method: OECD Guide-line 473
Year: 2006
GLP: yes
Test substance: other TS

Result: GENOTOXIC EFFECTS:
- With metabolic activation: no biologically relevant increases in chromosomal aberrations and frequencies of polyploid metaphases
- Without metabolic activation: no biologically relevant increases in chromosomal aberrations and frequencies of polyploid metaphases
PRECIPITATION CONCENTRATION: 156.3 µg active ingredient/ml (except experiment II after 18h preparation interval without S9 mix where precipitation occurred at 78.1 µg/ml and above)
CYTOTOXIC CONCENTRATION:
- With metabolic activation: 312.5 µg active ingredient/ml
- Without metabolic activation: 156.3 µg active ingredient/ml

Test condition: CELL CULTURE DETAILS:
- Type and identity of media: Minimal Essential Medium supplemented with 10% fetal calf serum.
- Properly maintained: yes
- Periodically checked for Mycoplasma contamination: yes
- Periodically checked for karyotype stability: yes

SYSTEM OF TESTING
- Species/cell type: Chinese hamster lung fibroblasts (V79)
- Metabolic activation system: Phenobarbital / ß-Naphthoflavone induced rat liver S9-mix
- Exposure duration, recovery period, total preparation interval:

	without S9 Mix			with S9 Mix	
	Exp. I	Exp. II		Exp. I	Exp. II
Exposure	4h	18h	28h	4h	4h
Recovery	14h	-	-	14h	24h
Total	18h	18h	28h	18h	28h

- Spindle inhibitor: 0.2 µg/ml Colcemid

- Stain: Giemsa
- No. of metaphases analyzed: 100

ADMINISTRATION:
- Dosing: Cytotoxic concentrations were determined in a range-finder study with and without metabolic activation. 312.5 µg/ml was chosen as top concentration in the actual experiments.
- Number of replicates: 2
- Application:
- Positive and negative control groups and treatment: 300-400 µg/ml Ethylmethane sulfonate (-S9), 1.4-2.0 µg/ml Cyclophosphamide (+S9) and Minimal Essential Medium
- Pre-incubation time:
DESCRIPTION OF FOLLOW UP REPEAT STUDY:
CRITERIA FOR EVALUATING RESULTS: Breaks, fragments, deletions, exchanges, and chromosome disintegrations were recorded as structural chromosome aberrations. Gaps were recorded as well, but not included in the calculation of aberration rates. Only metaphases with characteristic chromosome numbers (22+-1) were included in the analysis. The mitotic index (% cells in mitosis) and the percentage of polyploid cells in 500 metaphase plates/culture were determined.

Test substance: CAS 1344-09-8
Sodium silicate solution (weight ratio 3.3)
Tradename: Natronwasserglas 37/40 PE
36% active ingredient, 64% water

Reliability: (1) valid without restriction
Flag: Critical study for SIDS endpoint
05-APR-2006 (51)

5.6 Genetic Toxicity 'in Vivo'

5.7 Carcinogenicity

5.8.1 Toxicity to Fertility

Type: other: multigeneration study
Species: rat
Sex: male/female
Strain: Sprague-Dawley
Route of administration: drinking water
Exposure Period: 12 weeks, between weaning and sexual maturity, each generation F0, F1, F2, F3 & F4
Frequency of treatment: continuous
Premating Exposure Period
male: 12 weeks
female: 12 weeks
Duration of test: 2.5 years
No. of generation studies: 4
Doses: 79 and 159 mg sodium silicate/kg body weight/d
Control Group: yes, concurrent no treatment

Year: 1973
GLP: no
Test substance: other TS
Method: METHOD FOLLOWED: Rats were treated with 0, 600 and 1200 mg SiO2/l drinking water from weaning age (3 weeks) to maturity

(4 months). Six males and six females were then mated in each treatment group. Offspring from the control group were distributed among all water treatments upon weaning (3 weeks of age) -nine additional males and nine additional females were thereby added to each treatment group- and upon attainment of maturity these rats were also mated within their treatment groups. This process whereby offspring from control groups were distributed among treatments was repeated three times during a period of 2.5 years, and the mating procedure was repeated at four separate phases during the overall study, thereby providing data from 77 matings involving 59 females for each of the three treatments in the overall study.
DEVIATIONS FROM GUIDELINE: The study was not conducted according to any guideline.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Chi-square Test
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX: 600 and 1200 mg SiO2/l in drinking water, corresponding to 790 ppm and 1580 ppm sodium silicate, respectively. This converts to 79 and 159 mg/kg bw/d on the assumption of a mean body weight of 200 g and a mean daily water consumption of 20 ml/d.
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
Parental data and F1: No effects on mortality, the only parameter studied, were observed in the parental generation at any dose level. Reduced pup survival was observed in the treatment groups
- Body weight: Not reported
- Description, severity, time of onset and duration of clinical signs: Not reported
- Fertility index: Not reported
- Precoital interval: Not reported
- Duration of gestation: Not reported
- Gestation index: Not reported
- Changes in lactation: Not reported
- Changes in estrus cycles: Not reported
- Effects on sperm: Not reported
- Hematological findings incidence and severity: Not reported
- Clinical biochemistry findings incidence and severity: Not reported
- Mortality: No effects on length of life of the rats receiving sodium silicate in drinking water after weaning. Offspring from the treatment groups was frequently stillborn or small and weak, with survival limited to only a few days. Cannibalism was prevalent among females receiving sodium silicate, especially among those receiving 1200 ppm.
The results from the 4 consecutive breedings are reported in the publication as summed data only:

	0	600	1200 ppm SiO2
Number of matings	77	77	77
Number of litters	54	51	49
Total offspring born	517	346*	414*
Total offspring weaned	182	83*	44*
% of offspring weaned	35%	24%	11%
Difference, % of controls			

	born	-	67%	80%
	weaned	-	46%	24%

* Values differ from controls, P<0.001

- Gross pathology incidence and severity: Not reported
- Number of implantations: Not reported
- Number of corpora lutea: Not reported
- Ovarian primordial follicle counts: Not reported
- Organ weight changes: Not reported
- Histopathology incidence and severity: Not reported
- Offspring toxicity F1:
- Litter size and weights: On average 9.6, 6.8 and 8.4 animals/litter (at 0, 600 and 1200 mg SiO2/l). No data on body weights
- Sex and sex ratios: Not reported
- Viability index: see table above
- Post natal survival until weaning: 35%, 24% and 11 % (at 0, 600 and 1200 mg SiO2/l)
- Effects on offspring: Necrosis of the tail and of the feet as well in both treated groups. Litters were frequently stillborn or small and weak.
- Postnatal growth, growth rate: Not examined
- Vaginal opening (F) or preputial separation (M): Not examined
- Other observations: Not reported
- Statistical results: Not reported

Test condition: TEST CONDITION:
All animals were maintained on a normal diet (which contained 0.1 to 1.0% of SiO2 (based on dry weight). Housing conditions of the animals were not optimal, so that even in the control group survival of offspring until weaning was poor (35%).
MATING PROCEDURES: not reported
STANDARDIZATION OF LITTERS: Not reported
PARAMETERS ASSESSED DURING STUDY P AND F1:
- Clinical observations: Not executed
- Body weight: Not reported
- Estrous cycle: Not examined
- Sperm examination: Not executed
- Mortality: Examined, but frequency of observations not specified.
PARAMETERS ASSESSED DURING STUDY F1:
- Clinical observations and frequency: Not executed
OFFSPRING: Gross morphological anomalies, stillbirths
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC): Not reported
STATISTICAL METHODS: chi-square test

Test substance: SOURCE: Diamond Alkali Company, Cleveland, Ohio, USA
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Molar ratio 3.2

Reliability: (2) valid with restrictions
Non-guideline study with survival of offspring and gross morphological changes as the only parameters examined.

Flag: Critical study for SIDS endpoint

14-JUL-2003 (54)

5.8.2 Developmental Toxicity/Teratogenicity

5.8.3 Toxicity to Reproduction, Other Studies

Type:	other: male reproduction organs
In Vitro/in vivo:	In vivo
Species:	rat
Strain:	no data Sex: male
Route of administration:	other: intratesticularly or subcutaneously
Exposure period:	once
Frequency of treatment:	once
Duration of test:	7 days
Doses:	0.08 mmole/kg bw
Control Group:	yes

Method:	other: no guideline was followed
Year:	1964
GLP:	no
Test substance:	other TS: sodium silicate

Method:	METHOD FOLLOWED: Not reported DEVIATIONS FROM GUIDELINE: The study was not conducted according to any guideline. GLP: No, study executed before existence of GLP STATISTICAL METHODS: Not reported METHOD OF CALCULATION: Not reported ANALYTICAL METHODS: Not reported
Result:	ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX: 0.08 mmole/kg bw TOXIC RESPONSE/EFFECTS BY DOSE LEVEL: - Morphology: no alteration of the rat testis. - Histology: no alteration of the rat testis. - Organ weight: slight reduction in testis weight. - Spermatozoa: no effect on spermatozoa in the ductus deferens of the rats. STATISTICAL RESULTS: not reported
Test condition:	TEST ORGANISMS ADMINISTRATION / EXPOSURE - Type: colony bred rats - Strain: Swiss albino - weight at study initiation: 100-120 g - Type of exposure: single intratesticular or subcutaneous injection. - Duration of test/exposure: 7 days - Vehicle: sterile distilled water - Concentration in vehicle: not reported - Total volume applied: 0.2 ml - Doses: 0.08 mmole/kg bw - Concentrations: not reported - Control: sterile distilled water. For intratesticular injection the right testis served as control and the left testis received the test substance. EXAMINATIONS: - Morphology of testis - Histology of testis - Weight of testis - Spermatozoa in the ductus deferens STATISTICAL METHODS: not reported
Test substance:	SOURCE: Not indicated PURITY: Not indicated IMPURITY/ADDITIVE/ETC.: Not indicated

ANY OTHER INFORMATION: Molar ratio not indicated
Reliability: (2) valid with restrictions
Non-guideline study with sufficient detail.
Flag: Critical study for SIDS endpoint
06-MAR-2003 (25)

Type:	other: male and female reproduction organs
In Vitro/in vivo:	In vivo
Species:	rat
Strain:	other: Charles River Cesarean-Derived (CD) Sex: male/female
Route of administration:	oral feed
Exposure period:	4 weeks
Frequency of treatment:	ad libitum
Duration of test:	4 weeks
Doses:	2400 mg/kg bw/d
Control Group:	yes, concurrent vehicle
Result:	no effects on reproductive organs upon histopathological examination

Remark: For further details on this study see chapter 5.4
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
28-NOV-2003 (40)

Type:	other: male and female reproduction organs
In Vitro/in vivo:	In vivo
Species:	dog
Strain:	Beagle Sex: male/female
Route of administration:	oral feed
Exposure period:	4 weeks
Frequency of treatment:	ad libitum
Duration of test:	4 weeks
Doses:	2400 mg/kg bw/d
Control Group:	yes, concurrent vehicle
Result:	no effects on reproductive organs upon histopathological examination

Remark: For further details on this study see chapter 5.4
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
28-NOV-2003 (40)

5.9 Specific Investigations

5.10 Exposure Experience

Type of experience: other

Remark: In man, the lethal oral dose of sodium silicates has been estimated as 0.5-5 g/kg, depending on the molar ratio.

In the USA sodium silicate is considered "generally recognized as safe (GRAS)" for indirect food uses, and as additive to drinking water in concentrations of up to 100 ppm.
Test substance: Sodium silicate, no further information on molar ratio and

concentration given.
Reliability: (4) not assignable
Only secondary literature (review).
29-MAR-2005 (50) (52)

Type of experience: Human - Medical Data

Remark: A fifty-seven year old dyer was regularly exposed at work to 20 % sodium silicate solution of unknown molar ratio. The man had recurrent ulcerative lesions on his left hand over a period of two years. The ulcers were associated with chronic eczematous changes resulting from primary irritant contact dermatitis to sodium silicate, as indicated by a positive patch test. The man also had another type of cutaneous reaction to sodium silicate, contact urticaria. An immediate wheal and flare reaction was seen fifteen minutes after the application of sodium silicate to a scratch test site. Such a response was not seen in healthy control subjects.
Test substance: 20 % sodium silicate solution of unknown molar ratio.
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
21-NOV-2003 (59)

Type of experience: Direct observation, poisoning incidents

Remark: Ingestion of 200 ml of sodium silicate egg preserving solution (they have typically a molar ratio of 3.2 and concentrations in the range of 5-36%) caused severe vomiting, diarrhea and bleeding, elevated blood pressure, and renal damage, but was not fatal.
Test substance: Sodium Silicate solution of a molar ratio of 3.2, but unspecified concentration.
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
21-NOV-2003 (50)

Type of experience: Direct observation, poisoning incidents

Remark: Ingestion of 500 ml of an egg-preserving solution containing sodium silicate in suicidal intention led to death of a 68
year old woman within 1 hour by suffocation. Aspiration of the vomited silicate solution caused obstruction of the lungs by precipitation of amorphous silica. The transformation of sodium silicate from liquid to solid occured in the lungs by means of the carbonic acid of expiration air.
Test substance: Although the authors state that sodium metasilicate was used (in form of an egg preserving solution from a local
drug store), the relatively low pH of 12.5 makes it more likely that a silicate solution of a molar ratio of greater than 1.0 was ingested. Moreover, egg preservatives typically
contain 5-36% of 3.2 SiO2/Na2O silicate (Schleyer & Blumberg, 1982).
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
21-NOV-2003 (50) (53)

5.11 Additional Remarks

Remark: The average intake of silicon is 20-50 mg total Si/d (Pennington, 1991). An estimation of 0.31 mg Si/kg bw/d in females and 0.53 mg Si/kg bw/d in males made in an American study, is representative for the intake in the Western world. While the highest concentrations of total silicon are found in seafood, eggs and diary products; the main dietary sources are cereals and beverages.

21-NOV-2003 (43)

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I U C L I D

D a t a S e t

Existing Chemical	ID: 6834-92-0
CAS No.	6834-92-0
EINECS Name	disodium metasilicate
EC No.	229-912-9
TSCA Name	Silicic acid (H2SiO3), disodium salt
Molecular Formula	H2O3Si.2Na

Producer Related Part	
Company:	Cognis Deutschland GmbH
Creation date:	03-FEB-2003
Substance Related Part	
Company:	Cognis Deutschland GmbH
Creation date:	03-FEB-2003
Memo:	Dataset of CEES Soluble Silicates Consortium. Contains also data for 10213-79-3, Sodium Metasilicate Pentahydrate and 13517-24-3, Sodium Metasilicate Nonahydrate

Printing date:	03-FEB-2005
Revision date:	
Date of last Update:	03-FEB-2005

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Chapter (profile):	Chapter: 1, 2, 3, 4, 5
Reliability (profile):	Reliability: without reliability, 1, 2, 3, 4
Flags (profile):	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 Applicant and Company Information

Type:	lead organisation
Name:	Centre Europeen d'Etude des Silicates (CEES)
Contact Person:	Joël Wilmot Date: 28-FEB-2003
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Homepage:	http://www.cees-silicates.org

Remark: CEES, the Centre Europeen d'Etude des Silicates is a sector group of CEFIC and unites the Western European producers of silicates.
The Soluble Silicates Consortium is represented by the following companies:

Asahi Glass Co., Ltd. (JP)
Chimibase (IT)
Cognis Deutschland GmbH (DE)
FMC Foret SA (ES)
Industria Chimica Vera (IT)
Industrias Químicas del Ebro SA (ES)
Ineos Silicas Ltd (UK)
Ingessil (IT)
PQ Europe (NL)
Rhodia SA (FR)
Sasol Italy SpA (IT)
Silmaco NV (BE)
Solvay S.A. (BE)
Tokuyama Corp. (JP)
van Baerle & Cie (CH)
van Baerle GmbH (DE)
Woellner Silikat GmbH (DE)

23-JAN-2004

1.0.2 Location of Production Site, Importer or Formulator

1.0.3 Identity of Recipients

1.0.4 Details on Category/Template

1.1.0 Substance Identification

IUPAC Name:	Silicic acid (H2SiO3), disodium salt
Smiles Code:	not applicable
Mol. Formula:	Na2O3Si (anhydrous); Na2O3Si x 5H2O(pentahydrate); Na2O3Si x 9H2O (nonahydrate)
Mol. Weight:	Not applicable, sodium metasilicate is comprised of infinite chains of Na2SiO3 units of variable length. Molecular weight of monomer is 122.08

04-DEC-2003

1.1.1 General Substance Information

Purity type: typical for marketed substance
Substance type: inorganic
Physical status: solid
Purity: >= 98 - % w/w
Colour: colourless or white granules

Remark: Sodium metasilicate is commercially provided in three forms:

- as anhydrous substance (Na2SiO3, CAS-No. 6834-92-0)
- as crystalline pentahydrate (Na2SiO3 x 5 H2O, CAS-No. 10213-79-3)
- as crystalline nonahydrate (Na2SiO3 x 9 H2O, CAS-No. 13517-24-3)

23-JAN-2004

1.1.2 Spectra

1.2 Synonyms and Tradenames

Disodium metasilicate

Remark: Synonym for anhydrous metasilicate.
13-NOV-1995

Disodium metasilicate nonahydrate

Remark: Synonym for the nonahydrate.
12-DEC-2003

Disodium monosilicate

Remark: Synonym for anhydrous metasilicate.
13-NOV-1995

Disodium silicate

Remark: Synonym for anhydrous metasilicate.
13-NOV-1995

Disodium silicate pentahydrate

Remark: Synonym for the pentahydrate.
12-DEC-2003

Na2SiO3

Remark: Synonym for anhydrous metasilicate.
12-NOV-2002

Na2SiO3 . 5H2O

Remark: Synonym for the pentahydrate.
12-DEC-2003

Na2SiO3 . 9H2O

Remark: Synonym for the nonahydrate.
12-DEC-2003

Silicic acid (H2SiO3), disodium salt

Remark: Synonym for anhydrous metasilicate.
07-OCT-1994

silicic acid, disodium salt

Remark: Synonym for anhydrous metasilicate.
21-MAR-1994

Sodium metasilicate (Na2SiO3)

Remark: Synonym for anhydrous metasilicate.
13-NOV-1995

Sodium metasilicate nonahydrate

Remark: Synonym for the nonahydrate.
12-DEC-2003

Sodium metasilicate pentahydrate

Remark: Synonym for the pentahydrate.
12-DEC-2003

Sodium Metasilicate, Anhydrous

Remark: Synonym for anhydrous metasilicate.
08-MAR-1995

Sodium silicate (Na2SiO3)

Remark: Synonym for anhydrous metasilicate.
05-FEB-2003

Sodium silicate, nonahydrate

Remark: Synonym for the nonahydrate.
12-DEC-2003

Sodium silicate, pentahydrate

Remark: Synonym for the pentahydrate.
12-DEC-2003

1.3 Impurities

Purity type: typical for marketed substance

Remark: Impurities stem from the quartz sand used rather than from soda. Therefore, impurities of potassium silicates are similar to sodium silicates of comparable molar ratios. The following impurities were reported for sodium silicate lumps of weight ratio 3.35 (molar ratio 3.46):

Na2SO4: 0.06%

NaCl: 0.06%
Fe2O3: 0.033%
Al2O3: 0.097%
CaO: 0.03%
MgO: 0.02%
TiO2: 0.019%

Reliability: (4) not assignable
Review article only
Flag: Critical study for SIDS endpoint
03-DEC-2003 (12)

Purity type: typical for marketed substance

Remark: Soluble silicates are very pure substances with impurities less than 1%. The impurities stem from the quartz sand used rather than from the potash or soda components of the fusion mixture. Therefore, impurities of potassium silicates are similar to sodium silicates of comparable molar ratios.

Result: Composition range of a typical sodium silicate solution of weight ratio 3.3 (molar ratio 3.4):

K	20-50
Mg	5-20
Ca	1-80
Sr	1-5
Ba	<1-5
Al	50-200
P	<1-10
S	10-30
Ti	30-80
V	0.1-0.8
Cr	<1
Mn	<0.5-1
Fe	25-100
Co	<1
Ni	<0.5
Cu	<0.1-0.2
Zn	<0.2-1
La	0.2-1
Ce	<0.3-2
Zr	5-20
W	<1-25

all contents in ppm

Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
03-DEC-2003 (13)

1.4 Additives

1.5 Total Quantity

Quantity: ca. 77000 tonnes produced in 2000

Remark: Quantity expressed in metric tonnes of SiO2
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
04-DEC-2003 (29)

1.6.1 Labelling

Labelling: as in Directive 67/548/EEC
Symbols: (C) corrosive
Specific limits: no
R-Phrases: (34) Causes burns
(37) Irritating to respiratory system
S-Phrases: (1/2) Keep locked up and out of reach of children
(13) Keep away from food, drink and animal feeding stuffs
(24/25) Avoid contact with skin and eyes
(36/37/39) Wear suitable protective clothing, gloves and eye/face protection
(45) In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

23-JAN-2004

1.6.2 Classification

1.6.3 Packaging

1.7 Use Pattern

Type: type
Category: Wide dispersive use

05-FEB-2003

Type: industrial
Category: Personal and domestic use

05-FEB-2003

Type: industrial
Category: Public domain

05-FEB-2003

Type: use
Category: Cleaning/washing agents and disinfectants

Remark: Automatic dish-washing powders and technical cleaners where high alkalinity is needed.
15-DEC-2003 (8) (14) (34) (52)

Type: use
Category: Corrosive inhibitors

15-DEC-2003 (8)

Type: use
Category: Non agricultural pesticides

15-DEC-2003 (8)

Type: use
Category: Photochemicals

15-DEC-2003 (8)

Type: use
Category: Reprographic agents

15-DEC-2003 (8)

Type: use
Category: other: Anti-freezing agents

15-DEC-2003 (8)

Type: use
Category: other: car-care product

15-DEC-2003 (52)

1.7.1 Detailed Use Pattern

1.7.2 Methods of Manufacture

1.8 Regulatory Measures

1.8.1 Occupational Exposure Limit Values

Remark: No specific exposure limits have been established for alkali silicates.
For liquids the creation of aerosols should be avoided. For powders, general dust exposure limits according to national regulations, (typically from 6 to 10 mg/m3) will apply. For corrosive alkali silicates (MR </=1.6) the exposure limits set for sodium hydroxide NaOH (2 mg/m3) should be considered as a guideline.
Sodium metasilicate has not been given an Occupational Exposure Limit value.
16-DEC-2003 (5)

1.8.2 Acceptable Residues Levels

1.8.3 Water Pollution

Classified by: KBwS (DE)
Class of danger: 1 (weakly water polluting)

Reliability: (2) valid with restrictions
Official german classification
08-JAN-2004 (17)

1.8.4 Major Accident Hazards

1.8.5 Air Pollution

1.8.6 Listings e.g. Chemical Inventories

1.9.1 Degradation/Transformation Products

1.9.2 Components

1.10 Source of Exposure

Source of exposure: Human: exposure by production
Exposure to the: Substance

Remark: Accidental human exposure may occur during production and processing of silicates. No measured data are available.
21-OCT-2004

Source of exposure: Human: exposure through intended use
Exposure to the: Substance

Remark: Applications were exposure is possible: automatic dishwashing powders in the catering trade and technical cleaners.
From the use patterns listed in chapter 1.7 it can be inferred that accidental human exposure may occur during professional downstream use of silicates. No measured data are available.
21-OCT-2004

Source of exposure: Human: exposure of the consumer/bystander
Exposure to the: Substance

Remark: Applications were exposure is possible: automatic dishwashing powders
From the use patterns listed in chapter 1.7 it can be inferred that accidental human exposure may occur during consumer use of washing and cleaning agents containing silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure from production
Exposure to the: Substance

Remark: Accidental environmental exposure may occur during production of silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure through private use
Exposure to the: Substance

Remark: Applications were exposure is possible: automatic dishwashing powders
From the use patterns listed in chapter 1.7 it can be inferred that environmental exposure will occur during the use of consumer products containing silicates. No measured data are available.
21-OCT-2004

1.11 Additional Remarks

1.12 Last Literature Search

1.13 Reviews

2.1 Melting Point

Value: 1089 degree C
Sublimation: no

Method: other: no data
GLP: no data

Remark: The melting point of 1089 degr. C refers to the anhydrous form of sodium metasilicate. Hydrated forms (Na2SiO3xH2O) have a much lower melting point, depending on the hydration level.
Test substance: Sodium metasilicate, anhydrous (CAS 6834-92-0)
Reliability: (2) valid with restrictions
Peer-reviewed handbook data and publication providing sufficient information for evaluation.
Flag: Critical study for SIDS endpoint
30-SEP-2004 (3) (27)

Value: 72.2 degree C
Sublimation: no

Method: other: no data
GLP: no data

Test substance: Sodium metasilicate, pentahydrate (CAS 10213-79-3)
Reliability: (2) valid with restrictions
Peer-reviewed handbook data and publication providing sufficient information for evaluation.
Flag: Critical study for SIDS endpoint
30-SEP-2004 (1) (42) (47)

Value: 48 degree C

Test substance: Sodium metasilicate, nonahydrate (CAS 13517-24-3)
Reliability: (2) valid with restrictions
Peer-reviewed handbook data.
Flag: Critical study for SIDS endpoint
19-OCT-2004 (3)

Value: 47.9 degree C
Sublimation: no

Method: other: no data
GLP: no data

Test substance: Sodium metasilicate, nonahydrate (CAS 13517-24-3)
Reliability: (2) valid with restrictions
Publication providing sufficient information for evaluation.
19-OCT-2004 (1)

2.2 Boiling Point

Value: 100 degree C

Test substance: Sodium metasilicate, nonahydrate (CAS 13517-24-3)
Reliability: (2) valid with restrictions
Peer-reviewed handbook data.

16-DEC-2003 (30)

Value:

Remark: The determination of a boiling point is not practical for solid anhydrous silicates as they are glasses with high melting points. The boiling point of silicate solutions on the other hand will be primarily determined by the water present and thus will not differ significantly from the boiling point of water.
30-SEP-2004

2.3 Density

Type: density
Value: 2.61 g/cm³

Test substance: Sodium metasilicate, anhydrous (CAS 6834-92-0)
Reliability: (2) valid with restrictions
Peer-reviewed handbook data.
Flag: Critical study for SIDS endpoint
30-SEP-2004 (3)

Type: bulk density
Value: 1200 kg/m3

Test substance: Sodium metasilicate, anhydrous (CAS 6834-92-0)
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
20-OCT-2004 (34)

Type: density
Value: 1.75 g/cm³ at 20 degree C

Test substance: Sodium metasilicate, pentahydrate (CAS 10213-79-3)
Reliability: (2) valid with restrictions
Publication providing sufficient information for evaluation.
Flag: Critical study for SIDS endpoint
19-OCT-2004 (1)

Type: bulk density
Value: 1000 kg/m3

Test substance: Sodium metasilicate, pentahydrate (CAS 10213-79-3)
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
20-OCT-2004 (34)

Type: density
Value: 1.65 g/cm³ at 20 degree C

Test substance: Sodium metasilicate, nonahydrate (CAS 13517-24-3)
Reliability: (2) valid with restrictions

Publication providing sufficient information for evaluation.
Flag: Critical study for SIDS endpoint
19-OCT-2004 (1)

Type: bulk density
Value: 800 kg/m3

Test substance: Sodium metasilicate, nonahydrate (CAS 13517-24-3)
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
20-OCT-2004 (34)

2.3.1 Granulometry

2.4 Vapour Pressure

Value: .0103 hPa at 1175 degree C

Method: other (measured): Kroeger and Soerstroem
GLP: no data

Remark: The vapour pressure at environmental temperatures is negligibly low and thus not relevant.
Test substance: Sodium metasilicate, anhydrous (CAS 6834-92-0)
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
08-JAN-2004 (28)

2.5 Partition Coefficient

Remark: Alkali silicates are totally insoluble in n-octanol (as for most other organic solvents). The oil/water partition coefficient of these substances (as normally determined with n-octanol/water) is therefore not applicable or relevant.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
Flag: Critical study for SIDS endpoint
19-OCT-2004 (5)

Remark: Sodium metasilicate is insoluble in alcohol indicating that this would also apply to n-octanol. The oil/water partition coefficient (as normally determined with n-octanol/water) is therefore not applicable or relevant.
Reliability: (2) valid with restrictions
Peer-reviewed handbook data.
Flag: Critical study for SIDS endpoint
20-OCT-2004 (3)

2.6.1 Solubility in different media

Remark: Anhydrous sodium metasilicate is soluble in water and insoluble in alcohol, acids and salt solutions.
Test substance: Sodium metasilicate, anhydrous (CAS 6834-92-0)
Reliability: (2) valid with restrictions
Peer-reviewed handbook data.
Flag: Critical study for SIDS endpoint
30-SEP-2004 (30) (33)

Solubility in: Water
Value: = 210 g/l at 20 degree C
pH value: 12.7
Conc.: 1 vol% degree C

Test substance: Sodium metasilicate, anhydrous (CAS 6834-92-0)
Reliability: (4) not assignable
Manufacturers data without proof.
Flag: Critical study for SIDS endpoint
21-OCT-2004 (43)

Solubility in: Water
Value: = 610 g/l at 30 degree C

Test substance: Sodium metasilicate, pentahydrate (CAS 10213-79-3)
Reliability: (4) not assignable
Manufacturers data without proof.
Flag: Critical study for SIDS endpoint
21-OCT-2004 (44)

Remark: Sodium metasilicate nonahydrate is very soluble in water and insoluble in alcohol and acids.
Test substance: Sodium metasilicate, nonahydrate (CAS 13517-24-3)
Reliability: (2) valid with restrictions
Peer-reviewed handbook data.
30-SEP-2004 (30)

Solubility in: Water
Value: 115 mg/l at 25 degree C

Remark: Amorphous silica which precipitates when alkaline silicate solutions are neutralized has a water solubility of 115 mg/l at 25°C and neutral pH.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
30-SEP-2004 (35)

pH value: 10 - 13

Remark: Alkaline silicates are completely insoluble in n-octanol. The pH in alkaline silicates is dependant on the silica to alkali ratio and the concentrations of the individual solutions. Concentrated solutions usually have a pH between 10 and 13.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.

Flag: Critical study for SIDS endpoint
19-OCT-2004 (5)

Remark: Soluble silicates are incompatible with most organic compounds.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (34)

2.6.2 Surface Tension

2.7 Flash Point

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (5) (34)

2.8 Auto Flammability

Value:

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (5) (34)

2.9 Flammability

Result: non flammable

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (5) (34)

2.10 Explosive Properties

Result: not explosive

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (5) (34)

2.11 Oxidizing Properties

Result: no oxidizing properties

Remark: Soluble silicates have no oxidizing properties.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
21-OCT-2004 (5)

2.12 Dissociation Constant

2.13 Viscosity

2.14 Additional Remarks

3.1.1 Photodegradation

Remark: The basic structural unit of soluble silicates is a tetrahedral arrangement of four oxygen atoms surrounding a central silicon atom. Tetrahedra are linked with each other via Si-O-Si bonds resulting in an infinite three-dimensional network where the oxygen atoms at the corners of a given tetrahedron are shared with neighbouring tetrahedra. Not all corners in the tetrahedra are shared; the negative charge of unshared oxygen atoms is balanced by the presence of sodium or potassium cations which are randomly spaced in the interstices of the silicate structure.
Based on these structural considerations a significant breakdown of soluble silicates via photodegradation is not expected.
Reliability: (2) valid with restrictions
Expert judgement
26-JAN-2004 (6)

3.1.2 Stability in Water

Remark: Polymerisation-Depolymerisation:
Upon dilution of concentrated commercial silicate solutions with water, the highly cross-linked polysilicate ions depolymerize rapidly to monosilicate ions, the extent of depolymerisation depending on the dilution factor.
Reliability: (2) valid with restrictions
Acceptable procedure and publication
18-DEC-2003 (37)

Remark: The basic consideration is that silica dissolves according to : $SiO_2 + H_2O = Si(OH)_4$. At low concentrations most species are present as monomers, at higher concentrations polymerisation will occur.
Most soluble silicates are in the form:
$M_2O \cdot mSiO_2 \cdot nH_2O$
where M = alkali metal, predominantly Na, but also K. The index m (molar ratio) ranges between 0.5 - 4, most commonly m = 3.3. Stability depends to a large extent on pH, above pH 10.6 the solutions are chemically stable. The increase of ionic strength accelerates nucleation and deposition and decreases the SiO_2 solubility. Coating of surfaces by organic matter may hamper dissolution, but at the same time $Si(OH)_4$ may form complexes with organic matter, a process which favours dissolution.
Reliability: (4) not assignable
Handbook data
18-DEC-2003 (13)

3.1.3 Stability in Soil

3.2.1 Monitoring Data (Environment)

Type of measurement: background concentration

Medium: other: surface-, ground- or drinking water

Remark: Dissolved silica from commercial soluble silicates is indistinguishable from natural dissolved silica since depolymerisation of polysilicate anions to monomeric dissolved silica occurs very rapidly when commercial soluble silicate solutions are diluted with water. Therefore any soluble silica input to the natural silica cycle as a result of the production or use of commercial soluble silicates will be insignificant in view of the size and high flux of the natural silica cycle.
Reliability: (2) valid with restrictions
Acceptable procedure and publication
Flag: Critical study for SIDS endpoint
18-DEC-2003 (13) (37) (48)

Type of measurement: background concentration
Medium: ground water
Concentration: ca. 17 mg/l

Remark: The median value in the US was reported to be 17 mg SiO2/l for ground waters.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (9)

Type of measurement: background concentration
Medium: surface water
Concentration: ca. 14 mg/l

Remark: The median value in the US was reported to be 14 mg SiO2/l for streams.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (9)

Type of measurement: background concentration
Medium: surface water
Concentration: ca. 13 mg/l

Remark: The worldwide mean concentration in rivers is 13 mg SiO2/l.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (11)

Remark: Natural occurence:
Compounds of silicon comprise ca. 59% of the earth's crust, constituted by minerals, soils and sediments, dissolved silica, amorphous silica in the solid phase and silica bound to organic matter.

Dissolved silica is a minor but ubiquitous constituent of the hydrosphere. Dissolved silica is supplied to the environment by chemical and biochemical weathering processes.
Reliability: (4) not assignable
Handbook data

Flag: Critical study for SIDS endpoint
18-DEC-2003 (13) (20)

Remark: SiO2 enters surface waters via the four main application areas where emissions to water systems might occur (household detergents, pulp-and paper production, water treatment, and soil stabilisation).
Seen in the context of the natural silica cycle, and natural loading of water systems with silicates due to weathering of soil and rocks, weathering of sediments and atmospheric deposition, this amount is small.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (48) (54)

3.2.2 Field Studies

3.3.1 Transport between Environmental Compartments

Remark: Due to a strong dependance on pH and concentration which leads to a complex dynamic polymerisation-depolymerisation equilibrium with speciation into a variety of mono-, oligo-, and polymeric anions and amorphous silica, calculations on the distribution in various environmental compartments are not feasible.
The contribution of anthropogenic inputs to the occurrence in the various compartments will be negligible compared to the concentrations contributed to by the natural silica flux.
Reliability: (4) not assignable
Handbook data
19-DEC-2003 (13)

3.3.2 Distribution

Remark: See remark in 3.3.1
18-DEC-2003

3.4 Mode of Degradation in Actual Use

3.5 Biodegradation

Remark: Not applicable (inorganic substance).
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
18-DEC-2003 (5)

3.6 BOD5, COD or BOD5/COD Ratio

Method:
Year:

Method:
Remark: Not applicable (inorganic compound).
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
18-DEC-2003 (5)

3.7 Bioaccumulation

Remark: Ingested silicates are excreted via urine and to a lesser extent via the faeces. Markedly increased and rapid urinary excretion of silica was observed when soluble sodium silicates were administered to rats (Benke & Osborn, 1979), dogs (King et al., 1933), cats (King & McGeorge, 1938) and guinea pigs (Sauer et al., 1959). The urinary silicon excretion half-life after administration of sodium silicate to rats via stomach tube was 24 h (Benke & Osborn, 1979).

Based on these metabolic considerations no bioaccumulation is to be expected.
Reliability: (2) valid with restrictions
Well documented publications giving sufficient detail for evaluation.
Flag: Critical study for SIDS endpoint
19-DEC-2003 (2) (25) (26) (46) (46)

Remark: Soluble silicates have no bioaccumulation potential. There are no structural alerts to suspect such a hazard.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
08-JAN-2004 (5)

3.8 Additional Remarks

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type: semistatic
Species: other: Brachydanio rerio (now Danio rerio)
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no
LC0: = 180
LC50: = 210
LC100: = 250

Method: other: ISO 7346/2
Year: 1982
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: ISO guideline 7346/2, which conforms to OECD 203
DEVIATIONS FROM GUIDELINE: the report is limited in detail
GLP: The present study was carried out before 1990, i.e. at a time when GLP wasn't yet implemented.
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported
Result: RESULTS: EXPOSED
- Nominal/measured concentrations: not reported
- Effect data (Mortality): at 48 hours exposure all fish had died at 250 mg/l
- Concentration / response curve: not reported
- Effect concentration vs. test substance solubility: not reported
- Other effects: the fish did not show any abnormal behaviour
RESULTS: CONTROL
- Number/percentage of animals showing adverse effects: not reported
- Nature of adverse effects: not reported
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: not reported
- Results: not reported
Test condition: TEST ORGANISMS
- Strain: Brachydanio rerio
- Pretreatment: none
- Feeding during test: no
DILUTION WATER
- Hardness: 250 mg CaCO3/l
- pH: 7.8 ± 0.2
- Oxygen content: saturated
TEST SYSTEM
- Test type: determination of the acute toxicity to Zebra-fish according to the ISO-guideline 7346/2
- Concentrations: 90, 130, 180, 250 mg product/l (nominal)
- Renewal of test solution: daily
- Exposure vessel type: test vessels, 10 l fish basins containing 5 l test water
- Test temperature: about 23°C
- Dissolved oxygen: oxygen saturated
- pH: 9.1-9.8
- Photoperiod: about 16 hours illumination per day
DURATION OF THE TEST: 96 hours

	TEST PARAMETER: mortality
Test substance:	SOURCE: Cognis Deutschland GmbH PURITY: 100% active matter IMPURITY/ADDITIVE/ETC.: none ANY OTHER INFORMATION: Sodium Metasilicate (anhydrous) soluble and not volatile at room temperature
Reliability:	(2) valid with restrictions Guideline study, but the study report is limited in detail.
Flag:	Critical study for SIDS endpoint

30-SEP-2004 (41)

Type:	static
Species:	Gambusia affinis (Fish, fresh water)
Exposure period:	96 hour(s)
Unit:	mg/l Analytical monitoring: no data
LC50:	2320
Method:	other
Year:	1957
GLP:	no
Test substance:	other TS
Method:	METHOD FOLLOWED: not reported GLP: No, study executed before the existence of GLP STATISTICAL METHODS: not reported METHOD OF CALCULATION: median tolerance limit (TLm) derived from lethal concentrations plotted on logarithmic paper ANALYTICAL METHODS: not reported
Result:	RESULTS: EXPOSED - Nominal/measured concentrations: not reported - Effect data (Mortality): LC50 (24 h): 3200 mg/l; LC50 (48 h): 2400 mg/l, LC50 (96 hrs) 2320 mg/l - Concentration / response curve: not reported - Effect concentration vs. test substance solubility: not reported - Other effects: not reported RESULTS: CONTROL - Number/percentage of animals showing adverse effects: not reported - Nature of adverse effects: not reported RESULTS: TEST WITH REFERENCE SUBSTANCE There was no reference substance tested
Test condition:	TEST ORGANISMS - Strain: Gambusia affinis - Wild caught: collected from Stillwater Creek in Payne country, Oklahoma, USA - Feeding: plankton and detritus collected locally and various artificial foods DILUTION WATER - Source: water from two local farm ponds - Aeration: artificial from a compressor - pH: 7.8-8.3 TEST SYSTEM - Test type: acute toxicty of sodium silicate to Gambusia affinis - Concentrations: 10,18,32,56 and 100 ppm. If deaths did not occur within 96h the same series was used between 1000 and 10000 ppm. - Exposure vessel type: cylindrical pyrex jars (12 inch high and 12 inch in diameter) - Number of replicates, fish per replicate: 10 fish in each

aquarium, no replicates
- Test temperature: 21-22°C
- pH: 8.9 - 10.1
DURATION OF THE TEST: 96 h
TEST PARAMETER: mortality
SAMPLING: temperature, turbidity and pH of the experimental water were measured after the chemical was added and daily throughout the experiment. The turbidity was 110 mg/l

Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: The test substance is indicated to be "Sodium silicate - Na2SiO3". Although the name sodium silicate is not specific enough to differentiate, the chemical formula clearly stands for disodium silicate which is in other words sodium metasilicate. On the basis of the precise chemical formula, the test substance was identified as the metasilicate. Whether it is the anhydrous or a hydrated form of metasilicate cannot be decided.

Reliability: (2) valid with restrictions
well documented study, several shortcomings to today's standard methods

Flag: Critical study for SIDS endpoint

30-SEP-2004 (53) (55)

4.2 Acute Toxicity to Aquatic Invertebrates

4.3 Toxicity to Aquatic Plants e.g. Algae

Species: Selenastrum capricornutum (Algae)
Endpoint: biomass
Exposure period: 96 hour(s)
Unit: mg/l Analytical monitoring: no

Method: other: Algal Assay Bottle Test EPA-600/9-78-018
Year: 1996
GLP: no

Result: Populations increased in all flasks throughout the test period. Log growth was obtained in control cultures, and in treatment cultures up to 25 ppm silicate. The addition of sodium silicate caused a slight stimulation of growth at 6.25-25 ppm when compared to controls at the final populations (96 hours). Populations of Selenastrum were less in 50 and 100 ppm silicate treatments in final populations at 96 hours when compared to control flasks, but a NOEC and EC50 was not calculated.

Test condition: TEST ORGANISMS
- Strain: Selenastrum capricornutum Printz
- Source/supplier: Carolina Biological Supply Co. Burlington, NC, USA
- Laboratory culture: no data
- Method of cultivation: no data
- Pretreatment: no data
- Controls: no data
- Initial cell concentration:
STOCK AND TEST SOLUTION AND THEIR PREPARATION
- Dispersion: no
- Vehicle, solvent: water / algal growth medium

- Concentration of vehicle/ solvent:
- Other procedures: stock solution of 100 ppm active ingredient (w/v) prepared in distilled water; serial dilutions made in algal growth medium according to Algal Assay Bottle Test EPA-600/9-78-018 (no further information).
STABILITY OF THE TEST CHEMICAL SOLUTIONS: no data
REFERENCE SUBSTANCE: no data
DILUTION WATER
- Source: no data
- Aeration: no data
GROWTH/TEST MEDIUM CHEMISTRY
- Alkalinity: no data
- Hardness: no data
- Salinity: no data
- TOC: no data
- EDTA: no data
- TSS: no data
- pH: 7.5
- Dissolved oxygen: no data
TEST SYSTEM
- Test type:
- Concentrations: inoculum of 5300 cells/ml
- Renewal of test solution: no data
- Exposure vessel type: 250 ml Erlenmeyer flasks
- Number of replicates: 3
- Concentrations: 100, 50, 25, 12.5, 6.25 & 0 ppm active ingredient w/v
- Test temperature: 24 °C
- pH: initial pH 7.2 (0 ppm) - 10.7 (100 ppm); at end of test 7.7 - 10
- Intensity of irradiation: 200 footcandles
- Photoperiod: continuous illumination
TEST PARAMETER: cell count using a hemocytometer
MONITORING OF TEST SUBSTANCE CONCENTRATION: no data

Test substance: Sodium metasilicate, pentahydrate (CAS 10213-79-3)
SOURCE: Chemical Products Technologies, Inc. Dawson, GA. U.S.A
PURITY: 58% active ingredient in water
IMPURITY/ADDITIVE/ETC.: no data
ANY OTHER INFORMATION:

Reliability: (4) not assignable
Short summary of partly illegible, handwritten laboratory notes. Insufficient information extractable.

03-FEB-2005 (50)

4.4 Toxicity to Microorganisms e.g. Bacteria

Type: aquatic
Species: activated sludge, domestic
Exposure period: 3 hour(s)
Unit: mg/l Analytical monitoring: no
EC50: > 100

Method: OECD Guide-line 209 "Activated Sludge, Respiration Inhibition Test"
Year: 1994
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD 209 and EEC Directive 88/302 (1988)
DEVIATIONS FROM GUIDELINE: none

GLP: yes
STATISTICAL METHODS: Finney's probit method for the estimation of the EC50 after 3 hours of the reference substance only
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported as no analysis required

Result: RESULTS: EXPOSED
- Nominal/measured concentrations: 0-100 mg test substance/l (nominal)
- Effect data (Mortality): No significant inhibition of respiration at 100 mg test substance/l
- Concentration / response curve: not relevant, as no significant inhibitory effect
- Effect concentration vs. test substance solubility: not relevant, as no significant inhibitory effect
- Other effects: not reported
RESULTS: CONTROL
- Number/percentage of animals showing adverse effects: 1% respiration inhibition at 100 mg/l
- Nature of adverse effects: not relevant, as no significant inhibitory effect
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: 5,15 and 30 mg/l dichlorophenol
- Results: EC50 (3 hours) 9.8 mg/l

Test condition: TEST ORGANISMS
- Strain: a mixture of different strains of micro-organisms (inoculum) found in activated sludge
- Supplier: activated sludge from a sewage treatment plant treating predominantly domestic sewage (Pierre Benite-F-69310 Lyon)
- Age/size/weight/loading: the sludge was used 24 hours after collecting the sample, and had 1600 mg suspended solids/l.
DILUTION WATER
- Source: distilled water
TEST SYSTEM
- Concentrations: 1,10, 50 and 100 mg test substance/l
- Exposure vessel type: 1000 ml beakers with covers
- Test temperature: 17.7-20.2 °C
- Dissolved oxygen:continuous aeration and continuous magnetic stirring
- pH: ranged from 6.56-8.95 at start of study and 5.96-8.07 at end of study
DURATION OF THE TEST: 3 hours

Test substance: SOURCE: Rhone-Poulenc Chimie
PURITY: 100% active matter
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: Sodium Metasilicate (anhydrous). Test substance described as SIMET AP. Reported in the certificate of analysis: rejected on 80 mm sieve, 0.1 bulk density 1.15, whiteness 93.15

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (4)

Type: aquatic
Species: Pseudomonas putida (Bacteria)
Exposure period: 30 minute(s)
Unit: mg/l Analytical monitoring: no data

EC0: = 1000

Method: other: DIN 38412-27
Year: 1982
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: DIN 38412, Teil 27, German National guidelines
GLP: The present study was carried out before 1990, i.e. at a time when GLP was not yet implemented.
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported
Result: RESULTS: EXPOSED
- Nominal/measured concentrations: not reported
- Effect data (Mortality): at 1000 mg product/l the oxygen consumption of Pseudomonas was not inhibited
- Concentration / response curve: not reported
- Effect concentration vs. test substance solubility: not reported
- Other effects: not reported
RESULTS: CONTROL
- Number/percentage of animals showing adverse effects: not reported
- Nature of adverse effects: not reported
RESULTS: TEST WITH REFERENCE SUBSTANCE
- Concentrations: not reported
- Results: not reported
Test condition: TEST ORGANISMS
- Strain: Pseudomonas putida MIGULA Strain Berlin 33/2 (DSM 50026)
- Supplier: Strain collection of the department of Ecology of Henkel KGaA
- Wild caught: none
- Age/size/weight/loading: age of bacterial suspension is 24 hours
- Feeding: mineral medium, glucose (2%)
TEST SYSTEM
- Test type: acute bacterial toxicity (Pseudomonas oxygen consumption inhibition test, DIN 38412-27)
- Concentrations: 1000 mg product/l (nominal)
- Exposure vessel type: 100 ml Erlenmeyer flasks
- Dissolved oxygen: aeration directly over the surface of the test medium
DURATION OF THE TEST: 30 minutes
TEST PARAMETER: Pseudomonas oxygen consumption inhibition
Test substance: SOURCE: Cognis Deutschland GmbH
PURITY: 100% active matter
IMPURITY/ADDITIVE/ETC.: none
ANY OTHER INFORMATION: Silicic acid, disodium salt (anhydrous) soluble and not volatile at room temperature
Reliability: (2) valid with restrictions
Guideline study, but the study report is limited in detail.
Flag: Critical study for SIDS endpoint
25-FEB-2003 (40)

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

4.5.2 Chronic Toxicity to Aquatic Invertebrates

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Sediment Dwelling Organisms

4.6.2 Toxicity to Terrestrial Plants

4.6.3 Toxicity to Soil Dwelling Organisms

4.6.4 Toxicity to other Non-Mamm. Terrestrial Species

4.7 Biological Effects Monitoring

4.8 Biotransformation and Kinetics

4.9 Additional Remarks

5.0 Toxicokinetics, Metabolism and Distribution

Result: In guinea pigs the total silica eliminated (urinary and fecal SiO2) was measured after oral administration of (1) a single dose of sodium metasilicate (pentahydrate) equivalent to 80 mg SiO2, and (2) four doses of sodium metasilicate (pentahydrate) equivalent to 80 mg SiO2 at 48-hr intervals. Within 8 days, 60% of the silica administered as a single dose and 96% of the silica administered as multiple doses was excreted. The urinary excretion was apparently limited by restricted absorption from the gastrointestinal tract.
Reliability: (2) valid with restrictions
Well documented publication giving sufficient detail for evaluation.
21-NOV-2003 (46)

Result: The excretion of silica (SiO2) in urine after oral or inhalative administration of silicate to cats was studied by King & McGeorge (1938). Administration of silicic acid freshly precipitated from a sodium metasilicate solution (corresponding to 5 g SiO2) lead to markedly increased silica excretion in the urine as compared to the control. The urinary silica excretion returned to the normal level of excretion within 3 days. A fog of 2% sodium metasilicate solution carefully neutralized with hydrochloric acid to avoid precipitation of silicic acid was administered to cats by means of an atomizer blowing into a rubber mask attached to the cat's nostrils. A marked increase in the silica (SiO2) of the urine was observed which persisted for several days after the experiment was concluded. The dust of air-dried and finely ground amorphous silica obtained from a sodium metasilicate solution by acid precipitation was adminstered for 6 hours to the nostrils of cats using a
rubber mask. A big transitory increase in urinary silica excretion was observed.
Reliability: (2) valid with restrictions
Well documented publication giving sufficient detail for evaluation.
21-NOV-2003 (25)

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type: LD50
Species: rat
Strain: Wistar
Sex: male
Vehicle: no data
Doses: no data
Value: 1750 mg/kg bw

Method: other
Year: 1971
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Litchfield-Wilcoxon (1949)
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY:
- Time of death: from 3 hours up until 2 days after exposure
- Number of deaths at each dose: Not reported
CLINICAL SIGNS: Apathy, staggering gait, dyspnoea, piloerection and abdominal discomfort
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported
Test condition: TEST ORGANISMS:
- Source: Wistar
- Age: Not reported
- Weight at study initiation: 180 g
- Number of animals: 10 animals/dose
- Controls: Not reported
ADMINISTRATION:
Doses: Not reported
Doses per time period: Not reported
Volume administered or concentration: Not reported
Post dose observation period: 8 days
EXAMINATIONS: Clinical signs
Test substance: SOURCE: Not reported
PURITY: 51 wt% Na2O and 47 wt% SiO2
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Not reported
Reliability: (4) not assignable
Too little data available.
05-FEB-2003 (16)

Type: LD50
Species: rat
Strain: Wistar
Sex: male/female
No. of Animals: 110
Vehicle: no data
Doses: 538-2000 (males), 910-2600 (females)
Value: 1152 - 1349 mg/kg bw

Method: other: not specified
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY:
- Time of death: 30 min-96 hrs
- LD50 females: 1189.6-1530 mg/kg
- LD50 males: 994.7-1335.9 mg/kg
- Number of deaths at each dose: not reported
CLINICAL SIGNS: lethargy, increased breathing frequency immediately after dosing, 20 minutes later the animals became lethargic, cyanosis and platycoria was observed. At 30 min the first animals developed clonicity and tonic

cramps, dying of respiratory paralysis. The symptoms increased in intensity, had an earlier onset, and were observed in a higher number of animals in the group with increasing dose level.
NECROPSY FINDINGS: the animals that died had localised bleeding at the rim of the "glandular stomach", which partly depended on the dose, and bleeding and rubefaction in the duodenum. Some animals in the high dosage group had considerable stomach bleeding. Surviving animals had no significant changes.
POTENTIAL TARGET ORGANS: stomach.
SEX-SPECIFIC DIFFERENCES: no

Test condition: TEST ORGANISMS:
- Source: Nippon Kurea
- Age: 4 weeks
- Weight at study initiation: not reported
- Controls: not reported
ADMINISTRATION:
- Doses: 538-2000 mg/kg for male rats (6 doses, 1.3 as common ratio), 910-2600 mg/kg for females (5 doses, 1.3 as common ratio)
- Doses per time period: not applicable
- Volume administered or concentration: 0.265-1 ml/100 g for males, 0.455-1.3 ml/100g for females
- Post dose observation period: seven days
EXAMINATIONS: mortality, clinical symptoms, histopathology

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium metasilicate was administered as a 20% solution

Reliability: (2) valid with restrictions
Study performed according to basic scientific principles, study report provides only summary of data, with no/very few tables with data from individual animals.

Flag: Critical study for SIDS endpoint

05-FEB-2003 (18) (45)

Type: LD50
Species: mouse
Strain: other:ddy
Sex: male/female
Vehicle: no data
Doses: 500-1920.8 mg/kg (males), 500-1372 mg/kg (females)
Value: 770 - 820 mg/kg bw

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: MORTALITY:
- Time of death: 4 to hrs-5 days
- LD50 females: 661.5-896.3 mg/kg
- LD50 males: 666.7-1008.6 mg/kg (66.7-1087.6 mg/kg is reported in Ito, 1986)

- Number of deaths at each dose: not reported
CLINICAL SIGNS: 2 minutes after administration males and females became lethargic and had a hunched posture. Tear flow increased with dose level. Surviving animals recovered within 2-4 days. The animals that died were lethargic, did not react to external stimuli, had hanging eyelids, paralysis of hind legs, clonicity and tonic cramps, followed by cyanosis and respiratory paralysis.
NECROPSY FINDINGS: the following symptoms increased with increasing dose: localised bleeding in the mucous membranes of the "glandular stomach", duodenum, mucous membranes of the central part of the "small gut", capillary dilation, rarefaction of the stomach lining, clear liver lobules, faded colour of the liver rim, redness of the gall. Animals dosed 1372 mg/kg and above had bleeding and inflammation extending from the "glandular stomach"to the central part of the "small gut". In surviving animals the liver lobules looked slightly clearer and the spleen showed slight rubefaction, compared to control group animals.
POTENTIAL TARGET ORGANS: stomach, liver, gut.
SEX-SPECIFIC DIFFERENCES: no
Other: Renal lesions reported in Ito (1986) were not present in a significant number of animals.

Test condition: TEST ORGANISMS:
- Source: Sankyo Laboratory Service
- Age: 4 weeks
- Weight at study initiation: not reported
- Controls: not reported
ADMINISTRATION:
- Doses: 500-1920.8 mg/kg for males (35 doses, 1.4 as common ratio), 500-1372 mg/kg (34 doses, 1.4 as common ratio)
- Doses per time period: not applicable
- Volume administered or concentration: 0.05-0.19 ml/10g for males, 0.05-0.14 ml/10g for females
- Post dose observation period: seven days
EXAMINATIONS: mortality, clinical symptoms, histopathology

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium metasilicate was administered as a 10% solution.

Reliability: (2) valid with restrictions
Study performed according to basic scientific principles, study report provides only summary of data, with no/very few tables with data from individual animals. There were discrepancies between the study report and the abstract (Ito, 1986).

Flag: Critical study for SIDS endpoint

05-FEB-2003 (18) (45)

Type: LD50
Species: rat
Value: = 800 mg/kg bw

Method: other: not specified
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported

METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: Not reported
CLINICAL SIGNS: Not reported
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 50 wt% Sodium Metasilicate.
Reliability: (4) not assignable
Only secondary literature available (review).
05-FEB-2003 (48)

Type: LD50
Species: rat
Value: = 600 mg/kg bw

Method: other: not specified
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
DEVIATIONS FROM OECD GUIDELINE: Not reported
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: Not reported
CLINICAL SIGNS: Not reported
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 99 wt% Sodium Metasilicate.
Reliability: (4) not assignable
Only secondary literature available (review).
05-FEB-2003 (48)

Type: LD50
Species: mouse
Sex: male
Vehicle: no data
Value: = 1200 - 1700 mg/kg bw

Method: other
Year: 1973
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: NO, study executed before existence of GLP

STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY: Not reported
CLINICAL SIGNS: "uncharacteristic" according to the authors of the study report
NECROPSY FINDINGS: Not reported
POTENTIAL TARGET ORGANS: Not reported
Test condition: TEST ORGANISMS:
- Source: Not reported
- Age: Not reported
- Weight at study initiation: 22 g (mean weight)
- Number of animals: 10 animals/group
- Controls: Not reported
ADMINISTRATION:
- Doses: Not reported
- Doses per time period: animals were dosed once, by gavage
- Volume administered or concentration: Not reported
- Post dose observation period: 8 days
EXAMINATIONS: mortality, clinical signs
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium metasilicate pentahydrate was tested.
Reliability: (4) not assignable
Too little data available.
05-FEB-2003 (15)

5.1.2 Acute Inhalation Toxicity

5.1.3 Acute Dermal Toxicity

5.1.4 Acute Toxicity, other Routes

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species: rabbit
Concentration: 10 other:wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 5,6
Result: corrosive

Method: other: FHSA method 16 C.F.R. 1500.41 et.seq.
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 CFR 1500.41 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported

OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: Not reported
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: Not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Post exposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS:
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 10 wt% Sodium Metasilicate. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while 0.5 ml liquid was applied directly.
Reliability: (4) not assignable
Only secondary literature available (review).
05-FEB-2003 (48)

Species: rabbit
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 1
Vehicle: water
PDII: 8
Result: corrosive

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1985
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: No
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Erythema: 4
- Edema: 4
REVERSIBILITY: Effects persisted for up to 5 days after exposure
OTHER EFFECTS: Some evidence of necrosis was observed. When the test substance was applied as dry powder, no erythema and oedema was observed.
Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: Male
- Source: Cheshire Rabbit Farms ltd.
- Age: approx. 11 weeks
- Weight at study initiation: 2.3 - 3.0 kg
- Number of animals: 1

- Controls: no
ADMINISTRATION/EXPOSURE
- Preparation of test substance: moistened before application with distilled water
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: distilled water
- Concentration in vehicle: not applicable
- Total volume applied: 0.5 g
- Postexposure period: 5 days
- Removal of test substance: yes (washed away with water)
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: skin irritation index according to OECD 404
- Examination time points: 1, 24, 48, 72 hours and 5 days

Test substance: SOURCE: EKA Kemi AB
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium metasilicate (anhydrous). Applied as moistened substance (concentration not indicated).

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (7)

Species: rabbit
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 1
Vehicle: water
PDII: 8
Result: corrosive

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1985
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: No
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS USED: Not reported

Result: AVERAGE SCORE:
- Erythema: 4
- Edema: 4
REVERSIBILITY: Effects persisted for up to 5 days after exposure
OTHER EFFECTS: Severe reactions with some evidence of necrosis occured. When the test substance was applied as dry powder, no erythema and oedema was observed.

Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: Female
- Source: Cheshire Rabbit Farms ltd.
- Age: approx. 11 weeks
- Weight at study initiation: 2.3 - 3.0 kg
- Number of animals: 1

- Controls: no
ADMINISTRATION/EXPOSURE
- Preparation of test substance: moistened before application with distilled water
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: distilled water
- Concentration in vehicle: not applicable
- Total volume applied: 0.5 g
- Postexposure period: 5 days
- Removal of test substance: yes (washed away with water)
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: skin irritation index according to OECD 404
- Examination time points: 1, 24, 48, 72 hours and 5 days

Test substance: SOURCE: EKA Kemi AB
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium Metasilicate (pentahydrate). Applied as moistened substance (concentration not indicated).

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (7)

Species: rabbit
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 1
Vehicle: water
PDII: 8
Result: corrosive

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1985
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: No
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS USED: Not reported

Result: AVERAGE SCORE:
- Erythema: 4
- Edema: 4
REVERSIBILITY: The erythema with necrosis and oedema persisted until day 5
OTHER EFFECTS: Some evidence of necrosis was observed. When the test substance was applied as dry powder, no erythema or oedema was observed.

Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: Male
- Source: Cheshire Rabbit Farms Ltd.
- Age: approx. 11 weeks
- Weight at study initiation: 2.3 - 3.0 kg
- Number of animals: 1

- Controls: no
ADMINISTRATION/EXPOSURE
- Preparation of test substance: moistened before application with distilled water
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: distilled water
- Concentration in vehicle: not applicable
- Total volume applied: 0.5 g
- Postexposure period: 5 days
- Removal of test substance: yes (washed away with water)
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: skin irritation index according to OECD 404
- Examination time points: 1, 24, 48, 72 hours and 5 days

Test substance: SOURCE: EKA Kemi AB
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Sodium Metasilicate (nonahydrate). Applied as moistened substance (concentration not indicated).

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (7)

Species: rabbit
Concentration: 97 other:wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 3
PDII: 5,1
Result: corrosive

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1984
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: The powder was not moistened before application.
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Erythema: 2.8
- Edema: 2.3
REVERSIBILITY: Effects persisted for up to 14 days.
OTHER EFFECTS: At the first examination two of the three exposed animals showed necrosis. The wounds of these two animals (1 and 3 cm2) together with a well defined oedema remained at all examinations and were not healed after the observation period of 14 days. The third animal showed four small wounds after 48 and 72 hours. The animal had fast growing fur which made it difficult to get close contact between the test substance and the exposed skin area. The wounds were healed within 14 days (observation period).

Test condition: TEST ANIMALS:

- Strain: White Landrace
- Sex: not reported
- Source: Dörröds Djur -och Foderservice, Veberöd
- Age: not reported
- Weight at study initiation: 2.7 kg (average)
- Number of animals: 3 animals
- Controls: not reported

ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied as a dry powder according to the request made by the client
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusion
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 g
- Postexposure period: 7 days or 14 days (for animals with wounds)
- Removal of test substance: rinsed with water after 4 hrs exposure

IN VITRO TEST SYSTEM: Not relevant

EXAMINATIONS
- Scoring system: skin irritation index, according to OECD 404
- Examination time points: 1, 24, 48 and 72 hours

Test substance: SOURCE: Eka Kemi AB
PURITY: 97 wt% Sodium Metasilicate (anhydrous)
IMPURITY/ADDITIVE/ETC.: H2O 2 wt% and CO2 1 wt%
ANY OTHER INFORMATION: Sodium metasilicate (anhydrous) solid. Molecular weight of 122. Classified according to Swedish standards.

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (22)

Species: rabbit
Concentration: 57,5 other:wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 3
PDII: 7,8
Result: corrosive

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1984
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: The powder was not moistened before application.
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Erythema: 4
- Edema: 3.8

REVERSIBILITY: Effects persisted for up to 14 days.
OTHER EFFECTS: 2 out of 3 exposed animals showed an acute

skin necrosis. The third animal had a pigmented necrosis (2 cm2) on the exposed area. The necrosis and the acute oedema outside the tissue lesion remained during the following examinations. The wound was not healed after 14 days.

Test condition: TEST ANIMALS:
- Strain: White Landrace
- Sex: not reported
- Source: Dörröds Djur -och Foderservice, Veberöd
- Age: not reported
- Weight at study initiation: 2.7 kg (average)
- Number of animals: 3 animals
- Controls: not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied as a dry powder as requested by the client
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusion
- Vehicle: none
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 g
- Postexposure period: 7 days or 14 days for animals with wounds
- Removal of test substance: rinsed with water after 4 hrs exposure
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: skin irritation index, according to OECD 404
- Examination time points: 1, 24, 48 and 72 hours

Test substance: SOURCE: Eka Kemi AB
PURITY: 57.5 wt% Sodium Metasilicate
IMPURITY/ADDITIVE/ETC.: H2O 42.5 wt%
ANY OTHER INFORMATION: Sodium Metasilicate solid (pentahydrate) Molecular weight of 210. Classified according to Swedish standards.

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (22)

Species: rabbit
Concentration: 50 %
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 3
Vehicle: water
PDII: 3,67
Result: irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1995
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: Not reported
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Primary irritation index formula
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:

- Erythema: 2.33
- Edema: 1.33
REVERSIBILITY: Not reported
OTHER EFFECTS: Reaction extended outside application site

Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: not reported
- Number of animals: 3
- Controls: not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: water
- Concentration in vehicle: 50%
- Total volume applied: 0.5 ml
- Postexposure period: not reported
- Removal of test substance: not reported
IN VITRO TEST SYSTEM: Not relevant
EXAMINATIONS
- Scoring system: Primary irritation index, according to OECD 404
- Examination time points: 24, 48 and 72 hours

Test substance: SOURCE: Fischer Scientific
PURITY: Reagent grade
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 50 % aq Sodium Metasilicate. The information is stored in a database run by ECETOC, all studies are OECD compliant.

Reliability: (1) valid without restriction
Guideline study

Flag: Critical study for SIDS endpoint

01-AUG-2003 (10)

Species: rabbit
Concentration: 10 %
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 3
Vehicle: water
PDII: 1,22
Result: slightly irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1995
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404
DEVIATIONS FROM OECD GUIDELINE: Not reported
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Primary irritation index formula
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Erythema: 1.11
- Edema: 0.11

REVERSIBILITY: The severity of erythema was reduced from 2 to 1 by day 2, but persisted. The oedema observed in 1 animal had reversed by day 2.
OTHER EFFECTS: Not reported

Test condition: TEST ANIMALS:
- Strain: Not reported
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: not reported
- Number of animals: 3
- Controls: not reported

ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: water
- Concentration in vehicle: 10%
- Total volume applied: 0.5 ml
- Postexposure period: not reported
- Removal of test substance: not reported

IN VITRO TEST SYSTEM: Not relevant

EXAMINATIONS
- Scoring system: Primary irritation index, according to OECD 404
- Examination time points: 24, 48 and 72 hours

Test substance: SOURCE: Fischer Scientific
PURITY: reagent grade
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 10 %aq Sodium Metasilicate. The information is stored in a database run by ECETOC, all studies are OECD compliant.

Reliability: (1) valid without restriction
Guideline study

Flag: Critical study for SIDS endpoint

05-FEB-2003 (10)

Species: rabbit
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 3
Vehicle: water
PDII: 4,67
Result: corrosive

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1990
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404 and EEC Directives 67/548, 79/831, 83/467, 84/449
DEVIATIONS FROM OECD GUIDELINE: Not reported
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Erythema: 4
- Edema: 0.67

REVERSIBILITY: Erythema persisted for at least 14 days, while oedema, observed within 1 hour after exposure, disappeared 72 hours after exposure.
OTHER EFFECTS: Necrosis persisted in the entire area of application for 7 days and in parts of the test area for at least 14 days.

Test condition: TEST ANIMALS:
- Strain: New-Zealand hybrid
- Sex: male
- Source: Bancel
- Age: adult
- Weight at study initiation: 2.6 - 2.7 kg
- Number of animals: 3
- Controls: not reported
ADMINISTRATION/EXPOSURE
- Preparation of test substance: moistened
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusion
- Vehicle: purified water
- Concentration in vehicle: 0.5 g/0.10 g purified water
- Total volume applied: 0.3 ml
- Postexposure period: 14 days
- Removal of test substance: yes
IN VITRO TEST SYSTEM: not relevant
EXAMINATIONS
- Scoring system: according to OECD 404
- Examination time points: 1, 24, 48 and 72 hours, 7 and 14 days

Test substance: SOURCE: Rhone-Poulenc
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Test substance Simet AG. pH of 12.4, applied as a 83% (w/w) aqueous paste (0.5 g powder + 0.1 g water).

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

21-JAN-2004 (32)

Species: rabbit
Concentration: 6 other:wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 8
Result: corrosive

Method: other: FHSA (Federal Hazardous Substances Act) test specified in C.F.R. 1500.41 et.seq.
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: not reported

Result: AVERAGE SCORE: not reported
REVERSIBILITY: not reported
OTHER EFFECTS: not reported

Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE:
- Preperation of test substance: Not reported
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Post-exposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS:
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours

Test substance: SOURCE: not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: 6 wt% Sodium Metasilicate. The article does not specify whether the substance was a dry powder or a liquid. Powders were applied dry (0.5g) and liquids were applied directly (0.5 ml).

Reliability: (4) not assignable
Only secondary literature available (review).

05-FEB-2003 (48)

Species: rabbit
Concentration: 99 other:wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
Result: not irritating

Method: other: DOT test, FHMTA 49 C.F.R. 173.240
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: DOT skin test, Federal Hazardous Materials Transportation Act (FHMTA) 49 C.F.R. 173.240
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: not reported

Result: AVERAGE SCORE: not reported
REVERSIBILITY: not reported
OTHER EFFECTS: not reported

Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: applied directly to the test area
- Area of exposure: intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Post-exposure period: 72 hours
- Removal of test substance: after 4 hours
EXAMINATIONS:
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores included
- Examination time points: 24 and 72 hours

Test substance: SOURCE: Not reported
PURITY: Not reported

IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 99 wt% Sodium Metasilicate. It is not specified whether the substance was a dry powder or a liquid. Powders were applied dry (0.5 g) and liquids were applied directly (0.5 ml).
Reliability: (4) not assignable
Only secondary literature available (review).
05-FEB-2003 (48)

Species: rabbit
Concentration: 37 other:wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 5
Vehicle: water
PDII: 7,4
Result: corrosive

Method: other: Skin irritation test
Year: 1975
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Skin irritation test, FSHA procedure proposed by the FDA (Edwards, 1972).
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result: AVERAGE SCORE
- Erythema: Not reported.
- Edema: Not reported.
REVERSIBILITY: Lesions remained for at least 96 hrs.
OTHER EFFECTS: PII intact skin: 6.8. PII abraded skin: 8.0. PII: 7.4. There was tissue destruction in 5/5 intact skin sites, and 5/5 abraded skin sites. Irritancy: corrosive.
Test condition: TEST ANIMALS: Not reported.
- Strain: Not reported.
- Sex: Not reported.
- Source: Not reported.
- Age: Not reported.
- Weight at study initiation: Not reported.
- Number of animals: 5.
- Controls: No.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: A dilution was applied to the test site.
- Area of exposure: Abraded and non-abraded skin area.
- Occlusion: Semi-occluded.
- Vehicle: Water.
- Concentration in vehicle: 50%
- Total volume applied: Not reported.
- Postexposure period: 96 hrs.
- Removal of test substance: After 4 hrs exposure.
EXAMINATIONS
- Scoring system: Scoring of erythema and oedema according to Edwards (1972) and Draize (1959), The Primary Irritation Index is based on abraded and non-abraded skin.
- Examination time points: Sites were examined at 4, 24 and 48 hrs after aplication of the patches. Serious lesions were observed up to 30 days for reversibility.
Test substance: SOURCE: Not reported.

PURITY: 37wt% metasilicate.
IMPURITY/ADDITIVE/ETC.: 25wt% H2O, 23wt% sodium carbonate, 7wt% sodium sulfate, 4wt% linear alkylbenzenesulfonate, 2wt% alkyl etoxylate.
ANY OTHER INFORMATION: pH of 1% aqueous solution is 12.0.

Reliability: (3) invalid
The method was not validated at the time the study was performed. The article is limited in detail.

06-FEB-2003 (36)

Species: rabbit
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 6
Vehicle: water
PDII: 8
Result: corrosive

Method: other: Skin irritation test
Year: 1975
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Skin irritation test, FSHA procedure proposed by the FDA (Edwards, 1972).
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.

Result: AVERAGE SCORE
- Erythema: Not reported.
- Edema: Not reported.
REVERSIBILITY: Lesions remained for at least 96 hrs.
OTHER EFFECTS: PII intact skin: 8.0. PII abraded skin: 8.0. PII: 8.0. There was tissue destruction in 6/6 intact skin sites, and 6/6 abraded skin sites. Irritancy: corrosive.

Test condition: TEST ANIMALS: Not reported.
- Strain: Not reported.
- Sex: Not reported.
- Source: Not reported.
- Age: Not reported.
- Weight at study initiation: Not reported.
- Number of animals: 6.
- Controls: No.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: A dilution was applied to the test site.
- Area of exposure: Abraded and non-abraded skin area.
- Occlusion: Semi-occluded.
- Vehicle: Water.
- Concentration in vehicle: 50%
- Total volume applied: Not reported.
- Postexposure period: 96 hrs.
- Removal of test substance: After 4 hrs exposure.
EXAMINATIONS
- Scoring system: Scoring of erythema and oedema according to Edwards (1972) and Draize (1959), The Primary Irritation Index is based on abraded and non-abraded skin.
- Examination time points: Sites were examined at 4, 24 and 48 hrs after application of the patches. Serious lesions were observed up to 30 days for reversibility.

Test substance: SOURCE: Not reported.

PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Test substance is a 50% aqueous solution of metasilicate of unknown concentration.

Reliability: (3) invalid
The method was not validated at the time the study was performed. The article is limited in detail.

06-FEB-2003 (36)

Species: rabbit
Concentration: undiluted
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 3
Vehicle: other: none
PDII: ,17
Result: not irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1990
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 404 and EEC Directives 67/548, 79/831, 83/467, 84/449
DEVIATIONS FROM OECD GUIDELINE: Not reported
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Erythema: 0.22
- Oedema: 0.11
REVERSIBILITY: Erythema and oedema observed within 1 hour after exposure in one of three animals disappeared 72 hours after exposure.
OTHER EFFECTS: Only one animal developed a well defined erythema and a barely perceptible oedema within 1 hour after exposure; the other two animals did not reveal erythema or oedema at any time.

Test condition: TEST ANIMALS:
- Strain: New-Zealand hybrid
- Sex: male
- Source: Bancel
- Age: adult
- Weight at study initiation: 2.4-2.6 kg
- Number of animals: 3
- Controls: not reported
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: dry powder prepared in a mortar, applied as a powder
- Area of exposure: intact skin (shaved)
- Occlusion: semiocclusion
- Vehicle: no
- Concentration in vehicle: not relevant
- Total volume applied: 0.5 g
- Postexposure period: 72 hours
- Removal of test substance: yes
IN VITRO TEST SYSTEM: not relevant
EXAMINATIONS:
- Scoring system: according to OECD 404

- Examination time points: 1, 24, 48 and 72 hours
Test substance: SOURCE: Rhone-Poulenc
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Test substance Simet AG. pH of 12.4 as a fine powder.
Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.
Flag: Critical study for SIDS endpoint
25-NOV-2003 (31)

Species: guinea pig
Concentration: 37 other:wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 6
Vehicle: water
PDII: ,3
Result: not irritating

Method: other: Skin irritation test
Year: 1975
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Skin irritation test, FSHA procedure proposed by the FDA (Edwards, 1972).
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result: AVERAGE SCORE
- Erythema: Not reported.
- Edema: Not reported.
REVERSIBILITY: Not reported.
OTHER EFFECTS: PII intact skin: 0.0. PII abraded skin: 0.6. PII: 0.3. There was tissue destruction in 0/6 intact skin sites, and 0/6 abraded skin sites. Irritancy: negligible.
Test condition: TEST ANIMALS: Not reported.
- Strain: Hartley
- Sex: Not reported.
- Source: Not reported.
- Age: Young adults.
- Weight at study initiation: Not reported.
- Number of animals: 6
- Controls: No.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: A dilution was applied to the test site.
- Area of exposure: Abraded and non-abraded skin area
- Occlusion: Semi-occluded.
- Vehicle: Water.
- Concentration in vehicle: 50%
- Total volume applied: Not reported.
- Postexposure period: 96 hrs.
- Removal of test substance: After 4 hrs exposure.
EXAMINATIONS
- Scoring system: Scoring of erythema and oedema according to Edwards (1972) and Draize (1959), The Primary Irritation Index is based on abraded and non-abraded skin.
- Examination time points: Sites were examined at 4, 24 and

48 hrs after application of the patches. Serious lesions were observed up to 30 days for reversibility.
Test substance: SOURCE: Not reported.
PURITY: 37wt% metasilicate.
IMPURITY/ADDITIVE/ETC.: 25wt% H2O, 23wt% sodium carbonate, 7wt% sodium sulfate, 4wt% linear alkylbenzenesulfonate, 2wt% alkyl etoxylate.
ANY OTHER INFORMATION: pH of 1% aqueous solution is 12.0.
Reliability: (3) invalid
The method was not validated at the time the study was performed. The article is limited in detail.
06-FEB-2003 (36)

Species: guinea pig
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 6
PDII: 2,4
Result: moderately irritating

Method: other: Skin irritation test
Year: 1975
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Skin irritation test, FSHA procedure proposed by the FDA (Edwards, 1972).
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result: AVERAGE SCORE
- Erythema: Not reported.
- Edema: Not reported.
REVERSIBILITY: Lesions remained less than 96 hrs.
OTHER EFFECTS: PII intact skin: 1.7. PII abraded skin: 3.2. PII: 2.4. There was tissue destruction in 0/6 intact skin sites, and 3/6 abraded skin sites. Irritancy: moderate.
Test condition: TEST ANIMALS: Not reported.
- Strain: Not reported.
- Sex: Not reported.
- Source: Not reported.
- Age: Not reported.
- Weight at study initiation: Not reported.
- Number of animals: 6.
- Controls: No.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: A dilution was applied to the test site.
- Area of exposure: Abraded and non-abraded skin area.
- Occlusion: Semi-occluded.
- Vehicle: Water.
- Concentration in vehicle: 50%
- Total volume applied: Not reported.
- Postexposure period: 96 hrs.
- Removal of test substance: After 4 hrs exposure.
EXAMINATIONS
- Scoring system: Scoring of erythema and oedema according to Edwards (1972) and Draize (1959), The Primary Irritation Index is based on abraded and non-abraded skin.
- Examination time points: Sites were examined at 4, 24 and 48 hrs after application of the patches. Serious lesions

were observed up to 30 days for reversibility.
Test substance: SOURCE: Not reported.
PURITY: Not reported.
IMPURITY/ADDITIVE/ETC.: Not reported.
ANY OTHER INFORMATION: Test substance is a 50% aqueous solution of metasilicate of unknown concentration.
Reliability: (3) invalid
The method was not validated at the time the study was performed. The article is limited in detail.
06-FEB-2003 (36)

Species: human
Concentration: 37 other:wt%
Exposure: Semiocclusive
Exposure Time: 4
No. of Animals: 8
PDII: 3,6
EC classificat.: irritating

Method: other: Skin irritation test
Year: 1975
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Skin irritation test, FSHA procedure proposed by the FDA (Edwards, 1972).
STATISTICAL METHODS: Not reported.
METHOD OF CALCULATION: Not reported.
ANALYTICAL METHODS: Not reported.
Result: AVERAGE SCORE
- Erythema: Not reported.
- Edema: Not reported.
REVERSIBILITY: Lesions disappeared after unknown time period.
OTHER EFFECTS: PII intact skin: 3.0. PII abraded skin: 4.2. PII: 3.6. There was tissue destruction in 0/8 intact skin sites, and 1/8 abraded skin sites. Irritancy: severe. A single subject developed a severe erythematous and vesicular reaction on intact skin. The lesion was not permanent.
Test condition: TEST ANIMALS:
Human voluntary subjects.
- Sex: Not reported.
- Age: Not reported.
- Number of subjects: 8.
- Controls: No.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: A dilution was applied to the test site.
- Area of exposure: Abraded and non-abraded skin area.
- Occlusion: Semi-occluded.
- Vehicle: Water.
- Concentration in vehicle: 50%
- Total volume applied: Not reported.
- Postexposure period: 96 hrs.
- Removal of test substance: After 4 hrs exposure.
EXAMINATIONS
- Scoring system: Scoring of erythema and oedema according to Edwards (1972) and Draize (1959), The Primary Irritation Index is based on abraded and non-abraded skin.
- Examination time points: Sites were examined at 4, 24 and 48 hrs after application of the patches. Serious lesions

were observed up to 30 days for reversibility.
Test substance: SOURCE: Not reported.
PURITY: 37wt% metasilicate.
IMPURITY/ADDITIVE/ETC.: 25wt% H2O, 23wt% sodium carbonate, 7wt% sodium sulfate, 4wt% linear alkylbenzenesulfonate, 2wt% alkyl etoxylate.
ANY OTHER INFORMATION: pH of 1% aqueous solution is 12.0.
Reliability: (3) invalid
The method was not validated at the time the study was performed. The article is limited in detail.
06-FEB-2003 (36)

Species: rat
Exposure: Open
Exposure Time: 1 hour(s)
Result: corrosive

Method: other: comparable to Directive 2000/33/EC, B.40
Year: 1988
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: rat skin transcutaneous electrical resistance (TER) assay, comparable to Directive 2000/33/EC, B.40. The study was used as a basis for elaborating the guideline.
DEVIATIONS FROM THE GUIDELINE: In comparison to the guideline , the following parts of the study were not in line.
- The skin was not washed in antibiotica before harvesting;
- The skin was clipped approximately 48 hrs before harvesting, instead of 3-7 days;
- Physiological saline was used to hydrate the skin during measurement of TER, instead of MgSO4 (154 mM);
- The water used to rinse the skin discs was 40-45°C instead of 30°C;
- No negative control was used;
- The threshold value was 4kOhm instead of 5 kOhm.
GLP: No
STATISTICAL METHODS: Not reported
METHOD OF CALULATION: The substance is classified as corrosive if the electrical resistance value was reduced below the set treshold level of 4 kOhm.disc (3.2 kOhm.cm2)
ANALYTICAL METHODS: Transcutaneous electrical resistance measurements and tritiated water permeability measurement.
Result: ELECTRICAL RESISTANCE VALUE (kOhm.disc): kOhm.disc (1 hr): 0.4 (SD 0.1)
ANY OTHER INFORMATION: Not reported.
Test condition: TEST ANIMALS:
- Strain: Alderley Park (Wistar)
- Sex: male
- Age: 28 days
- Weight at study initiation: 60-80 grams
- Number of animals: Not reported
- Controls: Not reported
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: applied directly to the skin disc.
- Area of exposure: 18 mm X 80 mm
- Occlusion: no
- Vehicle: none

- Concentration in vehicle: not relevant
- Total volume applied: 0.3 ml
- Removal of test substance: with warm water
IN VITRO TEST SYSTEM:
- Cell type: Not applicable.
- Test conditions: Discs of rat skin were mounted epidermal side up on a polytetrafluoroethylene tube with an O-ring. Excess tissue and fat was removed. The O-ring/tube interface was sealed with soft paraffin wax. The tube was supported by a plastic coated spring glip inside a plastic tube containing eletrolyte solution (154 mM MgSO4 in deionised water). The chemical was applied to the epidermal surface, and removed with a jet of water after the exposure period. The stratum corneum was treated with 20 microliter 70% aqueous ethanol for 2 seconds before 3 ml electrolyte solution was added and the transcutaneous electricla resistance was measured.
EXAMINATIONS:
- Number of discs per substance: 3.
- Scoring system: Electrical resistance over the skin was measured. Resistance < 4 kOhm.disc (3.2 kOhm.cm2) was regarded as positive with respect to corrosive properties. The positive in vivo controls were scored according to Draize.
- Examination time points: 1 hour

Test substance: SOURCE: Imperial Chemical Industries
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY ITHER INFORMATION: Sodium metasilicate of unknown concentration was tested undiluted (pH 13.4, gel)

Reliability: (2) valid with restrictions
Comparable to guideline study.

01-AUG-2003 (38)

5.2.2 Eye Irritation

Species: rabbit
Concentration: 10 other: wt%
Result: irritating

Method: other: FHSA (Federal Hazardous Substances Act) specified in C.F.R. 1500.42 et.seq.
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) method 16 CFR 1500.42
GLP: No
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported

Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not reported
EXAMINATIONS: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported

IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 10 wt% Sodium metasilicate
Reliability: (4) not assignable
Only secondary literature available (review).
05-FEB-2003 (48)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: ,17 minute(s)
Vehicle: no data
Result: corrosive

Method: other: in vitro rabbit eye irritation study
Year: 1994
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies, providing the test substance is shown to be skin irritating/corrosive. The method is described in several publications: York et al., 1994; York et al., 1982; Burton et al., 1981. Primarily, chicken eyes are used to assess the irritation potential, while rabbit eyes have been used in this study.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Maximum macroscopic and microscopic opacity score: 4 (complete corneal opacity, iris not discernible)
- Mean maximum corneal swelling: 41.30% (increase in thickness)
- Fluorescein staining: extreme (intense staining of very badly damaged cornea, appears yellow/orange as opposed to the bright green in previous grades).
- Loss of corneal cell layers: 3-6 (a normal cornea has ca. 8 layers)
REVERSIBILITY: Not applicable
OTHER EFFECTS: The overall result was severe irritation (moderate/severe opacity and/or >35% swelling and/or 7-8 cell layers of the cornea lost)
Test condition: TEST ANIMALS:
- Strain: New Zealand white
- Sex: not reported
- Source: Huntingdon Research centre (HRC) ltd.
- Age: not reported
- Weight at study initiation: not relevant
- Number of animal eyes: 1
- Controls: One eye was only exposed to saline.
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface
- Amount of substance per eye: 50 mg
- Vehicle: none
- Postexposure period: No
IN VITRO TEST SYSTEM:
- Cell type: not relevant
- Test conditions: To prevent drying of the enucleated eyes

in the flask, each eye was thoroughly wetted with physiological saline and the humidity was maintained by a quantity of freestanding distilled water (37°C) in the bottom of the flask. After 30-40 minutes the eyes were immediately mounted in clamps and placed under the saline drips in cells of the maintenance chambers. The eyes were stained with 1% (w/v) Fluorescein for 10 seconds to detect damage. The corneal thickness was measured and left for 60 minutes to allow the eye to equilibrate. Then the test substance was applied to the corneal surface for 10 seconds before rinsing with saline.
EXAMINATIONS
- Opacification of the cornea: the macroscopic appearance of each eye was noted after treatment, at 30 minutes, 1, 2, 3 and 4 hours after treatment. The microscopic appearance of each eye was observed using Zeiss slit lamp/biomicroscope, at 30 minutes, 1, 2, 3 and 4 hours after treatment.
- Corneal thickness and appearance of the slit image of the corneal surface: measured using the slit lamp, prior to treatment (at approx. - 5 minutes), at 30 minutes, 1, 2, 3 and 4 hours after treamtent.
- Fluorescein staining: Fluorescein solution 1% (w/v) was applied to the eyes 1 hr after treatment . The rate of fluorescein diffusion into the corneal stroma and possible corneal damage was assessed with a slit lamp.
- Histological assessment: 4 hours after treatment enucleated eyes were dissected and corneas were fixed in physiological saline for sectioning and histological assessment.

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Water-soluble granules of Sodium Metasilicate.

Reliability: (4) not assignable
The method is well-documented, but not validated. There are no guidelines for this kind of study, but the protocol is in use as an alternative to in vivo eye irritation studies for substances which are shown to be skin irritating/corrosive in in vivo studies.

Flag: Critical study for SIDS endpoint

26-JAN-2004 (56)

Species: rabbit
Concentration: 6 other: wt%
Result: irritating

Method: other: FHSA (Federal Hazardous Substances Act) specified in C.F.R. 1500.42 et.seq.
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) Draize method specified in 16 C.F.R. 1500.42
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported

Result: AVERAGE SCORE: not reported
DESCRIPTION OF LESIONS: not reported
REVERSIBILITY: not reported

OTHER EFFECTS: not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not applicable
EXAMINATIONS: Not reported
Test substance: SOURCE: not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: 6 wt% Sodium Metasilicate
Reliability: (4) not assignable
Only secondary literature available (review).
05-FEB-2003 (48)

Species: rabbit
Concentration: 5 other: wt%
Result: irritating

Method: other: FHSA (Federal Hazardous Substances Act) specified in C.F.R. 1500.42 et.seq.
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act)
Draize method specified in 16 C.F.R. 1500.42
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported
Result: AVERAGE SCORE: not reported
DESCRIPTION OF LESIONS: not reported
REVERSIBILITY: not reported
OTHER EFFECTS: not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not applicable
EXAMINATIONS: Not reported
Test substance: SOURCE: not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: 5 wt% Sodium Metasilicate
Reliability: (4) not assignable
Only secondary literature available (review).
05-FEB-2003 (48)

Species: rabbit
Concentration: 3 other: wt%
Result: irritating

Method: other: FHSA (Federal Hazardous Substances Act) specified in C.F.R. 1500.42 et.seq.
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act)
Draize method specified in 16 C.F.R. 1500.42
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported
Result: AVERAGE SCORE: not reported
DESCRIPTION OF LESIONS: not reported

REVERSIBILITY: not reported
OTHER EFFECTS: not reported
Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not applicable
EXAMINATIONS: Not reported
Test substance: SOURCE: not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: 3 wt% Sodium Metasilicate
Reliability: (4) not assignable
Only secondary literature available (review).
05-FEB-2003 (48)

Species: rabbit
Concentration: undiluted
Dose: 50 other: mg
Exposure Time: ,17 minute(s)
Vehicle: no data
Result: corrosive

Method: other: in vitro rabbit eye irritation study
Year: 1994
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: In vitro rabbit eye irritation study. The method is not validated yet, but is in use as an alternative to in vivo eye irritation studies, providing the test substance is shown to be skin irritating/corrosive. The method is also described in several publications: York et al., 1982; Burton et al., 1981. Primarily, chicken eyes are used to assess the irritation potential, while rabbit eyes have been used in this study.
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Maximum macroscopic and microscopic opacity score: 4 (complete corneal opacity, iris not discernible)
- Mean maximum corneal swelling: 43.18% (increase in thickness)
- Fluorescein staining: extreme (intense staining of very badly damaged cornea, appears yellow/orange as opposed to the bright green in previous grades).
- Loss of corneal cell layers: 2-4 (a normal cornea has ca. 8 layers)
REVERSIBILITY: Not applicable
OTHER EFFECTS: The overall result was severe irritation (moderate/severe opacity and/or >35% swelling and/or 7-8 cell layers of the cornea
Test condition: TEST ANIMALS:
- Strain: New Zealand white
- Sex: not reported
- Source: Not reported
- Age: not reported
- Weight at study initiation: not relevant
- Number of animal eyes: not reported
- Controls: not reported
ADMINISTRATION/EXPOSURE

- Preparation of test substance: applied directly as a water-soluble powder to the corneal surface
- Amount of substance per eye: 50 mg
- Vehicle: none
- Postexposure period: No
IN VITRO TEST SYSTEM:
- Cell type: not relevant
- Test conditions: eyes handled and treated according to description in Burton et al. (1981). 50 mg of test material was sprinkled over the cornea. At the end of the treatment period the test material was rinsed using an excess (usually 20 ml) of warm isotonic saline.
EXAMINATIONS
- Opacification of the cornea: the macroscopic appearance of each eye was noted after treatment, at 30 minutes, 1, 2, 3 and 4 hours after treatment. The microscopic appearance of each eye was observed using Zeiss slit lamp/biomicroscope, at 30 minutes, 1, 2, 3 and 4 hours after treatment.
- Corneal thickness and appearance of the slit image of the corneal surface: measured using the slit lamp, prior to treatment (at approx. - 5 minutes), at 30 minutes, 1, 2, 3 and 4 hours after treamtent.
- Fluorescein staining: Fluorescein solution 1% (w/v) was applied to the eyes 1 hr after treatment . The rate of fluorescein diffusion into the corneal stroma and possible corneal damage was assessed with a slit lamp.
- Histological assessment: 4 hours after treatment enucleated eyes were dissected and corneas were fixed in physiological saline for sectioning and histological assessment.

Test substance: SOURCE: Crosfield Group (Warrington, UK)
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Water-soluble powder of Sodium Metasilicate.

Reliability: (4) not assignable
The method is well-documented, but not validated. There are no guidelines for this kind of study, but the protocol is in use as an alternative to in vivo eye irritation studies for substances which are shown to be skin irritating/corrosive in in vivo studies.

Flag: Critical study for SIDS endpoint

26-JAN-2004 (57)

Species: rabbit

Method: other: Esophageal test
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Esophageal test performed by the FDA as an alternative to acute oral exposure via gavage. Microscopic examination of the esophagus was used as the primary criterion for categorizing results as either "corrosive" or "negative".
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Remark: Schleyer et al. (1982) reports on a series of esophageal tests (oral, rabbit) conducted under the auspicies of the

Consumer Product Safety Commission.
Microscopic examination of the esophagus was used as the primary criterion for categorizing results as either "corrosive" or "negative". The data is given below.

SiO2/Na2O weight ratio	Concentration	Results
1.0	10% w/v	+,+

Result: MORTALITY: Not reported
CLINICAL SIGNS: Not reported
NECROPSY FINDINGS: Corrosive effects in the esophagus
POTENTIAL TARGET ORGANS: Not reported
SEX-SPECIFIC DIFFERENCES: Not reported
Test condition: TEST ORGANISMS: Not reported
ADMINISTRATION: Not reported
EXAMINATIONS: Not reported
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 10% w/v Sodium Metasilicate.
Reliability: (3) invalid
Method not validated and only secondary literature available.
05-FEB-2003 (48)

5.3 Sensitization

Type: Mouse ear swelling test
Species: mouse
Concentration 1st: Induction 4 % open epicutaneous
2nd: Challenge 6 % open epicutaneous
Vehicle: other: 15% ethanol
Result: sensitizing

Method: other: MEST
Year: 2002
GLP: no data
Test substance: other TS

Method: METHOD FOLLOWED:
DEVIATIONS FROM GUIDELINE: no Guideline method
GLP: not reported
STATISTICAL METHODS: Bartlett's chi-square Test, one-way ANOVA and Dunnett's Multiple Range t Test.
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported
Result: RESULTS OF PILOT STUDY: minimal irritating concentration: 6%; maximal non-irritating concentration: 4%
RESULTS OF TEST
- Sensitization reaction: 15% increase in ear swelling 48 h after challenge for mice that were sensitized with 4% metasilicate. 28% increase with positive control. According to the authors sodium metasilicate is a weak sensitizer in this test system.
- Clinical signs: not reported
- Rechallenge: not performed
Test condition: TEST ANIMALS:
- Strain: BALB/c
- Sex: female
- Source: National Cancer Institute, USA
- Age: 45 - 60 days

- Weight at study initiation: 17 - 20 g
- Number of animals: not stated
- Controls: 1-fluoro-2,4-dinitrobenzene (DNFB)
ADMINISTRATION/EXPOSURE
- Study type:
- Preparation of test substance for induction: test solutions were prepared daily in amber vials using 15% ethanol.
- Induction schedule: day 1-3
- Concentrations used for induction: 0.4, 2 & 4%
- Concentration in Freuds Complete Adjuvant (FCA): not applicable for MEST
- Challenge schedule: not reported
- Concentrations used for challenge: 6%
- Rechallenge: no
- Positive control: 1-fluoro-2,4-dinitrobenzene (DNFB)
EXAMINATIONS
- Grading system: not applicable for MEST
- Pilot study: a primary irritancy assay was performed to establish the minimal irritating and the maximal non-irritating concentration

Test substance: SOURCE: Aldrich Chemical Company, Milwaukee, WI, USA
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: not reported

Reliability: (3) invalid
Method not validated; unsuitable test system. The MEST failed to prove as a valid test in the validation process (ECETOC Technical Report No. 78, 1999).

10-JUL-2003 (23)

Type: Mouse local lymphnode assay
Species: mouse
Concentration 1st: Induction 2 % open epicutaneous
2nd: Induction 4 % open epicutaneous
3rd: Induction 6 % open epicutaneous
Vehicle: other: 15% ethanol
Result: not sensitizing

Method: other: OECD-Guideline 429
Year: 2002
GLP: no data
Test substance: other TS

Method: METHOD FOLLOWED:
DEVIATIONS FROM GUIDELINE: 1-fluoro-2,4-dinitrobenzene (DNFB) as positive control; test substance applied to both sides of each ear.
GLP: not reported
STATISTICAL METHODS: Bartlett's chi-square Test, one-way ANOVA and Dunnett's Multiple Range t Test.
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported

Result: RESULTS OF PILOT STUDY: minimal irritating concentration: 6%; maximal non-irritating concentration: 4%
RESULTS OF TEST
- Sensitization reaction: sensitization with 2-6% did not significantly alter cell proliferation in the auricular lymph nodes, even though an increase of 30% and 40% at the 4% and 6% treatment levels was measured, respectively. A greater than 30-fold increase was measured in the positive control.
- Clinical signs: not reported

- Rechallenge: not applicable for LLNA
Test condition: TEST ANIMALS:
- Strain: BALB/c
- Sex: female
- Source: National Cancer Institute, USA
- Age: 45 - 60 days
- Weight at study initiation: 17 - 20 g
- Number of animals: not stated
- Controls: 1-fluoro-2,4-dinitrobenzene (DNFB)
ADMINISTRATION/EXPOSURE
- Study type:
- Preparation of test substance for induction: test solutions were prepared daily in amber vials using 15% ethanol.
- Induction schedule: day 1-3
- Concentrations used for induction: 2, 4 & 6%
- Concentration in Freuds Complete Adjuvant (FCA): not applicable for LLNA
- Challenge schedule: not applicable for LLNA
- Concentrations used for challenge: not applicable for LLNA
- Rechallenge: not applicable for LLNA
- Positive control: 1-fluoro-2,4-dinitrobenzene (DNFB)
EXAMINATIONS
- Grading system: not applicable for LLNA
- Pilot study: a primary irritancy assay was performed to establish the minimal irritating and the maximal non-irritating concentration.
Test substance: SOURCE: Aldrich Chemical Company, Milwaukee, WI, USA
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: not reported
Reliability: (2) valid with restrictions
Guideline study
Flag: Critical study for SIDS endpoint
21-NOV-2003 (23)

5.4 Repeated Dose Toxicity

Type: Sub-chronic
Species: rat Sex: male
Strain: Sprague-Dawley
Route of administration: oral feed
Exposure period: 8 weeks
Frequency of treatment: daily
Doses: 0, 500 ppm Si
Control Group: yes

Method: other
Year: 1999
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
ANY OTHER INFORMATION: The study was conducted to study the effects of silicon-deficiency and the possibility to overcome this deficiency using different silicon sources.
Result: TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:

- Mortality and time to death: No mortality
- Body weight gain: No effects
- Clinical chemistry: decreased Ca (8%), Mg (7%) at p<0.05 level
- Haematology: No effects
- Organ weights: No effects
- Other: decreased Zn in liver (8%) at p<0.05 level

Test condition: TEST ORGANISMS
- Age: 8-12 weeks
- Weight at study initiation: 45.0 g (257 g after 8 weeks)
- Number of animals: 18/dose

ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 8 weeks
- Type of exposure: oral via diet.
- Vehicle: dextrose-egg-albumin type diet
- Concentration in vehicle: <5 ppm Si
- Doses: 0, 500 ppm Si, corresponding to 0 and 3777 mg Na2SiO3x5H2O/kg diet. Assuming a daily food consumption of 15 g and a body weight of 45 g, the rats were dosed 0 and 1259 mg sodium metasilicate, pentahydrate/kg bw/d.

CLINICAL OBSERVATIONS AND FREQUENCY:
- Clinical signs: Not reported
- Mortality: Not reported
- Body weight: Registered once a week
- Food consumption: Not reported
- Water consumption: Not reported
- Ophthalmoscopic examination: Not reported
- Haematology: Hemoglobin, hematocrit registered at necropsy
- Biochemistry: Plasma minerals (Ca, P, Mg, Cu, Zn), plasma cholesterol, alkaline phosphatase activity registered. Cu and Zn was registered in nitric acid digests of liver and heart tissues.
- Urinalysis: Not reported

ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: Heart, liver, femurs (organ weights only)
- Microscopic: Not reported

OTHER EXAMINATIONS: Concentrations of Cu and Zn in excised organs were measured.

STATISTICAL METHODS: General linear model (GLM) analysis of variance (ANOVA); Fisher protected least square difference (LSD) test; standard error of the means calculated from mean squares.

Test substance: SOURCE: Matheson, Coleman and Bell, Northwood-Cincinnati, Ohio, USA

PURITY: Not reported

IMPURITY/ADDITIVE/ETC.: Not reported

ANY OTHER INFORMATION: Disodium metasilicate (pentahydrate) was tested.

Reliability: (2) valid with restrictions
Well-documented study, but limited number of parameters studied.

Flag: Critical study for SIDS endpoint

22-MAY-2003 (24)

Type: Sub-acute
Species: rat Sex: male
Strain: Fischer 344
Route of administration: oral feed
Exposure period: 26 days
Frequency of treatment: daily
Doses: 10 and 50 mg of silicon/100g diet and lower, not

	specified levels
Control Group:	yes
Method:	other
Year:	1972
GLP:	no
Test substance:	other TS
Method:	METHOD FOLLOWED: Not reported GLP: No, study executed before existence of GLP STATISTICAL METHODS: Not reported METHOD OF CALCULATION: Not reported ANALYTICAL METHODS: Not reported ANY OTHER INFORMATION: Not reported
Result:	Tooth pigmentation, hairloss, seborrhoea, loss of tonicity observed. TOXIC RESPONSE/EFFECTS BY DOSE LEVEL: - Clinical signs: Significant improvements of tooth pigmentation (21%), compared to animals on silicate-free diet. Hairloss, seborrhoea and loss of tonicity is probabaly due to the lack of other minerals in the diet. - Body weight gain: Increased 25-34% at p<0.005 level. Lower levels of silicon gave statistically insignificant results. - Gross pathology: No effects OTHER: Silicon deficiency causes retarded skull growth
Test condition:	TEST ORGANISMS - Age: Weanlings - Weight at study initiation: Not reported - Number of animals: 11-15/dose ADMINISTRATION / EXPOSURE - Duration of test/exposure: 26 days - Type of exposure: oral via diet - Vehicle: amino acid based diet - Concentration in vehicle: <5 ppm Si - Doses: 100, 500 mg/kg (Na2SiO3.9H2O was added to the diet in doses equivalent to 0, 100 and 500 ppm Si) - Control: diet contained < 5 ppm SATELLITE GROUPS AND REASONS THEY WERE ADDED: None CLINICAL OBSERVATIONS AND FREQUENCY: - Clinical signs: Registered every 3-4 days - Mortality: Registered with unknown frequency - Body weight: Registered every 3-4 days - Food consumption: Not reported - Water consumption: Not reported - Ophthalmoscopic examination: Not reported - Haematology: Not reported - Biochemistry: Not reported - Urinalysis: Not reported ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC): - Macroscopic: Not reported - Microscopic: Not reported OTHER EXAMINATIONS: Tooth pigmentation, measured on day 26 STATISTICAL METHODS: Covariance analysis; study was conducted to study the effects of silicon-deficiency.
Test substance:	SOURCE: Not reported PURITY: Not reported IMPURITY/ADDITIVE/ETC.: Not reported ANY OTHER INFORMATION: Disodium Metasilicate (nonahydrate) was tested.
Reliability:	(3) invalid

Unsuitable test system as it concerns a study on the growth promoting effects of silicon and not a toxicology study. Furthermore, many relevant parameters are not evaluated.
22-MAY-2003 (49)

Type: Sub-chronic
Species: rat Sex: male/female
Strain: Wistar
Route of administration: drinking water
Exposure period: 3 months
Frequency of treatment: daily
Doses: 200, 600 and 1800 ppm
Control Group: yes
NOAEL: > 227 - 237 mg/kg bw

Method: other
Year: 1975
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Similar to OECD 408; the study was performed before OECD 408 came into force, but conforms to a number of the conditions.
GLP: No, study executed before existence of GLP.
STATISTICAL METHODS:Not reported.
METHOD OF CALCULATION:Not reported.
ANALYTICAL METHOD: Not reported.
Result: No clearly treatment related effects at tested dose levels of 200, 600 and 1800 ppm (corresponding to 26.4, 76.2 and 227.1 mg/kg/day, respectively, for males; and 32.1, 97.6 and 237.2 mg/kg/day, respectively, for females).
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Mortality and time to death: None
- Clinical signs: No effects
- Body weight gain: No effects
- Food/water consumption: No effects
- Clinical chemistry: No effects
- Haematology: No effects
- Urinalysis: No effects
- Organ weights: No effects
- Gross pathology: No effects
- Histopathology: Except for the kidneys, no morphological changes have been observed in the organs examined. The observed histological changes in the kidneys (tubule wall calcinosis, glomerular swelling, tubule swelling, weakening of the renal tubule cell walls and dilation of the tubule lumen) were not dose-related and occurred also in the controls. Cylindrical inclusions in the renal tubular cells were only observed in the medium dosage group.
Test condition: TEST ORGANISMS
- Age: 7 weeks
- Weight at study initiation: not reported
- Number of animals: 40 animals (5/sex/dose)
ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 3 months
- Type of exposure: oral in drinking water
- Post exposure period: not reported
- Vehicle: tap water
- Concentration in vehicle: not reported
- Doses: 0, 200, 600 and 1800 ppm
200 ppm corresponding to 26.4 mg/kg/day for males and 32.1

mg/kg/day for females.
600 ppm corresponding to 76.2 mg/kg/day for males and 97.6 mg/kg/day for females.
1800 ppm corresponding to 227.1 mg/kg/day for males and 237.2 mg/kg/day for females.
SATELLITE GROUPS AND REASONS THEY WERE ADDED: not reported
CLINICAL OBSERVATIONS AND FREQUENCY:
- Clinical signs: daily
- Mortality: daily
- Body weight: once a week
- Food consumption: once a week
- Water consumption: measured daily
- Ophthalmoscopic examination: not reported
- Haematology: after the test period erythrocytes and leukocytes were counted, hemoglobin value, blood cell volume and leukocyte percentage
- Biochemistry: after the test period s-GOT, s-GPT and alkali phosphatase activity measurement
- Urinalysis: after the test period measurements were made on pH-value, sugar, protein, ketone and blood value.
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: wet weight of liver, kidney, heart, lung, spleen, suprarenal glands, thymus, thyroid gland, testicles and ovaries. Also dissected: pancreas, intestines, stomachs, bone marrow.
- Microscopic: liver, kidney, heart, lung, spleen, suprarenal glands, thymus, thyroid gland, testicles and ovaries were fixed with 10% formalin, packed in paraffin, cut into thin sections and subjected to hematoxylin and eosin staining.
OTHER EXAMINATIONS: not reported
STATISTICAL METHODS: not reported

Test substance: SOURCE: Nihon Nohyaku Co., Ltd
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Poly sodium silicate is assumed to be metasilicate (designated in tables and figures as 'meta silicate' and in the text as $Na_2O.SiO_2$, indicating a molar ratio of 1.0). Designated by authors as Porikuron, a product based on poly sodium silicate ($Na_2O.nSiO_2$).

Reliability: (2) valid with restrictions
Study performed according to basic scientific principles.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (19)

Type: Sub-chronic
Species: rat Sex: male/female
Strain: other: Wistar-DLC
Route of administration: drinking water
Exposure period: 3 months
Frequency of treatment: continously
Post exposure period: no
Doses: 23, 47, 110 mg/d (males), 21, 37, 84 mg/d (females)
Control Group: yes

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: not reported

GLP: no
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported

Result: NOAEL (NOEL), LOAEL (LOEL): Not possible to assess.
ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX: the actual dose received was given as "individual specimen intake", the cumulative intake over the entire exposure period. The intake has been divided by 90 to find the average daily intake. Males administered the nominal dose 750, 1500 or 3000 ppm, had an actual intake during the exposure period of 23, 47 or 110 mg/d, respectively. Females had an actual intake during the exposure period of 21, 37 or 84 mg/d, respectively. Exact dosing regime unsure due to a confusing study report.
- Time of death: no mortality
- Number of deaths at each dose: no mortality
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Mortality and time to death: no mortality
- Clinical signs: no effects
- Body weight gain: no significant effects
- Food/water consumption: there were no effects on food consumption. The water consumption was not mentioned in the report.
- Ophthalmoscopic examination: not reported
- Clinical chemistry: Increase in S-GOT in high and medium male dose groups, decrease in high female dose group. Increase in S-GPT in males in high and medium dose group. Increase in cholesterol level in all male exposure groups. Decrease in Na-levels in all male exposure groups, increase in female high dose group. Cl-levels decreased in male high dose group.
- Haematology: the erythrocytes count can not be assessed as the report contains a contradiction between the text and the respective table. An increase of N-seg and decrease of lymphocytes was observed in the medium and high female dose groups.
- Urinalysis: the protein content was increased in the high dose groups.
- Organ weights: a decrease in weight was observed for the right seminal glands of males exposed to 3000 ppm, for adrenal glands in all exposed male groups, and pituitary bodies in all exposed male groups. It is not stated whether these changes are statistically significant. in the corresponding table the column indicating the organs is missing.
- Gross pathology: not reported
- Histopathology: no treatment-related effects
- Other: the renal effects referred to in the abstract (Ito, 1986) are not mentioned in the study report.
STATISTICAL RESULTS: not reported

Test condition: TEST ORGANISMS
- Age: 4 weeks
- Weight at study initiation: not reported
- Number of animals: probably 80, 10 per dose group (in one part of the translation, it is stated that there were 14 rats per dose group, however, as 10 rats per dose group is given in another part of the document, and there were 10 mice per dose group in the other 90-day study, it is assumed that the latter number is correct).
ADMINISTRATION / EXPOSURE

- Duration of test/exposure: 90 days
- Type of exposure: oral in drinking water
- Post exposure period: not reported
- Vehicle: Tap water
- Concentration in vehicle: not reported
- Doses: probably 750, 1500 or 3000 ppm (in one part of the translation, the dose levels are given as 166.7, 1000 or 1500 ppm, but as the alternative dose levels 750, 1500 or 3000 ppm are cited in the tables, it is assumed that the latter
are correct numbers).
SATELLITE GROUPS AND REASONS THEY WERE ADDED: not reported
CLINICAL OBSERVATIONS AND FREQUENCY:
- Clinical signs: registered once daily
- Mortality: registered once daily
- Body weight: registered once a week
- Food consumption: registered once a week
- Water consumption: registered twice a week
- Ophthalmoscopic examination: not reported
- Haematology: erythrocytes, leucocytes, haemoglobin, haematocrit, blood serum protein content, leucocyte composition.
- Biochemistry: S-GOT, S-GTP, S-AlP (alkali phosphatase), bilirubin, blood glucose, BUN, cholesterol, A/G, potassium, sodium, chloride.
- Urinalysis: performed at the end of the study. pH, sugar (assumed to be glucose), protein, ketone, blood concentration, urobilinogen.
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: the wet weight of liver, kidney, spleen, suprarenal glands, thyroid glands, testicles, pituitary glands, heart, lung, brain was measured. The organs of the thoracic and abdominal cavity were macroscopically examined.
- Microscopic: liver, kidney, spleen, suprarenal glands, thyroid glands, testicles, pituitary glands, heart, lung, brain, pancreas, stomach, duodenum, jejenum, ileum, cecum, rectum, urinary bladder, prostate, uterus, arteries, lymphatic glands were fixed in 10% formalin, packed in paraffin, cut into thin sections, subjected to haematoxylin and eosin staining and examined microscopically.
OTHER EXAMINATIONS: not reported
STATISTICAL METHODS: not reported

Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: the test substance was sodium metasilicate with an unknown concentration.

Reliability: (3) invalid
Study performed according to basic scientific principles, however, the report contains inconsistencies and incomplete tables that make the credibility questionable.

22-MAY-2003 (45)

Type:	Chronic	
Species:	rat	Sex: male/female
Strain:	other: Wistar-SLC	
Route of administration:	drinking water	
Exposure period:	14 months	
Frequency of treatment:	continously	
Post exposure period:	no	
Doses:	167, 500, 1500 ppm	

Control Group: no

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: not reported
DEVIATIONS FROM GUIDELINE: not reported
GLP: no
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported

Result: MORTALITY AND TIME TO DEATH: there were sporadical deaths in all groups from the sixth month of exposure onward, with the number increasing from month 12. The study was terminated in month 14 due to difficulties in continuing for 24 months as planned. The exact number of mortalities is not specified. Deaths were caused by pneumonia.
CLINICAL SIGNS: no significant effects
BODY WEIGHT GAIN: 2-3 months after exposure started, the medium dose group had a reduced body weight gain. The same was observed in the low dose group exposure month 3-7. The effects were transient.
FOOD/WATER CONSUMPTION: the food intake was slightly low in the female low dose group after the first month of exposure, and in the male low dose group after month 3 of exposure. The article states that later there were no significant changes, however, the length of the period with reduced food intake is unknown.
OPHTALMOSCOPIC EXAMINATION: not reported
CLINICAL CHEMISTRY: Females in the high dose group had a decreased glucose level (14 months) and an increase in A/G (12 months). The BUN increased in females administered medium and high doses (after 6 and 12 months' exposure), and decreased in males exposed to the medium and high doses for 12 months. A decreased in sodium concentration was observed in the female high and medium dose groups (six months).
HAEMATOLOGY: the haematocrit level in all exposed male groups was significantly decreased after 14 months of exposure, compared to the control group, but within the expected range according to the authors of the report. The significant changes in leucocyte composition were as follows: increase of N-Seg in the male medium dose group at 6 months; increase of eosinophils and monocytes in the male high dose group, increase of basophiles in the female high and medium dose group, increase of lymphocytes and decrease of N-Seg in the female low dose group after 12 months' exposure; decrease of lymphocytes in the male medium dose group and increase of monocytes in all female exposure groups after 14 months of dosing.
URINALYSIS: pH in the male high dose group after six months' exposure was 6.5-9.0 compared to 7.0-7.5 in the control group. This range was not registered after 12 or 14 months of exposure. The protein concentration in the male high dose group after 12 months of exposure was higher than for the control group, but not after 6 or 14 months of exposure.
ORGAN WEIGHTS: all results are statistically significant, and reported after 14 months of exposure. Males in the high and low dose groups had an increase in thyroid gland weight.

A weight decrease was observed for the livers of males in low and high dose groups, the left ovary of females in the medium and high dose groups and the hearts and brains of all exposed females. The thymus glands could not be weighed due to fatty degeneration.
GROSS PATHOLOGY: see histopathology
HISTOPATHOLOGY: 3/40 males in the high dose group had purulent pneumonia after 14 months' exposure.
OTHER: no significant effects were discovered by electron microscopy of liver tissue. The renal effects mentioned in the abstract (Ito, 1986) are not present in significant numbers.
TIME TO TUMOURS: no significant effects
STATISTICAL RESULTS: not reported

Test condition: TEST ORGANISMS
- Age: four weeks
- Weight at study initiation: not reported
- Number of animals: 320, 40 per group
ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 14 months
- Type of exposure: oral in drinking water
- Post exposure period: not reported
FOR ORAL STUDIES:
- Vehicle: tap water
- Concentration in vehicle: not reported
- Total volume applied: not applicable
- Doses: 167, 500 and 1500 ppm sodium metasilicate, stated in the report to correspond to 5.5, 16,7 and 50 mg/kg bw/d. However, assuming an average water uptake of 25 ml/d and an average weight of 250 g/animal for rats, the doses are calculated to be 16.7, 50 and 150 mg/kg bw/d.
CLINICAL OBSERVATIONS AND FREQUENCY
- Body weight: registered once a week
- Food consumption: registered twice a week
- Water consumption: registered twice a week
- Clinical signs: registered daily
- Mortality: registered daily
- Macroscopic examination: all organs in the thoracic and abdominal cavity were examined at necropsy
- Ophthalmoscopic examination: not reported
- Haematology: erythrocyte count, leucocyte count, haemoglobin, haematocrit, blood serum protein, leucocyte composition
- Clinical chemistry: S-GOT, S-GTP, S-AlP (alkali phosphatase), bilirubin, blood glucose, BUN, cholesterol, A/G, potassium, sodium, chloride.
- Urinalysis: performed at the end of the study. pH, glucose, protein, ketone, blood concentration, urobilinogen.
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: liver, kidney, spleen, suprarenal glands, thymus, thyroid glands, testicles, pituitary glands, heart, lung, brain, ovary.
- Microscopic: liver, kidney, spleen, suprarenal glands, thyroid glands, testicles, pituitary glands, heart, lung, brain, pancreas, thymus, ovary, stomach, duodenum, jejenum, ileum, cecum, rectum, urinary bladder, prostate, uterus, arteries, lymphatic glands, bone marrow and mammary glands were fixed in 10% formalin, packed in paraffin, cut into thin sections, subjected to haematoxylin and eosin staining and examined microscopically.
OTHER EXAMINATIONS: after 6 and 12 months of the exposure

period, necropsy was performed on 6 males and six females from each group. Animals that died during the exposure period were necropsied. Liver tissue was prepared for examination by light microscope and electronmicroscope by cutting it into thin slices, which were fixed with 2% glutaraldehyde and thereafter fixed with 2% osmic acid solution. After dehydration with ethanol the fixed tissue specimen was packed in Epon 812, before subjecting to uranyl acetate and lead nitrate staining.
STATISTICAL METHODS: not reported

Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: the test substance was sodium metasilicate with an unknown concentration.

Reliability: (3) invalid
High mortality in all groups from month 6 onwards, including control.

26-JAN-2004 (45)

Type: Sub-acute
Species: rat Sex: male/female
Strain: other: Wistar-SLC
Route of administration: gavage
Exposure period: 14 days
Frequency of treatment: daily
Post exposure period: no
Doses: Females: 62.5, 125, 250, 500 or 1000 mg/kg bw/d. Males: 37.5, 75, 150, 300, 600 mg/kg bw/d.
Control Group: yes
NOAEL: = 125 mg/kg bw
LOAEL: = 250 mg/kg bw

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: not reported
GLP: no
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported

Result: NOAEL: 125 mg/kg bw/d
LOAEL: 250 mg/kg bw/d
ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX
- Time of death: no mortalities
- Number of deaths at each dose: no mortalities
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Mortality and time to death: 3/5 females administered 1000 mg/kg bw/d (2 died in the first week; 1 in the second week). 2/5 females administered 500 mg/kg bw/d (1 died in the first week; 1 in the second week), 2/5 males administered 600 mg/kg bw/d (both died in the first week).
- Clinical signs: a lower activity level, a lower level of reaction to external stimuli, and fading skin colour was observed from the first day of dosing in females exposed to 1000 mg/kg bw/d, and from day 3 in females administered 600 mg/kg bw/d. In general, females in these dose groups had secretion of nasal mucus and opacified body hairs, these symptoms improved from day 11 onward.

- Body weight gain: females administered 250 mg/kg bw/d had reduced body weight gain day 14 of the exposure, and females administered 300 mg/kg on day 7 and 14 of exposure. Females administered 250, males administered 300 mg/kg bw/d and all higher dose groups showed a reduced body weight gain during administration. Males recovered from the 14th day on. As no further details are given, it is unsure whether the reduced body weight gain is given for the specified days or the 7 preceding days.
- Food/water consumption: not reported
- Ophthalmoscopic examination: not reported
- Clinical chemistry: not reported
- Haematology: not reported
- Urinalysis: not reported
- Organ weights: not reported
- Gross pathology: not reported
- Histopathology: in surviving animals, localised bleeding in the thymus glands, lungs and semi-transparent fluid in the uterus were sporadically observed in all groups including the controls. In the animals that died there was considerable bleeding in the
stomach. The renal effects reported in the abstract (Ito, 1986) were not mentioned in the study report.
- Other: not reported

STATISTICAL RESULTS: not reported

Test condition: TEST ORGANISMS
- Age: 4 weeks
- Weight at study initiation: not reported
- Number of animals: 60, 5 per dose level

ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 14 days
- Type of exposure: oral, by gavage
- Post exposure period: not reported
- Vehicle: distilled water
- Concentration in vehicle: not reported
- Total volume applied: 0.1 ml/10 g
- Doses: Males were dosed with 37.5, 75, 150, 300 or 600 mg/kg bw/d. Females were dosed with 62.5, 125, 250, 500 or 1000 mg/kg bw/d.

SATELLITE GROUPS AND REASONS THEY WERE ADDED: not reported

CLINICAL OBSERVATIONS AND FREQUENCY:
- Clinical signs: reported daily
- Mortality: reported daily
- Body weight: animals were weighed daily
- Food consumption: measured twice a week
- Water consumption: not reported
- Ophthalmoscopic examination: not reported
- Haematology: not reported
- Biochemistry: not reported
- Urinalysis: not reported

ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: organs of the thoracic and abdominal cavity, not further specified
- Microscopic: organs of the thoracic and abdominal cavity, not further specified

OTHER EXAMINATIONS: not reported

STATISTICAL METHODS: not reported

Test substance: SOURCE: not reported

PURITY: not reported

IMPURITY/ADDITIVE/ETC.: not reported

ANY OTHER INFORMATION: the test substance was sodium

metasilicate with an unknown concentration.
Reliability: (3) invalid
Study report provides only summary of data, no tables with data from individual animals are given. In addition, inconsistencies were found. For example, the dose levels under "method" and "results" do not correlate, so the "results" section may have been switched with the "results" section of the 14 days mouse study, and therefore the data are tainted with uncertaintanties.
07-MAY-2003 (45)

Type: Sub-chronic
Species: mouse Sex: male/female
Strain: other: ddy
Route of administration: drinking water
Exposure period: 3 months
Frequency of treatment: continously
Post exposure period: no
Doses: 300, 900, 2700 ppm (males), 333, 1000, 3000 ppm (females)
Control Group: yes
NOAEL: = 260 - 284 mg/kg bw
LOAEL: = 716 - 892 mg/kg bw

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: not reported
GLP: no
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported
Result: NOAEL: 1000 ppm (females) = 6.5-7.1 mg/animal/d = 260-284 mg/kg bw/d (assuming 25 g/animal)
LOAEL: 3000 ppm (females) = 17.9-22.3 mg/animal/d = 716-892 mg/kg bw/d (assuming 25 g/animal)
ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX:
males:

nominal dose	300	900	2700 ppm
actual intake	2.4-2.5	6.6-7.0	19.4-20.8 mg/animal/d
actual dose	96-100	264-280	776-832 mg/kg bw/d

females:

nominal dose	333	1000	3000 ppm
actual intake	2.2-2.6	6.5-7.1	17.9-22.3 mg/animal/d
actual dose	88-104	260-284	716-892 mg/kg bw/d

(calculations are based on an average body weight for mice of 25 g)
- Time of death: no mortality
- Number of deaths at each dose: no mortality
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Mortality and time to death: no mortality
- Clinical signs: no treatment-related effects
- Body weight gain: no treatment-related effects
- Food/water consumption: there were no effects on food and water consumption.
- Ophthalmoscopic examination: not reported
- Clinical chemistry: no effects
- Haematology: There was an increase of the haematocrit level

in
the female high dose group. The leucocyte count in females was significantly reduced in the low and medium dose group, and reduced in the highest dose group.
- Urinalysis: the protein concentration in all female exposure groups was slightly increased compared with the control group.
- Organ weights: the relative pituitary gland weight in females was reduced in all dose groups compared to the control, statistically significant only in the highest dose group. The relative liver weight in males was increased in all dose groups compared to control group, significantly in the low and medium dose group.
With respect to the reproductive organs examined, the following wet weights (g) were determined:

	Testes		Ovaries	
	right	left	right	left
control	0.13	0.14	8.4	7.3
2700 ppm	0.14	0.14	7.7	7.4
900 ppm	0.13	0.13	9.7	9.1
300 ppm	0.13	0.12	8.3	8.4

- Gross pathology: see histopathology
- Histopathology: no treatment-related effects
- Other: not reported
STATISTICAL RESULTS: not reported

Test condition: TEST ORGANISMS
- Age: 4 weeks
- Weight at study initiation: not reported
- Number of animals: 80, 10 per dose group
ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 90 days
- Type of exposure: oral in drinking water
- Post exposure period: not reported
- Vehicle: Tap water
- Concentration in vehicle: not reported
- Doses: male animals were administered 300, 900 or 2700 ppm, females were administered 333, 1000 or 3000 ppm.
SATELLITE GROUPS AND REASONS THEY WERE ADDED: not reported
CLINICAL OBSERVATIONS AND FREQUENCY:
- Clinical signs: registered once daily
- Mortality: registered once daily
- Body weight: registered once a week
- Food consumption: registered once a week
- Water consumption: registered twice a week
- Ophthalmoscopic examination: not reported
- Haematology: erythrocyte count, leucocyte count, haemoglobin, haematocrit, blood serum protein content, leucocyte composition.
- Biochemistry: S-GOT, S-GTP, S-AlP (alkali phosphatase), bilirubin, blood glucose, BUN, cholesterol, A/G, potassium, sodium, chloride.
- Urinalysis: performed at the end of the study. pH, sugar (assumed to be glucose), protein, ketone, blood concentration, urinobilinogen.
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: the wet weight of liver, kidney, spleen, suprarenal glands, thyroid glands, testicles, pituitary glands, heart, lung, brain, ovary was registered. The organs

of the thoracic and abdominal cavity were examined macroscopically
- Microscopic: liver, kidney, spleen, suprarenal glands, thyroid glands, testicles, pituitary glands, heart, ovary, lung, brain, pancreas, stomach, duodenum, jejenum, ileum, cecum, rectum, urinary bladder, prostate, uterus, mammary glands, arteries, bone marrow, lymphatic glands were fixed in 10% formalin, packed in paraffin, cut into thin sections, subjected to haematoxylin and eosin staining and examined microscopically.
OTHER EXAMINATIONS: not reported
STATISTICAL METHODS: not reported

Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: the test substance was sodium metasilicate with an unknown concentration.

Reliability: (2) valid with restrictions
Study performed according to basic scientific principles, study report is unclear in some points.

Flag: Critical study for SIDS endpoint

28-NOV-2003 (45)

Type: Sub-acute
Species: mouse Sex: male/female
Strain: other: ddy
Route of administration: gavage
Exposure period: 14 days
Frequency of treatment: daily
Post exposure period: no
Doses: 37.5, 75, 150, 300, 600 mg/kg
Control Group: yes
NOAEL: = 75 mg/kg bw
LOAEL: = 150 mg/kg bw

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: not reported
GLP: no
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported

Result: NOAEL: 75 mg/kg bw/d
LOAEL: 150 mg/kg bw/d
ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX
- Time of death: no mortalities
- Number of deaths at each dose: no mortalities
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Mortality and time to death: no mortalities
- Clinical signs: animals administered 75 mg/kg bw/d or less, showed no effects. At dose level 150 mg/kg bw/d and above, the animals became lethargic immediately after administration. Animals administered 300 or 600 mg/kg bw/d became agitated and reacted more intensely to external stimuli. In the highest dose group rough hair coat and dull fur was observed from the fourth exposure day on.
- Body weight gain: in animals exposed to 600 mg/kg bw/d reduced body weight increase was observed from the third day

of exposure. Females recovered on the sixth day of exposure. No further details are given.
- Food/water consumption: not reported
- Ophthalmoscopic examination: not reported
- Clinical chemistry: not reported
- Haematology: not reported
- Urinalysis: not reported
- Organ weights: not reported
- Gross pathology: 2 males administered 600 mg/kg bw/d had white, hazy spots on the horizontally neighbouring faces of the right internal lobe of the liver, while 2 females in the same dose group had a coarse kidney surface (the surface of the kidney in one animals had a faded colour, the other showed white hazy spots).
- Histopathology: localised bleeding in the thymus glands and thickened uterus linings were sporadically observed in all groups.
- Other: the renal effects reported in the abstract (Ito, 1986) were not mentioned in the study report.
STATISTICAL RESULTS: not reported

Test condition: TEST ORGANISMS
- Age: 4 weeks
- Weight at study initiation: not reported
- Number of animals: 60, 5 per group
ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 14 days
- Type of exposure: oral, by gavage
- Post exposure period: not reported
- Vehicle: physiological saline solution
- Concentration in vehicle: not reported
- Total volume applied: 0.5 ml/100 g
- Doses: 37.5, 75, 150, 300 or 600 mg/kg bw/d.
SATELLITE GROUPS AND REASONS THEY WERE ADDED: not reported
CLINICAL OBSERVATIONS AND FREQUENCY:
- Clinical signs: reported daily
- Mortality: reported daily
- Body weight: animals were weighed daily
- Food consumption: measured twice a week
- Water consumption: not reported
- Ophthalmoscopic examination: not reported
- Haematology: not reported
- Biochemistry: not reported
- Urinalysis: not reported
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: organs of the thoracic and abdominal cavity, not further specified
- Microscopic: organs of the thoracic and abdominal cavity, not further specified
OTHER EXAMINATIONS: not reported
STATISTICAL METHODS: not reported

Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: the test substance was sodium metasilicate of an unknown concentration.

Reliability: (3) invalid
Study report provides only summary of data, no tables with data from individual animals are given. In addition, inconsistencies were found. For example, the dose levels under "method" and "results" do not correlate, so the "results" section may have been switched with the "results" section of

the 14 days mouse study, and therefore the data are tainted with uncertaintanties.

07-MAY-2003 (45)

Type: Sub-acute
Species: other: turkey Sex: male
Strain: other: Nicholas
Route of administration: oral feed
Exposure period: 4 weeks
Frequency of treatment: daily
Doses: 0, 270 ppm Si
Control Group: yes

Method: other
Year: 1999
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
GLP: No
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
ANY OTHER INFORMATION: Not reported

Result: ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX:
- Time of death: no mortality
- Number of deaths: no mortality
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Mortality and time to death: None
- Clinical signs: not reported
- Body weight gain: No effects
- Clinical chemistry: increased P (6%) and decreased Cu (29%) at $p<0.05$ level.
- Haematology: No effects
- Organ weights: No effects
STATISTICAL RESULTS: not reported

Test condition: TEST ORGANISMS
- Age: 4-6 weeks
- Weight at study initiation: 54.3 g (760 g after 4 weeks)
- Number of animals: 18/dose
ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 4 weeks
- Type of exposure: oral via diet
- Vehicle: 28% protein, dextrose-casein type formulated diet
- Concentration in vehicle: 0 ppm Si
- Doses: 0, 270 ppm Si, corresponding to 0 and 2039 mg $Na_2SiO_3x5H_2O$/kg diet.
CLINICAL OBSERVATIONS AND FREQUENCY:
- Clinical signs: Not reported
- Mortality: Not reported
- Body weight: Registered every week
- Food consumption: Not reported
- Water consumption: Not reported
- Ophthalmoscopic examination: Not reported
- Haematology: Hemoglobin, hematocrit recorded at necropsy
- Biochemistry: Plasma Ca, Mg, Zn, P, Cu and plasma cholesterol, alkaline phosphatase activity. Cu and Zn in nitric acid digests of liver.
- Urinalysis: Not reported
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: Heart, liver, tibia (organ weights only)
- Microscopic: Not reported

OTHER EXAMINATIONS: Concentrations of Cu and Zn in excised organs
STATISTICAL METHODS: General linear model (GLM) analysis of variance (ANOVA); Fisher protected least square difference (LSD) test; standard error of the means calculated from mean squares
Test substance: SOURCE: Matheson, Coleman and Bell, Northwood-Cincinnati, Ohio, USA
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Disodium Metasilicate (pentahydrate) was tested.
Reliability: (2) valid with restrictions
Well-documented study, but limited number of parameters studied.
Flag: Critical study for SIDS endpoint
22-MAY-2003 (24)

5.5 Genetic Toxicity 'in Vitro'

Type: DNA damage and repair assay
System of testing: Bacillus subtilis recombination-repair-deficient and wild type strains
Concentration: 0.005-0.5 M
Metabolic activation: without
Result: negative

Method: other: rec assay described by Kada et al. (1972)
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Rec assay reported in article as described by Kada et al. 1972
GLP: No, study executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: In the article Na2SiO3 is reported to give negative results in this study.
Test condition: SYSTEM OF TESTING:
- Species/cell type: B.subtilis H17 and M45
- Deficiencies/Proficiencies: H17 is recombination-repair-proficient, trp-deficient and arg-deficient. M45 is recombinant-repair-deficient, trp-deficient and arg-deficient.
- Metabolic activation system: Not used
ADMINISTRATION:
- Dosing: 0.005 - 0.5 M
- Number of replicates: Not reported
- Application: Not reported
- Pos control and neg control groups treatment: Not reported
DESCRIPTION OF FOLLOW UP REPEAT STUDY: Not reported
Test substance: SOURCE: Maruichi Chemicals Ltd., Misima, Japan
PURITY: Not reported
IMPURITY/ADDITIVE/ETC: Not reported
ANY OTHER INFORMATION: Sodium Metasilicate was tested.
Reliability: (2) valid with restrictions
Acceptable, well-documented publication report which meets basic scientific principles
15-JUL-2003 (21)

Type: Ames test
System of testing: Salmonella typhimurium TA98, TA100, TA1535, TA1537
Concentration: 0.1, 1 and 10 mg/plate
Cytotoxic Concentration: not reported
Metabolic activation: with and without
Result: negative

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Ames test, plate count
DEVIATIONS FROM GUIDELINE: not reported
GLP: no
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported
Result: GENOTOXIC EFFECTS:
- With metabolic activation: negative
- Without metabolic activation: negative
FREQUENCY OF EFFECTS: no effects
PRECIPITATION CONCENTRATION: not reported
MITOTIC INDEX: not reported
CYTOTOXIC CONCENTRATION:
- With metabolic activation: 10 mg/plate
- Without metabolic activation: 10 mg/plate
TEST-SPECIFIC CONFOUNDING FACTORS: not reported
STATISTICAL RESULTS: not reported
Test condition: SYSTEM OF TESTING
- Species/cell type: Salmonella typhimurium TA 98, TA 100, TA 1535, TA 1537
- Deficiences/Proficiences: not reported
- Metabolic activation system: S9 mix
ADMINISTRATION:
- Dosing: not reported
- Number of replicates: not reported
- Application: tested on plates
- Positive and negative control groups and treatment: the buffer solution was used as a negative control. 0.01 µg/plate AF2 without metabolic activation was used as a positive control for TA100 and TA 98, 100 µg/plate 9-aminoacridine without metabolic activation was used as a positive control for TA 1537, and 2 µg/plate 2-aminoanthracene with metabolic activation was used as a positive control for all strains.
- Pre-incubation time: not reported
DESCRIPTION OF FOLLOW UP REPEAT STUDY: not reported
CRITERIA FOR EVALUATING RESULTS: not reported
Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: the test substance was sodium metasilicate with an unknown concentration.
Reliability: (4) not assignable
Study seems to be performed according to established test procedures, but report too limited in detail.
10-FEB-2003 (18) (45)

5.6 Genetic Toxicity 'in Vivo'

Type: Cytogenetic assay
Species: mouse Sex: male
Strain: other: BDF1
Route of admin.: oral feed
Exposure period: 24 hours
Result: negative

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: cytogenetic assay using bone marrow cells of mice
DEVIATIONS FROM GUIDELINE: not reported
GLP: no
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported

Result: MORTALITY: not reported
CLINICAL SIGNS: not reported
NECROPSY FINDINGS: not reported
BODY WEIGHT CHANGES: not reported
FOOD AND WATER CONSUMPTION CHANGES: not reported
EFFECT ON MITOTIC INDEX OR PCE/NCE RATIO: not reported
GENOTOXIC EFFECTS: negative
NOAEL (NOEL) (C) / LOAEL (LOEL) (C): not reported
MUTANT/ABERRATION/mPCE/ POLYPLOIDY FREQUENCY: no significant increase of chromosomal aberrations compared to negative control even at dosage levels exceeding the M.T.D. of 940 mg/kg bw.
STATISTICAL RESULTS: not reported

Test condition: TEST ORGANISMS: BDF1 mouse, lowest dose was 740 mg/kg bw. Highest dose is not given, but exceeded 940 mg/kg bw, the concentration, where fatalities occurred in a range-finding test.
- Age: 9 weeks
- Weight at study initiation: not reported
- No. of animals per dose: 4-6
ADMINISTRATION: orally with dose levels of 740-1340 mg/kg bw (7 graduated levels)
- Vehicle: not reported
- Duration of test: 24 hrs
- Frequency of treatment: once, on day 0. 4 mg/kg bw colchicine was administered intraperitoneally 2 hours before necropsy.
- Sampling times and number of samples: 24 hours after administration of an acute dose
- Control groups and treatment: only negative controls were used.
EXAMINATIONS:
- Clinical observations: not reported
- Organs examined at necropsy: not reported
- Criteria for evaluating results: not reported
- Criteria for selection of M.T.D.: not reported.
The chromosomes were examined blind by three persons. Slides from femur bone marrow cells were prepared according to standard methods, and 100 metaphases per animal analyzed for chromosomal aberrations (including gaps, breaks, deletions,

and exchanges).
Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: the test substance was sodium metasilicate with an unknown concentration.
Reliability: (2) valid with restrictions
Study was performed similar to OECD TG 475, with the restriction that no positive controls were used.
Flag: Critical study for SIDS endpoint
01-OCT-2004 (18) (45)

5.7 Carcinogenicity

Species: rat Sex: male/female
Strain: other: Wistar-SLC
Route of administration: drinking water
Exposure period: 14 months
Frequency of treatment: continuous
Post exposure period: no
Doses: 167, 500, 1500 ppm
Control Group: yes

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: Not reported
DEVIATIONS FROM GUIDELINE: Not reported
GLP: No
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: MORTALITY AND TIME TO DEATH: there were sporadical deaths in all groups from the sixth month of exposure forward, with the number increasing from month 12. The study was terminated in month 14 due to difficulties in continuing for 24 months as planned. The exact number of mortalities is not specified.
CLINICAL SIGNS: no significant effects
BODY WEIGHT GAIN: 2-3 months after exposure started, the medium dose group had a reduced body weight gain. The same was observed in the low dose group exposure month 3-7. The effects were transient.
FOOD/WATER CONSUMPTION: the food intake was slightly low in the female low dose group after the first month of exposure, and in the male low dose group after month 3 of exposure. The article states that later there were no significant changes, however, the length of the period with reduced food intake is unknown.
OPHTALMOSCOPIC EXAMINATION: not reported
CLINICAL CHEMISTRY: Females in the high dose group had a decreased glucose level (14 months) and an increase in A/G (12 months). The BUN increased in females administered medium and high doses (after 6 and 12 months' exposure), and decreased in males exposed to the medium and high doses for 12 months. A decreased in sodium concentration was observed in the female high and medium dose groups (six months).

HAEMATOLOGY: the haematocrit level in all exposed male groups was significantly decreased after 14 months of exposure, compared to the control group, but within the expected range according to the authors of the report. The significant changes in leucocyte composition were as follows: increase of N-Seg in the male medium dose group at 6 months; increase of eosinophils and monophils in the male high dose group, increase of basophiles in the female high and medium dose group, increase of lymphocytes and decrease of N-Seg in the female low dose group after 12 months' exposure; decrease of lymphocytes in the male medium dose group and increase of monocytes in all female exposure groups after 14 months of dosing.
URINALYSIS: pH in the male high dose group after six months' exposure was 6.5-9.0 compared to 7.0-7.5 in the control group. This range was not registered after 12 or 14 months of exposure. The protein concentration in the male high dose group after 12 months of exposure was higher than for the control group, but not after 6 or 14 months of exposure.
ORGAN WEIGHTS: all results are statistically significant, and reported after 14 months of exposure. Males in the high and low dose groups had an increase in thyroid gland weight. A weight decrease was observed for the livers of males in low and high dose groups, the left ovary of females in the medium and high dose groups and the hearts and brains of all exposed females. The thymus glands could not be weighed due to fatty degeneration.
GROSS PATHOLOGY: see histopathology
HISTOPATHOLOGY: 3/40 males in the high dose group had purulent pneumonia after 14 months' exposure.
OTHER: no significant effects were discovered by electron microscopy of liver tissue. The renal effects mentioned in the abstract (Ito, 1986) are not present in significant numbers.
TIME TO TUMOURS: no significant effects
STATISTICAL RESULTS: not reported

Test condition: TEST ORGANISMS
- Age: four weeks
- Weight at study initiation: not reported
- Number of animals: 320, 40 per group
ADMINISTRATION / EXPOSURE
- Duration of test/exposure: 14 months
- Type of exposure: oral in drinking water
- Post exposure period: not reported
FOR ORAL STUDIES:
- Vehicle: tap water
- Concentration in vehicle: 167, 500 or 1500 ppm sodium metasilicate, stated in the report to correspond to 5.5, 16,7 and 50 mg/kg bw/d. However, assuming an average water uptake of 25 ml/d and an average weight of 250 g/animal for rats, the doses are calculated to be 16.7, 50 and 150 mg/kg bw/d.
- Total volume applied: not applicable
- Doses: unsure, due to different dose levels given in different parts of the report
CLINICAL OBSERVATIONS AND FREQUENCY
- Body weight: registered once a week
- Food consumption: registered twice a week
- Water consumption: registered twice a week
- Clinical signs: registered daily
- Mortality: registered daily
- Macroscopic examination: all organs in the thoracic and

abdominal cavity were examined at necropsy
- Ophthalmoscopic examination: not reported
- Haematology: erythrocyte count, leucocyte count, haemoglobin, haematocrit, blood serum protein, leucocyte composition
- Clinical chemistry: S-GOT, S-GTP, S-AlP (alkali phosphatase), bilirubin, blood glucose, BUN, cholesterol, A/G, potassium, sodium, chloride.
- Urinalysis: performed at the end of the study. pH, sugar (assumed to be glucose), protein, ketone, blood concentration, urobilinogen.
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Macroscopic: liver, kidney, spleen, suprarenal glands, thymus, thyroid glands, testicles, pituitary glands, heart, lung, brain, ovary.
- Microscopic: liver, kidney, spleen, suprarenal glands, thyroid glands, testicles, pituitary glands, heart, lung, brain, pancreas, thymus, ovary, stomach, duodenum, jejenum, ileum, cecum, rectum, urinary bladder, prostate, uterus, arteries, lymphatic glands, bone marrow and mammary glands were fixed in 10% formalin, packed in paraffin, cut into thin sections, subjected to haematoxylin and eosin staining and examined microscopically.
OTHER EXAMINATIONS: after 6 and 12 months of the exposure period, necropsy was performed on 6 males and six females from each group. Animals that died during the exposure period were necropsied. Liver tissue was prepared for examination by light microscope and electronmicroscope by cutting it into thin slices, which were fixed with 2% glutaraldehyde and thereafter fixed with 2% osmic acid solution. After dehydration with ethanol the fixed tissue specimen was packed in Epon 812, before subjecting to uranyl acetate and lead nitrate staining.
OTHER: Combined chronic toxicity/carcinogenicity study. The study was ended after 14 months instead of 2 years, due to high mortality.
STATISTICAL METHODS: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: the test substance was sodium metasilicate with an unknown concentration.

Reliability: (3) invalid
High mortality in all groups from month 6 onwards, including control.

22-JAN-2004 (18) (45)

5.8.1 Toxicity to Fertility

5.8.2 Developmental Toxicity/Teratogenicity

Species:	mouse	Sex: male/female
Strain:	other: JLC-TCR	
Route of administration:	gavage	
Exposure period:	17-18 days	
Frequency of treatment:	daily	
Duration of test:	18 days	
Doses:	12.5, 50 or 200 mg/kg bw/d, 10 ml/kg	
Control Group:	yes	

Method: other
Year: 1980
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: 10 animals/cage were raised until mating. Mating was performed with 1 female and 1 male. Males were kept individually beginning 1 week before mating. After mating, animals were kept individually. The gestation period was determined by identifying the vaginal plug as day "zero" of pregnancy. The pregnant animals were randomly divided into 4 groups receiving volumes of 10 ml/kg bw of water (control), 12.5, 50 and 200 mg/kg bw sodium metasilicate by gavage. Treatment was repeated daily from day "zero" until day "seventeen". After 18 days of pregnancy, the animals were killed, the uteri removed and the following examinations carried out: counting of nidations, corpi lutei and living/dead fetuses; weighing of living fetuses and important organs, sex determination, examination of integument anomalies, naked eye examination of other changes. The living fetuses of 5 mothers, randomly chosen from each group, were fixed with Bouin's fixative for examinations of inner organs. The living fetuses of the other mothers were fixed using 95% ethanol followed by staining with Alizarin Red S for examination of skeleton anomalies.
10 pregnant mice were allowed to deliver their young naturally. After parturition, neonates were arranged in groups of 8 randomly chosen neonates born by the same mother (if possible four male and four female/group) and nursed for 30 days. Parameters evaluated were: number of neonates, parturition failures, body weight gain, behavioral development in the Running and Rod Grasping Test (see below) and skeletal development. The weight of the main organs was determined in both mothers and neonates.
Running Test: animals were placed on their backs on a plane inclined at 45° and their reaction classified into four patterns: animal fell down immediately; stayed motionless on the center; turned 90° and moved to the right or to the left; turned and moved to the top.
Rod Grasping Test: the animals were gently held by their tails and lowered until their forefeet touched a fixed rod, when they were released. The time was measured from touching the rod until the animals fell from the rod. This test was conducted three times with each animal on the 6th, 8th, 10th and 14th day after birth.
DEVIATIONS FROM GUIDELINE: no guideline test
GLP: no
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported

Result: LOAEL: not possible to establish
ACTUAL DOSE RECEIVED BY DOSE LEVEL BY SEX: not reported
TOXIC RESPONSE/EFFECTS BY DOSE LEVEL:
- Parental data and F1:
- Body weight: no treatment-related effects were observed in either mother animals, fetuses delivered by hysterectomy or neonates.
- Food/water consumption: not reported
- Description, severity, time of onset and duration of clinical signs: not reported
- Fertility index:

Dose [mg/kg bw/d]	pregnancies/mated female	% pregnancies
0 (control)	20/26	77%
12.5	22/24	92%
50	20/31	65%
200	21/25	84%

- Precoital interval: not reported
- Duration of gestation: 18 days
- Gestation index: not reported
- Changes in lactation: not reported
- Changes in estrus cycles: not reported
- Effects on sperm: not reported
- Hematological findings incidence and severity: not reported
- Clinical biochemistry findings incidence and severity: not reported
- Mortality: 2/27 females administered 50 mg/kg and 2/33 females administered 200 mg/kg died during the exposure period. In one female of the highest dose group all fetuses died at an early stage. No parturition fatalities were observed when mothers were allowed to deliver their young naturally.
- Gross pathology incidence and severity: observed skeletal malformations in neonates like cervical vertebrae, tail vertebrae and vomer adhesion occurred in the controls, too, and did not show a dosage correlation. No malformations of the skeleton or the inner organs of fetuses delivered by hysterectomy were observed; the frequency of malformations and abnormalities of the external integument, like opened eyes, cleft palate and exencephaly showed a slight tendency toward dose dependance, but it was lower than in the control. No effects on main organs of both mothers and neonates as compared to controls.
- Number of implantations: not reported
- Number of corpora lutea: No significant differences between control and test groups, but actual numbers not reported.
- Ovarian primordial follicle counts: not reported
- Organ weight changes: No treatment-related effects of organ weights of mother animals and neonates; not reported for fetuses delivered by hysterectomy.
- Histopathology incidence and severity: not examined
- Offspring toxicity F1:
- Litter size and weights: There was a dose-related, but not statistically significant decrease in litter size.

Dose [mg/kg bw/d]	average no. of neonates/litter
0 (control)	14.7 +- 2.4
12.5	13.8 +- 2
50	12.9 +- 2
200	12.8 +- 2

- Sex and sex ratios: not reported
- Viability index:
- Post natal survival until weaning: no treatment-related effects on body weight gain.
- Effects on offspring: a dose-related, but not statistically significant decrease in embryo weight and delayed ossification process was observed.
- Postnatal growth, growth rate: no treatment related effects
- Other observations: no treatment-related effects in the Running Test and the Rod Grasping Test.

STATISTICAL RESULTS: not reported

Test condition: TEST ORGANISMS: Well developed males and females 8-13 weeks of age and 27-35 g/animal.
ADMINISTRATION / EXPOSURE
- Type of exposure: gavage
- Duration of test/exposure: day 0 to 17/18 of gestation
- Treatment: daily exposure by gavage
- Control group and treatment: drinking water was used as control
- Vehicle: distilled water
- Concentration in vehicle: not reported
- Total volume applied: 10 ml/kg bw
- Doses: 12.5, 50 or 200 mg/kg
MATING PROCEDURES: 1 male was caged with each female until a vaginal plug was observed, at which time the female was housed in a separate cage.
STANDARDIZATION OF LITTERS: after parturition the neonates were counted, and arranged into groups of 8 randomly chosen individuals born by the same mother (preferably 4 males and 4 females), for an unknown number of females from each group.
PARAMETERS ASSESSED DURING STUDY P AND F1:
- Clinical observations: registered daily
- Estrous cycle: not reported
- Sperm examination: not reported
PARAMETERS ASSESSED DURING STUDY F1 AND F2: not applicable
OFFSPRING: a running test on an inclined plane and a rod grasping test were conducted on day 6, 8, 10 and 14 after birth, to assess development.
ORGANS EXAMINED AT NECROPSY (MACROSCOPIC AND MICROSCOPIC):
- Organ weights P and F1: reported for F1 individuals only, 30 days after birth
- Histopathology P and F1: on day 30 after birth the offspring were necropsied and the skeletons stained and examined for anomalies.
OTHER EXAMINATIONS: not reported
STATISTICAL METHODS: not reported
Test substance: SOURCE: not reported
PURITY: not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: the test substance was sodium metasilicate, 20% aqueous solution.
Reliability: (2) valid with restrictions
No tables provided with report; results only discussed qualitatively. Therefore, limited amount of information available.
Flag: Critical study for SIDS endpoint
01-AUG-2003 (45)

5.8.3 Toxicity to Reproduction, Other Studies

Type: other: male and female reproduction organs
In Vitro/in vivo: In vivo
Species: rat
Strain: Wistar Sex: male/female
Route of administration: drinking water
Exposure period: 3 months
Frequency of treatment: ad libitum
Duration of test: 3 months
Doses: 200, 600 and 1800 ppm
Control Group: yes, concurrent vehicle
Result: no effects on reproductive organs upon macroscopic

and microscopic examination

Remark: For further details on this study see chapter 5.4
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
28-NOV-2003 (19)

Type: other: male and female reproduction organs
In Vitro/in vivo: In vivo
Species: mouse
Strain: other: ddy-SLC Sex: male/female
Route of administration: drinking water
Exposure period: 3 months
Frequency of treatment: ad libitum
Duration of test: 3 months
Doses: 300, 900, 2700 ppm (males), 333, 1000, 3000 ppm (females)
Control Group: yes, concurrent vehicle
Result: no effects on reproductive organs upon microscopic examination and wet weight determination

Remark: For further details on this study see chapter 5.4
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
28-NOV-2003 (45)

5.9 Specific Investigations

5.10 Exposure Experience

Type of experience: Direct observation, poisoning incidents

Remark: Ingestion of 500 ml of an egg-preserving solution containing
sodium silicate in suicidal intention led to death of a 68 year old woman within 1 hour by suffocation. Aspiration of the vomited silicate solution caused obstruction of the lungs by precipitation of amorphous silica. The transformation of sodium silicate from liquid to solid occured in the lungs by means of the carbonic acid of expiration air.
Test substance: Although the authors state that sodium metasilicate was used (in form of an egg preserving solution from a local
drug store), the relative low pH of 12.5 makes it more likely that a silicate solution of a molar ratio of greater than 1.0 was ingested. Moreover, egg preservatives typically
contain 5-36% of 3.2 SiO2/Na2O silicate (Schleyer & Blumberg, 1982).
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
21-NOV-2003 (48) (51)

5.11 Additional Remarks

Remark: The average intake of silicon is 20-50 mg total Si/d (Pennington, 1991). An estimation of 0.31 mg Si/kg bw/d in females and 0.53 mg Si/kg bw/d in males made in an American study, is representative for the intake in the Western world. While the highest concentrations of total silicon are found in seafood, eggs and diary products; the main dietary sources are cereals and beverages.

05-FEB-2003 (39)

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I U C L I D

D a t a S e t

Existing Chemical	ID: 10213-79-3
CAS No.	10213-79-3
Substance name	disodium metasilicate pentahydrate
Synonym	Silicic acid (H2SiO3), disodium salt, pentahydrate
Molecular Formula	H2O3Si.5H2O.2Na

Producer Related Part	
Company:	Cognis Deutschland GmbH
Creation date:	23-JAN-2004
Substance Related Part	
Company:	Cognis Deutschland GmbH
Creation date:	23-JAN-2004
Memo:	Dataset of CEES Soluble Silicates Consortium

Printing date:	22-NOV-2004
Revision date:	
Date of last Update:	23-JAN-2004

Number of Pages:	2

Chapter (profile):	Chapter: 1.0.1, 1.1.1
Reliability (profile):	Reliability: without reliability, 1, 2, 3, 4
Flags (profile):	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 Applicant and Company Information

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Remark: CEES, the Centre Europeen d'Etude des Silicates is a sector group of CEFIC and unites the Western European producers of silicates.
The Soluble Silicates Consortium is represented by the following companies:

Asahi Glass Co., Ltd. (JP)
Chimibase (IT)
Cognis Deutschland GmbH (DE)
FMC Foret SA (ES)
Industria Chimica Vera (IT)
Industrias Químicas del Ebro SA (ES)
Ineos Silicas Ltd (UK)
Ingessil (IT)
PQ Europe (NL)
Rhodia SA (FR)
Sasol Italy SpA (IT)
Silmaco NV (BE)
Solvay S.A. (BE)
Tokuyama Corp. (JP)
van Baerle & Cie (CH)
van Baerle GmbH (DE)
Woellner Silikat GmbH (DE)

23-JAN-2004

1.1.1 General Substance Information

Purity type:	typical for marketed substance
Substance type:	inorganic
Physical status:	solid
Purity:	ca. 57 - % w/w
Colour:	colourless or white granules

Remark: Sodium metasilicate pentahydrate is part of the ICCA HPV-category 'Soluble Silicates' and differs from anhydrous sodium metasilicate, CAS 6834-92-0 only by its water of hydration. In view of the close chemical relationship and the fact that only few data exist for the pentahydrate itself, these data are incorporated in the IUCLID data set of anhydrous sodium metasilicate, CAS 6834-92-0. Wherever data of the pentahydrate are mentioned in this data set, it is explicitly noted.
The water content is 43%

23-JAN-2004

I U C L I D

D a t a S e t

Existing Chemical ID:	13517-24-3
CAS No.	13517-24-3
Substance name	Sodium metasilicate nonahydrate
Synonym	Silicic acid (H2SiO3), disodium salt, nonahydrate
Molecular Formula	H2O3Si.9H2O.2Na

Producer Related Part
Company: Cognis Deutschland GmbH
Creation date: 23-JAN-2004

Substance Related Part
Company: Cognis Deutschland GmbH
Creation date: 23-JAN-2004

Memo: Dataset of CEES Soluble Silicates Consortium

Printing date: 23-NOV-2004
Revision date:
Date of last Update: 23-JAN-2004

Number of Pages: 2

Chapter (profile): Chapter: 1.0.1, 1.1.1
Reliability (profile): Reliability: without reliability, 1, 2, 3, 4
Flags (profile): Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 Applicant and Company Information

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Remark: CEES, the Centre Europeen d'Etude des Silicates is a sector group of CEFIC and unites the Western European producers of silicates.
The Soluble Silicates Consortium is represented by the following companies:

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Chimibase (IT)
Cognis Deutschland GmbH (DE)
FMC Foret SA (ES)
Industria Chimica Vera (IT)
Industrias Químicas del Ebro SA (ES)
Ineos Silicas Ltd (UK)
Ingessil (IT)
PQ Europe (NL)
Rhodia SA (FR)
Sasol Italy SpA (IT)
Silmaco NV (BE)
Solvay S.A. (BE)
Tokuyama Corp. (JP)
van Baerle & Cie (CH)
van Baerle GmbH (DE)
Woellner Silikat GmbH (DE)

23-JAN-2004

1.1.1 General Substance Information

Purity type:	typical for marketed substance
Substance type:	inorganic
Physical status:	solid
Purity:	ca. 43 - % w/w
Colour:	colourless or white granules

Remark: Sodium metasilicate nonahydrate is part of the ICCA HPV-category 'Soluble Silicates' and differs from anhydrous sodium metasilicate, CAS 6834-92-0 only by its water of hydration. In view of the close chemical relationship and the fact that only few data exist for the pentahydrate itself, these data are incorporated in the IUCLID data set of anhydrous sodium metasilicate, CAS 6834-92-0. Wherever data of the pentahydrate are mentioned in this data set, it is explicitly noted.
The water content is 57%

23-JAN-2004

I U C L I D

D a t a S e t

Existing Chemical	ID: 1312-76-1
CAS No.	1312-76-1
EINECS Name	Silicic acid, potassium salt
EC No.	215-199-1
TSCA Name	Silicic acid, potassium salt
Producer Related Part	
Company:	Cognis Deutschland GmbH
Creation date:	03-FEB-2003
Substance Related Part	
Company:	Cognis Deutschland GmbH
Creation date:	03-FEB-2003
Memo:	Dataset of CEES Soluble Silicates Consortium
Printing date:	22-NOV-2004
Revision date:	
Date of last Update:	21-OCT-2004
Number of Pages:	49
Chapter (profile):	Chapter: 1, 2, 3, 4, 5
Reliability (profile):	Reliability: without reliability, 1, 2, 3, 4
Flags (profile):	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 Applicant and Company Information

Type:	lead organisation
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Remark: CEES, the Centre Europeen d'Etude des Silicates is a sector group of CEFIC and unites the Western European producers of silicates.
The Soluble Silicates Consortium is represented by the following companies:

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Rhodia SA (FR)
Sasol Italy SpA (IT)
Silmaco NV (BE)
Solvay S.A. (BE)
Tokuyama Corp. (JP)
van Baerle & Cie (CH)
van Baerle GmbH (DE)
Woellner Silikat GmbH (DE)

21-NOV-2003

1.0.2 Location of Production Site, Importer or Formulator

1.0.3 Identity of Recipients

1.0.4 Details on Category/Template

1.1.0 Substance Identification

IUPAC Name:	Silicic acid, potassium salt
Smiles Code:	not applicable
Mol. Formula:	K2O · nO2Si
Mol. Weight:	248.44 (tetrapotassium orthosilicate)

Remark: Soluble silicates are generally not distinct stoichiometric chemical substances (with a specific chemical formula and molecular weight), but rather glasses or aqueous solutions of glasses.
For common silicates structural formulae are complex: monomer, linear or planar cyclic oligo-, and three-dimensional

polysilicate anions with potassium cations as counterions.
04-DEC-2003

1.1.1 General Substance Information

Purity type: typical for marketed substance
Substance type: inorganic
Physical status: solid
Purity: >= 99 - % w/w
Colour: Translucent, blue-greenish or yellow-brownish

Remark: Potassium silicate (potassium waterglass) is commercially provided as lumps, powders, and concentrated or diluted solutions. The purity given refers to the dry matter.

Potassium silicate is either made by high temperature fusion of silica sand (SiO2) and potash (K2CO3) at about 1300 degr. C., or by a hydro-thermal process using silica sand and potassium hydroxide as raw materials.

Solutions, which are the predominantly used form of soluble silicates, are prepared by solubilization of waterglass lumps in water at elevated temperature and pressure. Their water content lies mainly between 45% and 80%.

Powders are prepared by spray- or drum-drying of waterglass solutions. The residual water content can be between 0 - 25%.
Soluble silicates are characterized by the ratio of SiO2 versus Na2O (sodium silicates) or versus K2O (potassium silicates). For example, a potassium silicate solution, containing 21,5% SiO2 and 8.6% K2O would be said to have a weight ratio of 2.5. Weight ratios of potassium silicates can be converted to molar ratios by multiplication with 1.568.
The colour depends on the presence of iron ions: Fe 2+ will cause a blue-greenish colour, whereas Fe 3+ or Fe sulfides leads to a yellow-brownish colour of the silicate lumps.
The index x, equivalent to the quotient

$$\frac{\text{moles (SiO2)}}{\text{moles (K2O)}}$$

is generally defined as the molar ratio (silica/alkali).
12-DEC-2003 (3) (9) (12)

1.1.2 Spectra

1.2 Synonyms and Tradenames

Potassium polysilicate

09-JAN-2002

Potassium silicate

21-MAR-1994

Potassium waterglass

21-MAR-1994

Silicic acid, potassium salt

07-OCT-1994

Soluble potash glass

21-MAR-1994

Soluble potash waterglass

12-NOV-2002

1.3 Impurities

Purity type: typical for marketed substance

Remark: Impurities stem from the quartz sand used rather than from potash. Therefore, impurities of potassium silicates are similar to sodium silicates of comparable molar ratios. The following impurities were reported for sodium silicate lumps of weight ratio 3.35 (molar ratio 3.46):

Na2SO4: 0.06%
NaCl: 0.06%
Fe2O3: 0.033%
Al2O3: 0.097%
CaO: 0.03%
MgO: 0.02%
TiO2: 0.019%

Reliability: (4) not assignable
Review article only

Flag: Critical study for SIDS endpoint

03-DEC-2003 (9)

Purity type: typical for marketed substance

Remark: Soluble silicates are very pure substances with impurities less than 1%. The impurities stem from the quartz sand used rather than from the potash or soda components of the fusion mixture. Therefore, impurities of potassium silicates are similar to sodium silicates of comparable molar ratios.

Result: Composition range of a typical sodium silicate solution of weight ratio 3.3 (molar ratio 3.4):

Li	0.2-0.5
K	20-50
Mg	5-20
Ca	1-80
Sr	1-5
Ba	<1-5
Al	50-200
P	<1-10
S	10-30
Ti	30-80

	V	0.1-0.8
	Cr	<1
	Mn	<0.5-1
	Fe	25-100
	Co	<1
	Ni	<0.5
	Cu	<0.1-0.2
	Zn	<0.2-1
	La	0.2-1
	Ce	<0.3-2
	Zr	5-20
	W	<1-25 all contents in ppm

Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
03-DEC-2003 (10)

1.4 Additives

1.5 Total Quantity

Quantity: ca. 21600 tonnes produced in 2000

Remark: Quantity expressed in metric tonnes of SiO2
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
04-DEC-2003 (26)

1.6.1 Labelling

Labelling: provisionally by manufacturer/importer

Remark: The labelling of soluble silicates is governed by their molar ratio and concentration. Irritation is inversely correlated with the molar ratio (MR); it decreases with increasing MR. This inverse correlation is superimposed by the effect of concentration: higher concentrations cause higher irritation. However, there is a concentration limit above which silicate solutions become too viscous to be handled and turn into an intractable elastic mass. Typically, commercial silicate solutions have a solids content as high as can be conveniently handled at ordinary temperatures. This maximum concentration depends critically on the molar ratio of the silicate solution. By way of example, the typical marketed concentrations for some sodium silicate solutions of different molar ratios are as follows:

MR	Mean total solids [%]
1.65	47-53
2.1	42-54
2.6	44
2.8	46
3.3	36-40
3.5	36
4	28

Having in mind the maximum marketable concentrations of silicate solutions, the labelling of silicates is primarily dictated by the molar ratio.
There are numerous soluble silicate brands of varying molar ratios and concentrations from many different producers on the market. For specific labelling of a given product, the respective safety data sheet should be consulted. Generally, silicates with molar ratios 1.6 or lower are labelled as corrosive (R 34). Above MR 1.6 the labelling varies depending on the molar ratio and concentration from R 38, 41 to R 36/38. Solutions of MR > 3.2 and concentrations below 40% are not classified as dangerous. In addition, spray-dried powders should be labelled with R 37 (irritating to respiratory system) in combination with the above-mentioned R-phrases.

23-JAN-2004

1.6.2 Classification

1.6.3 Packaging

1.7 Use Pattern

Type: type
Category: Non dispersive use

04-FEB-2003

Type: type
Category: Use resulting in inclusion into or onto matrix

04-FEB-2003

Type: type
Category: Wide dispersive use

04-FEB-2003

Type: industrial
Category: Paints, lacquers and varnishes industry

04-FEB-2003

Type: industrial
Category: Personal and domestic use

21-JAN-2004

Type: industrial
Category: Photographic industry

15-DEC-2003

Type: industrial
Category: Public domain

15-DEC-2003

Type: use
Category: Adhesive, binding agents

15-DEC-2003 (37)

Type: use
Category: Cleaning/washing agents and disinfectants

15-DEC-2003 (6) (11) (37) (38)

Type: use
Category: Construction materials additives

Remark: Component of plasters and silicate-based impregnations in the building industry.
15-DEC-2003 (25)

Type: use
Category: Fertilizers

15-DEC-2003 (38)

Type: use
Category: Impregnation agents

15-DEC-2003 (6) (38)

Type: use
Category: Non agricultural pesticides

15-DEC-2003 (6) (38)

Type: use
Category: Photochemicals

15-DEC-2003 (6) (11) (38)

Type: use
Category: Welding and soldering agents

Remark: Carrier in welding rods
15-DEC-2003 (2) (25) (38)

Type: use
Category: other: car-care product

15-DEC-2003 (38)

Type: use
Category: other: cleaning agent in food and beverage industry

15-DEC-2003 (6)

Type: use
Category: other: paint additive

15-DEC-2003 (6) (11) (25) (37) (38)

1.7.1 Detailed Use Pattern

1.7.2 Methods of Manufacture

1.8 Regulatory Measures

1.8.1 Occupational Exposure Limit Values

Remark: No specific exposure limits have been established for alkali silicates.
For liquids the creation of aerosols should be avoided. For powders, general dust exposure limits according to national regulations, (typically from 6 to 10 mg/m3) will apply. For corrosive alkali silicates (MR </=1.6) the exposure limits set for sodium hydroxide NaOH (2 mg/m3) should be considered as a guideline.
Potassium silicates have not been given an Occupational Exposure Limit value.
16-DEC-2003 (2)

1.8.2 Acceptable Residues Levels

1.8.3 Water Pollution

Classified by: KBwS (DE)
Class of danger: 1 (weakly water polluting)

Reliability: (2) valid with restrictions
Official german classification
08-JAN-2004 (22)

1.8.4 Major Accident Hazards

1.8.5 Air Pollution

1.8.6 Listings e.g. Chemical Inventories

1.9.1 Degradation/Transformation Products

1.9.2 Components

1.10 Source of Exposure

Source of exposure: Human: exposure by production
Exposure to the: Substance

Remark: Accidental human exposure may occur during production and processing of silicates. No measured data are available.
21-OCT-2004

Source of exposure: Human: exposure through intended use

Exposure to the: Substance

Remark: Applications were exposure is possible: construction materials additives (component of plasters and silicate-based impregnations) and house paints (additive). From the use patterns listed in chapter 1.7 it can be inferred that accidental human exposure may occur during professional downstream use of silicates. No measured data are available.
21-OCT-2004

Source of exposure: Human: exposure of the consumer/bystander
Exposure to the: Substance

Remark: Applications were exposure is possible: cleaning/washing agents.
From the use patterns listed in chapter 1.7 it can be inferred that accidental human exposure can occur during consumer use of washing and cleaning agents containing silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure from production
Exposure to the: Substance

Remark: Accidental environmental exposure may occur during production of silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure from formulation
Exposure to the: Substance

Remark: Accidental environmental exposure may occur during formulation of products containing silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure from processing
Exposure to the: Substance

Remark: Accidental environmental exposure may occur during processing of silicates. No measured data are available.
21-OCT-2004

Source of exposure: Environment: exposure through private use
Exposure to the: Substance

Remark: Applications were exposure is possible: cleaning/washing agents.
From the use patterns listed in chapter 1.7 it can be inferred that environmental exposure will occur during the use of consumer products containing silicates. No measured data are available.
21-OCT-2004

1.11 Additional Remarks

1.12 Last Literature Search

1.13 Reviews

2.1 Melting Point

Value: >= 900 degree C

Remark: Due to their glass nature, solid amorphous silicates do not have discrete melting points but rather flow points. They reversibly solidify and soften within a broad temperature range depending on their molar ratio. Potassium silicate lumps start to soften at 700°C and reach the flow point at 900°C. Aqueous silicate solutions have a melting point only slightly lower than that of water.
Reliability: (4) not assignable
Collection of data
16-DEC-2003 (9)

Value: 905 degree C
Decomposition: no at degree C

Remark: Due to their glass nature, solid amorphous silicates do not have discrete melting points but rather flow points. They reversibly solidify and soften within a broad temperature range depending on their molar ratio. The given value relates to the flow point. The softening point is 700°C.
Test substance: Potassium silicate anhydrous glass of molar ratio 3.92
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
20-OCT-2004 (10)

2.2 Boiling Point

Value:

Remark: The determination of a boiling point is not practical for solid anhydrous silicates as they are glasses with high melting points. The boiling point of silicate solutions on the other hand will be primarily determined by the water present and thus will not differ significantly from the boiling point of water.
30-SEP-2004

2.3 Density

Type: density
Value: ca. 1.25 - 1.42 g/cm³ at 20 degree C

Remark: Density depends on solids content and molar ratio of sodium silicate solutions.
Test substance: Potassium silicate solutions
Reliability: (4) not assignable
Manufacturers data without proof and collection of data.
Flag: Critical study for SIDS endpoint
20-OCT-2004 (12) (21)

Type: density

Value: 1.26 - 1.49 g/cm³ at 20 degree C

Test substance: Potassium silicate solutions; molar ratios between 3.93 and 2.83
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
20-OCT-2004 (10)

Type: density
Value: 1.26 - 1.6 g/cm³ at 20 degree C

Test substance: Potassium silicate solutions; molar ratios between 3.89 and 2.24
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
20-OCT-2004 (27)

Type: bulk density
Value: ca. 750 kg/m3 at 20 degree C

Test substance: Spray-dried powder of potassium silicate solution of molar ratio 3.1. Ca. 16% residual water.
Reliability: (4) not assignable
Manufacturers data without proof.
Flag: Critical study for SIDS endpoint
20-OCT-2004 (33)

2.3.1 Granulometry

2.4 Vapour Pressure

Remark: The vapour pressure at environmental temperatures is negligibly low and thus not relevant.
The vapour pressures of potassium silicates have not been determined, but they are not expected to vary significantly from those established for the respective sodium silicates:

molar ratio (SiO2:Na2O)	vapour pressure	at °C
1.0	0.0103 hPa	1175
2.0	0.0031 hPa	1165
3.0	0.0016 hPa	1172

Reliability: (2) valid with restrictions
Well-documented scientific publication.
08-JAN-2004 (24)

2.5 Partition Coefficient

Remark: Alkali silicates are totally insoluble in n-octanol (as for most other organic solvents). The oil/water partition coefficient of these substances (as normally determined with

n-octanol/water) is therefore not applicable or relevant.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
Flag: Critical study for SIDS endpoint
20-OCT-2004 (2)

Remark: Potassium silicates are insoluble in alcohol indicating that this would also apply to n-octanol. The oil/water partition coefficient (as normally determined with n-octanol/water) is therefore not applicable or relevant.
Reliability: (2) valid with restrictions
Peer-reviewed handbook data.
Flag: Critical study for SIDS endpoint
20-OCT-2004 (1)

2.6.1 Solubility in different media

Solubility in: Water

Remark: Potassium silicate is very slowly soluble in cold water or, depending on the composition, almost insoluble. More readily soluble in water when heated with it under pressure.
Reliability: (2) valid with restrictions
Peer-reviewed handbook data.
Flag: Critical study for SIDS endpoint
19-OCT-2004 (1)

Solubility in: Water

Remark: Solid potassium silicate (lumps or ground glass) is practically insoluble in water at ambient temperature and pressure. Solutions containing up to 41% solids in water can be achieved at elevated temperature and pressure. They are stable at room temperature.
Reliability: (4) not assignable
Manufacturers data without proof.
21-OCT-2004 (21)

Solubility in: Water
Value: 115 mg/l at 25 degree C

Remark: Amorphous silica which precipitates when alkaline silicate solutions are neutralized has a water solubility of 115 mg/l at 25°C and neutral pH.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
03-DEC-2003 (28)

Solubility in: other: alcohol

Remark: Insoluble in alcohol.
Reliability: (2) valid with restrictions
Peer-reviewed handbook data.

Flag: Critical study for SIDS endpoint
17-DEC-2003 (1)

pH value: 11 - 13

Remark: Alkaline silicates are completely insoluble in n-octanol. The pH in alkaline silicates is dependant on the silica to alkali ratio and the concentrations of the individual solutions. Concentrated solutions usually have a pH between 10 and 13.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
Flag: Critical study for SIDS endpoint
21-OCT-2004 (2)

Remark: Powders obtained by water evaporation from solutions are readily soluble in water at room temperature due to their residual water content of about 20%.
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
21-OCT-2004 (10) (27)

Remark: Soluble silicates are incompatible with most organic compounds.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (27)

Remark: Potassium silicate flake glass of molar ratio 3.9 dissolves readily in water at ca. 88°C without pressure by incremental addition of glass to water.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (10)

2.6.2 Surface Tension

2.7 Flash Point

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
21-OCT-2004 (2)

2.8 Auto Flammability

Value:

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (2) (27)

2.9 Flammability

Result: non flammable

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (2) (27)

2.10 Explosive Properties

Result: not explosive

Remark: Soluble silicates are inorganic substances. They are not combustible, self-igniting or explosive.
Reliability: (4) not assignable
Handbook data
21-OCT-2004 (2) (27)

2.11 Oxidizing Properties

Result: no oxidizing properties

Remark: Soluble silicates have no oxidizing properties.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
21-OCT-2004 (2)

2.12 Dissociation Constant

2.13 Viscosity

Value: = 50 - 280 mPa s (dynamic) at 20 degree C

Remark: In addition to the temperature, the viscosity of a potassium silicate solution depends to a large degree on the concentration and the molar ratio SiO2/K2O.

For typical commercial silicate solutions the following viscosities are observed:

Solids content %	Molar ratio SiO2/K2O	Viscosity mPa.s at 20°C
29.1	4.06	50

	34.4	3.46	45
	39.5	3.28	950 (at 25°C)
	40.5	3.14	280
	41.1	2.87	45

Reliability: (4) not assignable
Collection of data
19-DEC-2003 (12)

Value: 30 - 200 mPa s (dynamic) at 20 degree C

Remark: In addition to the temperature, the viscosity of a potassium silicate solution depends to a large degree on the concentration and the molar ratio SiO2/K2O.

Viscosities reported for typical commercial silicate solutions:

Total solids wt %	Molar ratio SiO2/K2O	Viscosity mPa.s at 20°C
29.9	3.89	180
34.8	3.21	30
52.4	2.24	200

Reliability: (4) not assignable
Handbook data
21-OCT-2004 (27)

2.14 Additional Remarks

3.1.1 Photodegradation

Remark: The basic structural unit of soluble silicates is a tetrahedral arrangement of four oxygen atoms surrounding a central silicon atom. Tetrahedra are linked with each other via Si-O-Si bonds resulting in an infinite three-dimensional network where the oxygen atoms at the corners of a given tetrahedron are shared with neighbouring tetrahedra. Not all corners in the tetrahedra are shared; the negative charge of unshared oxygen atoms is balanced by the presence of sodium or potassium cations which are randomly spaced in the interstices of the silicate structure.
Based on these structural considerations a significant breakdown of soluble silicates via photodegradation is not expected.
Reliability: (2) valid with restrictions
Expert judgement
26-JAN-2004 (4)

3.1.2 Stability in Water

Remark: Polymerisation-Depolymerisation:
Upon dilution of concentrated commercial silicate solutions with water, the highly cross-linked polysilicate ions depolymerize rapidly to monosilicate ions, the extent of depolymerisation depending on the dilution factor.
Reliability: (2) valid with restrictions
Acceptable procedure and publication
18-DEC-2003 (29)

Remark: The basic consideration is that silica dissolves according to : $SiO_2 + H_2O = Si(OH)_4$. At low concentrations most species are present as monomers, at higher concentrations polymerisation will occur.
Most soluble silicates are in the form:
$M_2O \cdot mSiO_2 \cdot nH_2O$
where M = alkali metal, predominantly Na, but also K. The index m (molar ratio) ranges between 0.5 - 4, most commonly m = 3.3. Stability depends to a large extent on pH, above pH 10.6 the solutions are chemically stable. The increase of ionic strength accelerates nucleation and deposition and decreases the SiO_2 solubility. Coating of surfaces by organic matter may hamper dissolution, but at the same time $Si(OH)_4$ may form complexes with organic matter, a process which favours dissolution.
Reliability: (4) not assignable
Handbook data
18-DEC-2003 (10)

3.1.3 Stability in Soil

3.2.1 Monitoring Data (Environment)

Type of measurement: background concentration
Medium: other: surface-, ground- or drinking water

Remark: Dissolved silica from commercial soluble silicates is indistinguishable from natural dissolved silica since depolymerisation of polysilicate anions to monomeric dissolved silica occurs very rapidly when commercial soluble silicate solutions are diluted with water. Therefore any soluble silica input to the natural silica cycle as a result of the production or use of commercial soluble silicates will be insignificant in view of the size and high flux of the natural silica cycle.
Reliability: (2) valid with restrictions
Acceptable procedure and publication
Flag: Critical study for SIDS endpoint
18-DEC-2003 (10) (29) (34)

Type of measurement: background concentration
Medium: ground water
Concentration: ca. 17 mg/l

Remark: The median value in the US was reported to be 17 mg SiO2/l for ground waters.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (7)

Type of measurement: background concentration
Medium: surface water
Concentration: ca. 14 mg/l

Remark: The median value in the US was reported to be 14 mg SiO2/l for streams.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (7)

Type of measurement: background concentration
Medium: surface water
Concentration: ca. 13 mg/l

Remark: The worldwide mean concentration in rivers is 13 mg SiO2/l.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (8)

Remark: Natural occurence:
Compounds of silicon comprise ca. 59% of the earth's crust, constituted by minerals, soils and sediments, dissolved silica, amorphous silica in the solid phase and silica bound to organic matter.

Dissolved silica is a minor but ubiquitous constituent of the hydrosphere. Dissolved silica is supplied to the environment by chemical and biochemical weathering processes.
Reliability: (4) not assignable
Handbook data
Flag: Critical study for SIDS endpoint
18-DEC-2003 (10) (23)

Remark: SiO2 enters surface waters via the four main application areas where emissions to water systems might occur (household detergents, pulp-and paper production, water treatment, and soil stabilisation).
Seen in the context of the natural silica cycle, and natural loading of water systems with silicates due to weathering of soil and rocks, weathering of sediments and atmospheric deposition, this amount is small.
Reliability: (2) valid with restrictions
Well-documented scientific publication.
Flag: Critical study for SIDS endpoint
18-DEC-2003 (34) (39)

3.2.2 Field Studies

3.3.1 Transport between Environmental Compartments

Remark: Due to a strong dependance on pH and concentration which leads to a complex dynamic polymerisation-depolymerisation equilibrium with speciation into a variety of mono-, oligo-, and polymeric anions and amorphous silica, calculations on the distribution in various environmental compartments are not feasible.
The contribution of anthropogenic inputs to the occurrence in the various compartments will be negligible compared to the concentrations contributed to by the natural silica flux.
Reliability: (4) not assignable
Handbook data
19-DEC-2003 (10)

3.3.2 Distribution

Remark: See remark in 3.3.1
18-DEC-2003

3.4 Mode of Degradation in Actual Use

3.5 Biodegradation

Remark: Not applicable (inorganic substance)
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
18-DEC-2003 (2)

3.6 BOD5, COD or BOD5/COD Ratio

Method:
Year:
Method:
Remark: Not applicable (inorganic compound).
Reliability: (4) not assignable

Product brochure of producers association; data without proof.
18-DEC-2003 (2)

3.7 Bioaccumulation

Remark: Soluble silicates have no bioaccumulation potential. There are no structural alerts to suspect such a hazard.
Reliability: (4) not assignable
Product brochure of producers association; data without proof.
08-JAN-2004 (2)

3.8 Additional Remarks

AQUATIC ORGANISMS

4.1 Acute/Prolonged Toxicity to Fish

Type:	static
Species:	Leuciscus idus (Fish, fresh water)
Exposure period:	48 hour(s)
Unit:	mg/l Analytical monitoring: no data
LC0:	= 146
LC50:	> 146
LC100:	> 146
Method:	other: DIN 38412/15, part 15 (Golden orfe, acute toxicity test)
Year:	1976
GLP:	no
Test substance:	other TS

Method: METHOD FOLLOWED: DIN 38412, Teil 15 (Golden orfe, acute toxicity test). The German standard method for the examination of water, waste water and sludge; bioassays (group L); determination of the effect of substances in water on fish-fish test which corresponds to OECD 203 "Fish, acute toxicity test". The original test was performed in 1976.
DEVIATIONS FROM GUIDELINE: no
GLP: The present study was carried out before 1990, i.e. at a time when GLP was not yet implemented
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported

Result: RESULTS:EXPOSED
Nominal/measured concentrations: nominal 500 mg (146 mg active substance)
Effect data (Mortality): no mortality
Effect concentration vs. test substance solubility: not reported
Other effects: fish did not show any abnormal behaviour
RESULTS: CONTROL
No controls performed
RESULTS:TEST WITH REFERENCE SUBSTANCE
No reference substance tested

Test condition: TEST ORGANISMS
- Strain: not reported
- Supplier: not reported
- Wild caught: no
- Age/ /weight/loading: about 6 cm long
- Pretreatment: none
- Feeding during test: no
DILUTION WATER
Hardness: about 16°dH (about 93 mg Ca and 12 mg Mg per litre)
Source: copper and chlorine free drinking water
TEST SYSTEM
- Test type: fish acute toxicity
- Concentrations: 500 mg product/l (nominal)
- Renewal of test solution: no, static test
- Exposure vessel type: fish basins containing 10 l test water
- Number of replicates, fish per replicate: 10 fish per concentration; no replicates

- Test temperature: about 20 °C
- Dissolved oxygen: not reported
- pH: not reported
- Adjustment of pH: not reported
- Intensity of irradiation: not reported
- Photoperiod: about 16 hours illumination per day

DURATION OF THE TEST: 48 hours
TEST PARAMETER : mortality
MONITORING OF TEST SUBSTANCE CONCENTRATION: not reported

Test substance: SOURCE: Henkel KGaA
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: 29.1% potassium silicate, soluble and not volatile at room temperature, molar ratio SiO2/K2O: 3.9-4.1.

Reliability: (2) valid with restrictions
Test procedure according to national standards; report with limited detail.

Flag: Critical study for SIDS endpoint

05-FEB-2003 (32)

4.2 Acute Toxicity to Aquatic Invertebrates

Type: static
Species: Daphnia magna (Crustacea)
Exposure period: 24 hour(s)
Unit: mg/l Analytical monitoring: no data
EC0: = 146
EC50: > 146
EC100: > 146

Method: other: OECD Guide-line 202, part I
Year: 1976
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: OECD 202 part 1
Note that the test was performed before the guideline was approved
DEVIATIONS FROM GUIDELINE: the number of daphnids per concentration were about 20 but not exactly counted and the substance concentration was not followed by chemical analysis.
GLP: The present study was carried out before 1990, i.e. at a time when GLP was not yet implemented.
STATISTICAL METHODS: not reported
METHOD OF CALCULATION: not reported
ANALYTICAL METHODS: not reported

Result: RESULTS:EXPOSED
Nominal/measured concentrations: 500 mg product/l nominal (146 mg active matter/l)
Effect data (Mortality): no mortality at tested concentration
Effect concentration vs. test substance solubility: not reported
Other effects: no adverse effects were observed
RESULTS:CONTROL
No controls performed
RESULTS:TEST WITH REFERENCE SUBSTANCE
No reference substance tested

Test condition: TEST ORGANISMS
- Strain: Daphnia magna Straus, own breed, strain identical with the strain of the Bundesgesundheitsamt/Inst. Wasser-Boden-Luft
- Supplier: Henkel KGaA
- Wild caught: no
- Feeding: algae (Chlorella kessleri)
- Feeding during test: no
STOCK AND TEST SOLUTION AND THEIR PREPARATION:
Stock solution of 10 g test substance/l test medium.
Aliquots of 5 ml were pipetted into 95 ml test medium and distributed into test vessels.
DILUTION WATER
- Hardness: about 14°dH (80 mg Ca and 12.2 mg Mg per litre)
- Salinity: test medium
294 mg/l CaCl2 x 2H2O
123 mg/l MgSO4 x 7H2O
63 mg/l NaHCO3
5.5 mg/l KCl
TEST SYSTEM
- Test type: Daphnia magna acute toxicity
- Concentrations: 500 mg product/l (nominal)
- Renewal of test solution: no, static test
- Exposure vessel type: glass beakers, covered with glass plates
- Number of replicates, animals per replicate: approximately 20 animals per concentration, no replicates
- Test temperature: about 22 °C
- Dissolved oxygen: not reported
- pH: not reported
- Adjustment of pH: not reported
- Intensity of irradiation: not reported
- Photoperiod: about 16 hours photoperiod/day
DURATION OF THE TEST: 24 hours
TEST PARAMETER: Immobilisation
MONITORING OF TEST SUBSTANCE CONCENTRATION: no

Test substance: SOURCE: Henkel KGaA
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: not reported
ANY OTHER INFORMATION: 29.1% potassium silicate, soluble and not volatile at room temperature, molar ratio SiO2/K2O: 3.9-4.1

Reliability: (2) valid with restrictions
Guideline study, but the report details are limited.

Flag: Critical study for SIDS endpoint

05-FEB-2003 (31)

4.3 Toxicity to Aquatic Plants e.g. Algae

4.4 Toxicity to Microorganisms e.g. Bacteria

4.5 Chronic Toxicity to Aquatic Organisms

4.5.1 Chronic Toxicity to Fish

4.5.2 Chronic Toxicity to Aquatic Invertebrates

TERRESTRIAL ORGANISMS

4.6.1 Toxicity to Sediment Dwelling Organisms

4.6.2 Toxicity to Terrestrial Plants

4.6.3 Toxicity to Soil Dwelling Organisms

4.6.4 Toxicity to other Non-Mamm. Terrestrial Species

4.7 Biological Effects Monitoring

4.8 Biotransformation and Kinetics

4.9 Additional Remarks

5.0 Toxicokinetics, Metabolism and Distribution

5.1 Acute Toxicity

5.1.1 Acute Oral Toxicity

Type:	LD50
Species:	rat
Strain:	other: Cpb:Wu, Wistar Random
Sex:	male/female
Vehicle:	no data
Doses:	2.50, 3.00, 3.60, 4.32, 5.20 ml/kg bw
Value:	= 5700 mg/kg bw
Method:	other
Year:	1981
GLP:	no
Test substance:	other TS
Method:	METHOD FOLLOWED: partly in agreement with OECD 401, but performed before OECD guidelines were established DEVIATIONS FROM GUIDELINES: Only survivors were macroscopically examined upon autopsy. The report is very limited in detail. GLP: No, research executed before existence of GLP STATISTICAL METHODS: Not reported METHOD OF CALCULATION: Method of Weil (Biometrics 8 (1952) 249-263) ANALYTICAL METHODS: Not reported
Result:	MORTALITY: - Time of death: deaths occured between 2 hours and 2 days after dosing - Number of deaths at each dose: 1 at dose 2.50 ml/kg, 2 at dose 3.00 ml/kg, 2 at dose 3.60 ml/kg, 3 at dose 4.32 ml/kg and all 10 at dose 5.20 ml/kg. CLINICAL SIGNS: Sedation and signs of discomfort were observed within few hours after treatment and later on sluggishness and unconsciousness were frequently observed. The effects were reversible in the recovery period of the surviving animals. NECROPSY FINDINGS: No treatment-related gross alterations POTENTIAL TARGET ORGANS: Not reported SEX-SPECIFIC DIFFERENCES: Not reported
Test condition:	TEST ORGANISMS: - Source: Central Institute for the Breeding of Laboratory Animals TNO, Zeist, Netherlands - Age: "Young adult albino rats" - Weight at study initiation: 234-314 g (males) and 132-204 g (females) - Controls: not reported 5 animals/sex/dose were tested. ADMINISTRATION: - Doses: 2.50, 3.00, 3.60, 4.32, 5.20 ml/kg bw - Doses per time period: single doses administered - Volume administered or concentration: see doses - Post dose observation period: 14 days EXAMINATIONS: Macroscopic examination of survivors only
Test substance:	SOURCE: Not reported PURITY: Not reported

IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: Kaliwaterglass 35.5/36.5 (ratio 2.25). Density was stated to be 1.32; Clear colourless liquid. Concentration not indicated.
Reliability: (2) valid with restrictions
Test procedure according to national standards; report with limited detail.
Flag: Critical study for SIDS endpoint
05-FEB-2003 (35)

5.1.2 Acute Inhalation Toxicity

5.1.3 Acute Dermal Toxicity

5.1.4 Acute Toxicity, other Routes

5.2 Corrosiveness and Irritation

5.2.1 Skin Irritation

Species: rabbit
Concentration: 29 other: wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 0
Result: not irritating

Method: other: FHSA test specified in 16 C.F.R. 1500.41 et.seq.
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, research executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported.
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: Not reported
- Area of exposure: Intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: Not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Post-exposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS:
- Scoring system: Primary irritation indices, from 1 to 4; sum of intact and abraded scores reported
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported

IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 29 wt% Potassium silicate. Molar ratio of 3.45. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
12-JAN-2004 (34)

Species: rabbit
Concentration: 39 other: wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 2
Result: slightly irritating

Method: other: FHSA test specified in 16 C.F.R. 1500.41 et.seq.
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, research executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported.
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: Not reported
- Area of exposure: Intact and abraded skin
- Occlusion: Yes
- Vehicle: Not reported
- Concentration in vehicle: Not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Post-exposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS:
- Scoring system: Primary irritation indices, from 1 to 4; sum of intact and abraded scores reported
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 39 wt% Potassium Silicate. Molar ratio 3.33. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
04-FEB-2003 (34)

Species: rabbit
Concentration: 85 other: wt%
Exposure: Occlusive
Exposure Time: 24 hour(s)
PDII: 8

Result: highly irritating

Method: other: FHSA test specified in 16 C.F.R. 1500.41 et.seq.
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) test specified in 16 C.F.R. 1500.41 et.seq.
GLP: No, research executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Draize method (1944)
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS: Not reported.
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: Not reported
- Area of exposure: Intact and abraded skin
- Occlusion: yes
- Vehicle: Not reported
- Concentration in vehicle: Not reported
- Total volume applied: 0.5 ml or 0.5 g, not specified
- Post-exposure period: 72 hours
- Removal of test substance: after 24 hours
EXAMINATIONS:
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores reported
- Examination time points: 24 and 72 hours
Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 85 wt% Potassium silicate. Molar ratio 2.5. The article does not specify whether the substance was a dry powder or a liquid. Powders were moistened with physiological saline before application of 0.5 g, while liquids were applied directly in 0.5 ml doses.
Reliability: (4) not assignable
Only secondary literature available (review).
04-FEB-2003 (34)

Species: rabbit
Concentration: 8.8 other:wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
No. of Animals: 3
Vehicle: other: deionised water
PDII: 0
Result: not irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD 404
DEVIATIONS FROM OECD GUIDELINE: No
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Erythema: 0
- Edema: 0
REVERSIBILITY: 48 hours after treatment the effects were no longer present.
OTHER EFFECTS: Very slight erythema was observed 24 and 48 hours after treatment. None of these effects were observed thereafter. This is reported in the summary but not in the table of effects.

Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: 3.0 kg (average)
- Number of animals: 3
- Controls: yes (unexposed skin area on same animal)
ADMINSTRATION/EXPOSURE:
- Preparation of test substance: dilution in deionised water
- Area of exposure: Intact skin (shaved)
- Occlusion: yes
- Vehicle: deionised water
- Concentration in vehicle: 8.75%
- Total volume applied: 0.5 ml
- Post-exposure period: 7 days
- Removal of test substance: yes
IN VITRO TEST SYSTEM: not relevant
EXAMINATIONS:
- Scoring system: according to Draize
- Examination time points: 1, 24, 48, 72 hours and 7 days

Test substance: SOURCE: Woellner-Werke GmbH
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 25% dilution of 35 wt% potassium waterglass. Molar ratio 3.4.

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (19)

Species: rabbit
Concentration: 7 other:wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
No. of Animals: 5
Vehicle: other: deionised water
PDII: 0
Result: not irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1990
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD 404
DEVIATIONS FROM OECD GUIDELINE: 5 animals were tested instead of 3
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported

ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Erythema: 0
- Edema: 0
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: 3.2 kg (average)
- Number of animals: 5
- Controls: yes (unexposed skin area on same animal)
ADMINSTRATION/EXPOSURE:
- Preparation of test substance: dilution in deionised water
- Area of exposure: Intact skin (shaved)
- Occlusion: yes
- Vehicle: deionised water
- Concentration in vehicle: 7%
- Total volume applied: 0.5 ml
- Post-exposure period: 7 days
- Removal of test substance: yes
IN VITRO TEST SYSTEM: not relevant
EXAMINATIONS:
- Scoring system: according to Draize
- Examination time points: 1, 24, 48, 72 hours and 7 days
Test substance: SOURCE: Woellner-Werke GmbH
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 25% dilution of 29 wt% Potassium silicate. Molar ratio 3.9
Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.
Flag: Critical study for SIDS endpoint
25-NOV-2003 (16)

Species: rabbit
Concentration: 35 other:wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
No. of Animals: 3
Vehicle: other: deionised water
PDII: .17
Result: not irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD 404
DEVIATIONS FROM OECD GUIDELINE: No
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Erythema: 0.17
- Edema: 0

REVERSIBILITY: 48 hours after treatment no effects were observed anymore.
OTHER FINDINGS: Slight erythema after 1 hour, neglible erythema after 48 hours

Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: 3.0 kg (average)
- Number of animals: 3
- Controls: yes (unexposed skin area on same animal)
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: the test substance was applied to the skin directly
- Area of exposure: Intact skin (shaved)
- Occlusion: yes
- Vehicle: deionised water
- Concentration in vehicle: 35%
- Total volume applied: 0.5 ml
- Post-exposure period: 7 days
- Removal of test substance: yes
IN VITRO TEST SYSTEM: not relevant
EXAMINATIONS:
- Scoring system: according to Draize
- Examination time points: 1, 24, 48, 72 hours and 7 days

Test substance: SOURCE: Woellner-Werke GmbH
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 35 wt% Potassium Silicate. Molar ratio 3.4

Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (20)

Species: rabbit
Concentration: 33 other:wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 1
Vehicle: water
PDII: 3
Result: moderately irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1985
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD 404
DEVIATIONS FROM OECD GUIDELINE: yes (only 1 animal tested)
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Erythema: 2
- Edema: 1
REVERSIBILITY: The observed effects (well-defined erythema

and very slight oedema) persisted for at least 5 days, the period of observation.
OTHER EFFECTS: Not reported

Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: male
- Source: Cheshire Rabbit Farms Ltd.
- Age: approx. 11 weeks
- Weight at study initiation: 2.3 - 3.0 kg
- Number of animals: 1
- Controls: not reported
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: the test substance was applied directly to the skin
- Area of exposure: Intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: water
- Concentration in vehicle: 33%
- Total volume applied: 0.5 ml
- Post-exposure period: 5 days
- Removal of test substance: yes (washed away with water)
IN VITRO TEST SYSTEM: not relevant
EXAMINATIONS:
- Scoring system: according to Draize
- Examination time points: 1, 24, 48, 72 hours and 5 days

Test substance: SOURCE: EKA Kemi AB
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 33 wt% Potassium Waterglass. Molar ratio 3.0

Reliability: (2) valid with restrictions
Study according to OECD Guideline, but only 1 animal tested.

Flag: Critical study for SIDS endpoint

04-AUG-2003 (5)

Species: rabbit
Concentration: 29 other:wt%
Exposure: Occlusive
Exposure Time: 4 hour(s)
No. of Animals: 5
Vehicle: other: deionised water
PDII: .25
Result: not irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1990
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD 404
DEVIATIONS FROM OECD GUIDELINE: 5 animals tested instead of 3
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE:
- Erythema: 0.25
- Edema: 0
REVERSIBILITY: 24 hours after treatment no effects were observed.

OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS:
- Strain: New Zealand White
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: 3.2 kg (average)
- Number of animals: 5
- Controls: yes (unexposed skin area on same animal)
ADMIISTRATION/EXPOSURE:
- Preparation of test substance: applied as such
- Area of exposure: Intact skin
- Occlusion: yes
- Vehicle: deionised water
- Concentration in vehicle: 29%
- Total volume applied: 0.5 ml
- Post-exposure period: 7 days
- Removal of test substance: yes
IN VITRO TEST SYSTEM: not relevant
EXAMINATIONS:
- Scoring system: Primary irritation indices from 1 to 4; sum of intact and abraded scores reported
- Examination time points: 1, 24, 48 and 72 hours
Test substance: SOURCE: Woellner-Werke GmbH
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 29 wt% Potassium Silicate. Molar ratio 3.9.
Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.
Flag: Critical study for SIDS endpoint
25-NOV-2003 (15)

Species: rabbit
Concentration: 36 other:wt%
Exposure: Semiocclusive
Exposure Time: 4 hour(s)
No. of Animals: 1
Vehicle: water
PDII: 1
Result: slightly irritating

Method: OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year: 1985
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD 404
DEVIATIONS FROM OECD GUIDELINE: yes (only 1 animal tested)
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Erythema: 1
- Edema: 0
REVERSIBILITY: Test sample only elicited transient erythema which was clear by day 5.
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS:

- Strain: New Zealand White
- Sex: female
- Source: Cheshire Rabbit Farms Ltd.
- Age: approx. 11 weeks
- Weight at study initiation: 2.3 - 3.0 kg
- Number of animals: 1
- Controls: not reported

ADMIISTRATION/EXPOSURE:
- Preparation of test substance: applied as such
- Area of exposure: Intact skin (shaved)
- Occlusion: semiocclusive
- Vehicle: water
- Concentration in vehicle: 36%
- Total volume applied: 0.5 ml
- Post-exposure period: 5 days
- Removal of test substance: yes (washed away with water)

IN VITRO TEST SYSTEM: not relevant

EXAMINATIONS:
- Scoring system: according to Draize
- Examination time points: 1, 24, 48, 72 hours and 5 days

Test substance: SOURCE: EKA Kemi AB
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 36 wt% Potassium Waterglass. Molar ratio 2.0

Reliability: (2) valid with restrictions
Study according to OECD Guideline, but only 1 animal tested. No information on purity of test substance.

Flag: Critical study for SIDS endpoint

25-NOV-2003 (5)

5.2.2 Eye Irritation

Species: rabbit
Concentration: 80 other: wt%
Result: highly irritating

Method: other: FHSA Draize method specified in 16 C.F.R. 1500.42
GLP: no
Test substance: other TS

Method: METHOD FOLLOWED: FHSA (Federal Hazardous Substances Act) Draize method specified in 16 C.F.R. 1500.42
GLP: No, research executed before existence of GLP
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported

Result: AVERAGE SCORE: Not reported
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: Not reported
OTHER EFFECTS: Not reported

Test condition: TEST ANIMALS: Not reported
ADMINISTRATION/EXPOSURE: Not reported
IN VITRO TEST SYSTEM: Not applicable
EXAMINATIONS: Not reported

Test substance: SOURCE: Not reported
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 80 wt% Potassium Silicate. Molar ratio 3.9.

Reliability: (4) not assignable
Only secondary literature available (review).
12-JAN-2004 (34)

Species: rabbit
Concentration: 7 other:wt%
Dose: .1 ml
Comment: not rinsed
No. of Animals: 6
Vehicle: other: deionised water
Result: not irritating

Method: OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year: 1990
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 405
DEVIATIONS FROM OECD GUIDELINE: 6 animals were used instead of 3
GLP: Yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Cornea: 0
- Iris: 0
- Conjunctivae (redness): 0.7
- Conjunctivae (chemosis): 0
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: After 2 days no effects were observed.
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS:
- Strain: New Zealand
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: 3.0 -3.2 kg
- Number of animals: 6
- Controls: yes (one eye treated, one eye untreated)
ADMINISTRATION/EXPOSURE:
- Preparation of test substance: diluted in deionised water
- Amount of substance instilled: 0.1 ml
- Vehicle: deionised water
- Post-exposure period scoring at: 1, 2, 4, 8 hours and day 1-7 daily
IN VITRO TEST SYSTEM: not applicable
EXAMINATIONS
- Ophtalmoscopic examination: cornea, iris, conjunctivae
- Scoring system: according to OECD Guideline 405'
- Observation period: 7 days
- Tool used to assess score: not reported
Test substance: SOURCE: Woellner-Werke GmbH.
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 25% dilution of 29 wt% Potassium Silicate. Molar ratio of 3.9
Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.
Flag: Critical study for SIDS endpoint

25-NOV-2003 (14)

Species: rabbit
Concentration: 29 other:wt%
Dose: .1 ml
Comment: not rinsed
No. of Animals: 6
Vehicle: water
Result: not irritating

Method: OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year: 1990
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 405
DEVIATIONS FROM OECD GUIDELINE: 6 animals instead of 3 were used
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Cornea: 0
- Iris: 0
- Conjunctivae (redness): 1.5
- Conjunctivae (chemosis): 0.7
DESCRIPTIONS OF LESIONS: Not reported
REVERSIBILITY: After 2 days no effects were observed.
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS
- Strain: New Zealand
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: 3.0 - 3.2 kg
- Number of animals: 6
- Controls: yes (one eye treated, one eye untreated)
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied as such
- Amount of substance instilled: 0.1 ml
- Vehicle: water
- Postexposure period: scoring done at 1, 2, 4, 8 hours and 1-7 days daily
IN VITRO TEST SYSTEM: not relevant
EXAMINATIONS
- Ophtalmoscopic examination: cornea, iris, conjunctiva
- Scoring system: according to OECD Guideline 405
- Observation period: 7 days
- Tool used to assess score: not reported
Test substance: SOURCE: Woellner Werke GmbH
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 29 wt% Potassium Silicate. Molar ratio 3.9
Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.
Flag: Critical study for SIDS endpoint
25-NOV-2003 (13)
Species: rabbit

Concentration: 35 other:wt%
Dose: .1 ml
Comment: not rinsed
No. of Animals: 3
Vehicle: water
Result: slightly irritating

Method: OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 405
DEVIATIONS FROM OECD GUIDELINE: none
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Cornea: 0/0/0
- Iris: 0/0/0
- Conjunctivae (redness): 1.0/1.3/1.3
- Conjunctivae (chemosis): 1.5/1.3/1.5
DESCRIPTIONS OF LESIONS: Not reported
REVERSIBILITY: The effects observed persisted for at least 6 to 7 days after treatment (period of observation).
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS
- Strain: New Zealand
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: 3.0 -3.2 kg
- Number of animals: 3
- Controls: yes (one eye treated, one eye untreated)
ADMINISTRATION/EXPOSURE
- Preparation of test substance: applied as such
- Amount of substance instilled: 0.1 ml
- Vehicle: water
- Postexposure period: scoring done at 1, 2, 4, 8 hours and 1-7 days daily
IN VITRO TEST SYSTEM: not relevant
EXAMINATIONS
- Ophtalmoscopic examination: cornea, iris, conjuntiva
- Scoring system: according to OECD Guideline 405
- Observation period: 7 days
- Tool used to assess score: not reported
Test substance: SOURCE: Woellner-Werke GmbH
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 35 wt% Potassium Waterglass. Molar ratio 3.4.
Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.
Flag: Critical study for SIDS endpoint
25-NOV-2003 (18)

Species: rabbit
Concentration: 8.8 other:wt%
Dose: .1 ml

Comment: not rinsed
No. of Animals: 3
Vehicle: water
Result: not irritating

Method: OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year: 1993
GLP: yes
Test substance: other TS

Method: METHOD FOLLOWED: OECD Guideline 405
DEVIATIONS FROM OECD GUIDELINE: not reported
GLP: yes
STATISTICAL METHODS: Not reported
METHOD OF CALCULATION: Not reported
ANALYTICAL METHODS: Not reported
Result: AVERAGE SCORE:
- Cornea: 0/0/0
- Iris: 0/0/0
- Conjunctivae (redness): 0.7/0.7/0.7
- Conjunctivae (chemosis): 0/0/0
DESCRIPTION OF LESIONS: Not reported
REVERSIBILITY: After 2 days no effects were observed.
OTHER EFFECTS: Not reported
Test condition: TEST ANIMALS
- Strain: New Zealand
- Sex: not reported
- Source: not reported
- Age: not reported
- Weight at study initiation: 3.0 - 3.2 kg
- Number of animals: 3
- Controls: yes (one eye treated, one eye untreated)
ADMINISTRATION/EXPOSURE
- Preparation of test substance: dilution with deionised water
- Amount of substance instilled: 0.1 ml
- Vehicle: deionised water
- Postexposure period: scoring done at 1, 2, 4, 8 hours and 1-7 days daily
IN VITRO TEST SYSTEM: not relevant
EXAMINATIONS
- Ophtalmoscopic examination: cornea, iris, conjunctiva
- Scoring system: according to OECD Guideline 405
- Observation period: 7 days
- Tool used to assess score: not reported
Test substance: SOURCE: Woellner-Werke GmbH
PURITY: Not reported
IMPURITY/ADDITIVE/ETC.: Not reported
ANY OTHER INFORMATION: 25% dilution of 35 wt% Potassium waterglass. Molar ratio of 3.4
Reliability: (2) valid with restrictions
Guideline study, but no information on purity of test substance.
Flag: Critical study for SIDS endpoint
25-NOV-2003 (17)

5.3 Sensitization

5.4 Repeated Dose Toxicity

5.5 Genetic Toxicity 'in Vitro'

5.6 Genetic Toxicity 'in Vivo'

5.7 Carcinogenicity

5.8.1 Toxicity to Fertility

5.8.2 Developmental Toxicity/Teratogenicity

5.8.3 Toxicity to Reproduction, Other Studies

5.9 Specific Investigations

5.10 Exposure Experience

Type of experience: Human - Exposure through Food

Remark: The average intake of silicon is 20-50 mg total Si/d (Pennington, 1991). An estimation of 0.31 mg Si/kg bw/d in females and 0.53 mg Si/kg bw/d in males made in an American study, is representative for the intake in the Western world. While the highest concentrations of total silicon are
found in seafood, eggs and diary products; the main dietary sources are cereals and beverages.
Reliability: (2) valid with restrictions
Flag: Critical study for SIDS endpoint
25-NOV-2003 (30)

Type of experience: Human - Medical Data

Remark: A 60-year-old woman noted a necrotic lesion over the left ankle after applying potassium silicate fertilizer to her garden for 2.5 hours.
Reliability: (4) not assignable
.....
25-NOV-2003 (36)

5.11 Additional Remarks

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