FOREWORD INTRODUCTION

GLUTARADEHYDE

CAS N°: 111-30-8

SIDS INITIAL ASSESSMENT PROFILE

CAS NO.	111 - 30 - 8
CHEMICAL NAME	GLUTARALDEHYDE
STRUCTURAL FORMULA	(CHO) CH2 CH2 CH2 (CHO)

RECOMMENDATION OF THE SPONSOR COUNTRY

Glutaraldehyde presents a potential for risk to humans in a number of occupational settings so effective risk reduction measures are essential for its use. Glutaraldehyde presents a low potential risk to the environment in most situations, however, in situations of insufficient dilution of the aquatic compartment, further risk management may be required.

There is no current priority for further testing, exposure analysis or in-depth assessment.

SHORT SUMMARY OF THE REASONS WHICH SUPPORT THE RECOMMENDATION

The principal health effects of glutaraldehyde are irritation of the skin, eye and respiratory tract, skin sensitisation and occupational asthma. Exposure data indicated that, in some situations, particularly the health care industry (disinfection), x-ray film processing and the animal health industry (spray use), health concerns may arise where available control measures such as ventilation have not been implemented to minimise exposure.

Due to low and intermittent exposure, the public health risk from the industrial use of glutaraldehyde is minimal. For the use of glutaraldehyde in cosmetics, a safety margin of >400 for extensive use indicated low concern.

Glutaraldehyde is hydrophilic, biodegradable and non-bioaccumulative. There is no apparent risk to the terrestrial compartment. In most situations, the risk to the aquatic environment is low, however, in some situations, for example, paper mill effluent or during drought, there may be some risk to aquatic organisms, specifically algae.

IF FURTHER WORK IS RECOMMENDED, SUMMARISE ITS NATURE

No further testing, exposure analysis or an in-depth assessment is recommended. However, given the potential for risk to human health in some industries, it is recommended that written guidance on effective risk reduction measures be available.

SIDS PROFILE SUMMARY

GLUTARALDEHYDE

CAS NO: 111-30-8		SPECIES	PROTOCOL	RESULTS
PHYSICAL-CHEMICAL				
2.1	Melting Point			- 14°C
2.2	Boiling Point			188°C (at 1002 hPa)
2.3	Density			0.72 kg/m^3
2.4	Vapour Pressure		estimate	60 Pa at 20°C
2.5	Partition Coefficient (log Pow)			- 0.01
2.6A	Water Solubility			miscible
B	pH			mildly acid (50% solution)
	pKa			
2.12	Oxidation/Reduction Potential			n/a
ENVIRONMENTAL FATE/BIODEGRADATION				
3.1.1	Photodegradation			In water, no statistical change after 24h.
3.1.2	Stability in Water		US EPA	abiotic, $T_{1/2}$= 102d at pH7 biotic, $T_{1/2}$= 10.6h
3.2	Monitoring Data			No data available
3.3	Transport and Distribution			Main exposure aquatic, with some atmospheric. No significant transport expected due to limited persistence in air, soil and water.
3.5	Biodegradation		OECD 301D	Readily biodegradable
ECOTOXICOLOGY				
4.1	Acute/Prolonged Toxicity to Fish	Bluegill sunfish	US EPA 660/3-75-009	LC_{50} (24h)= 15 mg/l, LC_{50} (48h)= 12 mg/l, LC_{50} (96h)= 11mg/l, NOEC = 10 mg/l
4.2	Acute Toxicity to Aquatic Invertebrates (*Daphnia*)	D. magna	US EPA 660/3-75-009	LC_{50} (48h)= 0.35 mg/l LC_{50} (48h)= 2.1 mg/l, NOEC = 0.32 mg/l
4.3	Toxicity to Aquatic Plants e.g Algae	Sel.capricornutum	US EPA	ILm (96h)= 3.9 mg/l
		Scen.subspicatus	OECD 201	EC_{50} (96h)= 0.9 mg/l, NOEC (96h)= 0.625 mg/l

4.5.2	Chronic Toxicity to Aquatic Invertebrates *(Daphnia)*	D. magna	OECD 201	LC_{50} (21d) = >4.3 mg/l, NOEC (21d)= 2.1 mg/l
4.6.1	Toxicity to Soil Dwelling Organisms			No tests available
4.6.2	Toxicity to Terrestrial Plants			No tests available
4.6.3	Toxicity to Other Non-Mammalian Terrestrial Species (Including Birds)	Mallard duck Bobwhite quail	n/a n/a	LC_{50} = 466 mg/kg (acute oral) LC_{50} > 5000 mg/kg (21d dietary) LC_{50} > 5000 mg/kg (21d dietary)
TOXICOLOGY				
5.1.1	Acute Oral Toxicity	rat (SD)	US EPA CFR40	LD_{50} = 246 mg/kg (m), 154 mg/kg (f)
		rat (SD)	OECD 401	LD_{50} = 316 mg/kg (m), 285 mg/kg (f)
		rat (W)	US EPA CFR40	LD_{50} = 362 mg/kg (m), 418 mg/kg (f)
5.1.2	Acute Inhal. Toxicity - vapour	rat (F)	OECD 403	LC_{50} = 96 mg/m^3 (m), 164 mg/m^3 (f)
	- aerosol	rat (SD)	OECD 403	LC_{50} = 350 mg/m^3 (m), 280 mg/m^3 (f)
5.1.3	Acute Dermal Toxicity	rat (SD)	OECD 402	LD_{50} > 2000 mg/Kg
		rabbit	OECD 402	LD_{50} = 1800 mg/kg
		rabbit (NZ)	OECD 402	LD_{50} = 2240 mg/kg
5.2.1	Skin Irritation	rabbit	OECD 404	50,45% solution corrosive, 25% severe irritant, 2% slight irritant, 1% no effects
5.2.2	Eye Irritation	rabbit	OECD 405	5% solution severe irritant, 2,1% irritant, 0.5,0.2% slight irritant, 0.1% no effects
5.3	Skin Sensitisation	guinea-pig	OECD 406	positive
5.4	Repeat. Dose Tox. - Oral	rat (F)	OECD 408	90d NOEL = 5 mg/kg (drinking water)
	- Dermal	rat (F)	OECD 410	28d LOEL = 5 mg/Kg
	- Inhalation	rat (F)	OECD 413	90d NOEL = 21 ppb (resp. irritation)
		rat (F)	OECD 413	90d NOEL = 125 ppb (nasal lesions)
		mouse	OECD 413	90d LOEL = 62.5 ppb (nasal lesions)

5.5	Genetic Toxicity in Vitro			
A	Bacterial Test (Gene Mutation)	S.typhimur.	OECD 471	TA100, 102,104: + with and without metabolic activation; TA98,1535,1537 -.
B	Non-Bacterial In Vitro Test			
	- Chromosomal aberrations	Ch.hamster	OECD 473	- with and without metabolic activation
		Ch.hamster	OECD 473	- with metabolic activation, +/- without
	- Sister chromatid exchange	Ch.hamster	OECD 479	+ with and without metabolic activation
		Ch.hamster	OECD 479	+/- with and without metabolic activation
	- HGRPT forward mutation	Ch.hamster		- with and without metabolic activation
	- Mouse lymphoma	mouse	OECD 476	+ without metabolic activation
5.6	Genetic Toxicity In Vivo	mouse	OECD 474	negative
		rat	OECD 475	negative
		Drosophila melanogast	OECD 477	negative
5.7	Carcinogenicity	rat(F)	oral (dr.water)	inconclusive
5.8	Toxicity to Reproduction	rat (CD)	oral (dr.water)	NOEL = 50 ppm (General toxicity) NOEL = 1000 ppm (Reprotox. parental) NOEL = 1000 ppm (Reprotox. F1 gen.)
5.9	Developmental Toxicity/ Teratogenicity	rat (W)	OECD 414	NOEL = 5 mg/kg (General toxicity) NOEL = 68 mg/kg (Preg. /Litter, Foetal)
		rabbit	OECD 414	NOEL = 15 mg/kg (General toxicity) NOEL = 15 mg/kg (Preg. /Litter, Foetal)
5.11	Experience with Human Exposure			Dermatitis and eye, nose, throat irritation. Positive skin patch tests. Occupational asthma.

SIDS INITIAL ASSESSMENT REPORT

1. IDENTITY

Name:	Glutaraldehyde
CAS no.:	111-30-8
Synonyms:	1,5-pentanedial 1,3-diformylpropane Glutaral Glutardialdehyde Glutaric dialdehyde
Molecular Formula:	$C_5H_8O_2$
Structural Formula:	$CH_2–CH_2–CH_2$ $\vert \quad \vert$ CHO CHO

Glutaraldehyde is a colourless oily liquid which undergoes chemical reactions typical of aldehydes. It also cross-links with proteins and, in aqueous solutions, it partially polymerises to give oligomers. In the vapour state, glutaraldehyde has a pungent odour, with an odour threshold of 0.04 ppm.

2. GENERAL INFORMATION ON EXPOSURE

Glutaraldehyde is manufactured in Germany by BASF and in the USA by Union Carbide Corporation. It is usually sold commercially as a 45% or 50% aqueous solution.

International production volumes were not available, however, import volumes were available from some member countries. In Australia, over 100 tonnes per year of glutaraldehyde have been imported in recent years. Sweden imports approximately 165 tonnes/year, Denmark approximately 50 tonnes/year, France < 1000 tonnes/year, United Kingdom several hundred tonnes/year and Canada 33-333 tonnes/year. Norway imports approximately 12 700 tonnes of glutaraldehyde-containing products each year.

A summary of use data provided by OECD member countries is tabled in Appendix A. The table also includes information on classification, occupational exposure limits and occupational exposure data provided by members.

The main uses of glutaraldehyde are as follows:

Cold disinfectant in the health care industry. Glutaraldehyde is used in the form of a 1% or 2% aqueous solution which has to be activated by an alkaline buffer, for example, sodium bicarbonate. The activated solution can be used for up to two weeks and it is used in the chemical disinfection of instruments such as endoscopes, bronchoscopes, dental equipment and other clinical instruments. Disinfection involves immersion of the instrument in glutaraldehyde solution using either closed troughs, trolley systems or automated washing units.

Hardener in x-ray film processing. Glutaraldehyde is incorporated into developing solutions for black and white x-ray photography as a hardening (or cross-linking) agent to shorten the drying cycle in film processing. The developers containing glutaraldehyde are generally used in high temperature, automated

film processors, mainly in the medical field and, to a lesser extent, in engineering applications such as the non-destructive testing of welds. X-ray developers are usually supplied as concentrates containing free glutaraldehyde or the glutaraldehyde-sodium bisulfite complex, with the concentrate diluted to give a working strength solution containing less than 1% glutaraldehyde.

Water treatment. Aqueous solutions of glutaraldehyde at 10-50% are used for the treatment of water in cooling towers, air washers and other water recirculating systems to prevent corrosion and the build-up of microbial growth. The solution is administered in slugs as shock kill doses, either manually or by use of automatic dosing equipment, to give 50-100 ppm glutaraldehyde in treated water.

Glutaraldehyde is used significantly in off-shore operations. A 15-50% aqueous concentrate is added to well injection sea water to prevent the growth of sulfate reducing bacteria which cause metal corrosion. The solution is administered in slugs by automatic pumping system to give 100-300 ppm in water.

Biocide in the pulp and paper industry. Aqueous solutions of glutaraldehyde at 10-50% are used to reduce or inhibit the growth of micro-organisms in pulp slurries. The solution is administered in slugs by use of automatic dosing equipment to give 50-100 ppm glutaraldehyde in pulp stock.

Cleaning agent. Glutaraldehyde is used as a preservative in industrial cleaning agents, for example, in the food, beverage and tobacco manufacturing industries, and in retail detergents. In France, the glutaraldehyde content of 8 products used in disinfection, control, cleaning and repairing was in the range 0.024-6.5%. In the United Kingdom, the glutaraldehyde content in retail cleaning agents was 0.05-0.1%.

Biocide in the petroleum industry. Glutaraldehyde is used in the industry as a drilling mud additive, oil recovery agent and in treating oil wells. It is also used as a biocide in petroleum products such as lubricating oils.

Animal health industry. Glutaraldehyde is used in the animal health industry to disinfect animal and bird houses. Dilute solutions containing 0.1-0.3% glutaraldehyde are sprayed, washed or foamed onto the walls, floors and other surfaces. Fogging of animal sheds can be conducted with automatic equipment using a solution containing approximately 400 ppm. Solutions containing approximately 750 ppm are used to sanitise egg shells to assist in the removal of dirt and debris.

Tanning. Aqueous solutions of glutaraldehyde are used to soften leathers and to improve their resistance to water, alkalis and mould. The leathers are soaked in a solution containing 0.5-2% glutaraldehyde.

Microscopy/histology. Glutaraldehyde is used as a tissue fixative in histology and electron and light microscopy, generally as a 1.5-6% aqueous solution.

Aquaculture. Glutaraldehyde is used, generally in conjunction with wetting agents, to control viruses and other micro-organisms in fish farming.

Cosmetics. Glutaraldehyde is allowed as a preservative in cosmetics in Europe at concentrations up to 0.1%. It is not allowed in aerosols and sprays.

Glutaraldehyde has also been reported to be used as:

. a preservative in the printing industry;

. a biocide in sanitary solutions for aircraft and portable toilets;

. an intermediate in the production of adhesives, sealants, polyhydroxy materials, pharmaceuticals, pesticides and crop protection agents;

. a disinfectant for air ducts; and

. an embalming agent.

In Australia, it is estimated that glutaraldehyde is distributed in end-use as follows: 55% as a cold disinfectant in the health care industry, 20% in x-ray film processing, 10% in water treatment, 5% in animal housing, 5% in tanning and 5% in other uses such as toilet disinfection, microscopy, aquaculture and air duct disinfection. In France, 50% is used in disinfection/control, 40% in the photographic industry, 5% in the leather industry and 5% in the paper indusry. In Norway, 80% is used in industrial cleaning agents and 14% in photocopying developers. In the UK, glutaraldehyde is used mainly as a cold disinfectant and as a biocide in off-shore oil operations.

The results of a NIOSH (USA) survey detailing numbers of workers and types of workplaces using glutaraldehyde are listed in Appendix B.

3. ENVIRONMENT

3.1 Environmental Exposure

3.1.1 General Discussion

Use of glutaraldehyde entails exposure of aquatic and atmospheric compartments.

Waste glutaraldehyde solutions are disposed of to sewer. This provides a route for glutaraldehyde to enter the aquatic environment when residues that may remain in treated sewage effluent are discharged to receiving waters.

Glutaraldehyde's main application, as a cold disinfectant for use in such facilities as hospitals, surgeries and medical clinics, entails discharge of significant quantities to sewer as solutions that are disposed of retain at least 50% of their activity. Such disposal will occur predominantly in metropolitan areas. Smaller discharges to sewer will occur from formulation and other end-uses such as x-ray film processing, water cooling treatment and tanning.

Five-day biological oxygen demand and aquatic metabolism studies indicate that glutaraldehyde degrades readily. Accordingly, significant degradation is expected during passage through sewage treatment works. Reaction with proteins present in sewage effluent will also remove significant amounts from aqueous waste streams. Any glutaraldehyde that may enter receiving waters is likely to be rapidly diluted and undergo further biodegradation.

Small amounts of glutaraldehyde will volatilise to the atmosphere. Glutaraldehyde used as a biocide in cooling systems will be entrained in water cooling tower drift. However, glutaraldehyde is not expected to persist in the atmosphere as it would be subject, like other aliphatic aldehydes (for example, propanal, for which the USA has prepared a SIAR including an estimated half-life of 5.8 hours in air) to photochemically induced degradation in that compartment. In addition, the hydrophilicity of glutaraldehyde will ensure its removal through dissolution in rain.

Monitoring studies have been performed in Canada at a paper mill and a de-inking plant. Both studies showed a rapid decrease in glutaraldehyde concentration in the white water. In the paper mill, the white

water concentration decreased from 51 mg/L half an hour after dosing to 4 mg/L after 6 hours. In the de-inking plant, the corresponding concentration decreased from 56 mg/L half an hour after dosing to 5 mg/L after 7 hours. These results were attributed partly to dilution of the white water.

In the paper mill, the glutaraldehyde concentration in white water effluent to the clarifier was below the detection limit of 1 mg/L throughout the study. In the de-inking plant, the glutaraldehyde concentration in the clarifier decreased from 14 mg/L half an hour after dosing to 7 mg/L after 3 hours and below the detection limit of 5 mg/L after 7 hours. In effluent water from the clarifier, the concentration was below the detection limit of 5 mg/L throughout the study.

3.1.2 Predicted Environmental Concentration (PEC)

In Australia, environmental exposure primarily arises as a result of use as a cold chemical sterilant when spent solutions are disposed of to sewer. Assuming that 75% of the estimated 50 tonnes per year that is used for this purpose is so discharged, the average daily discharge across Australia would be 37500/365 = 100 kg. For a population of about 17 million with an average daily per capita wastewater discharge of 150L (a conservative estimate) the concentration in wastewater would be about 40 µg/L.

Note that the above estimate is a worst case as it takes no account of such factors as reaction with proteinaceous constituents of raw sewage and biodegradation, which are expected to significantly reduce concentrations of glutaraldehyde in wastewater before discharge. Any glutaraldehyde remaining in treated effluent will be further diluted in receiving waters and subject to further biodegradation.

In Australia, glutaraldehyde is also used in x-ray film processing, water treatment, tanning and animal housing, but in smaller volumes and at lower concentrations than as cold chemical sterilant. Free glutaraldehyde is not released from x-ray film processing because of reaction with sulfite from the fixer. Cooling towers discharge to sewer at a maximum concentration of 250 mg/L. Losses from tanning are estimated as 1-3% of the original charge, and would be expected to react with dissolved proteins in tannery effluent. Use in animal housing primarily involves atmospheric exposure as glutaraldehyde solutions are generally applied to surfaces and allowed to dry. These sources of exposure would not be expected to add significantly to the wastewater load.

Little information was available on antiprotozoal use of glutaraldehyde in aquaculture in Australia, but concentrations discharged would be expected to be low as higher concentrations may be damaging rather than therapeutic to aquatic fauna.

PEC values were calculated in Sweden for three different scenarios: a fine paper mill and a newspaper mill with one or two days retention time. Based on a glutaraldehyde concentration of 50 mg/L in white water during dosing periods, and assuming a dilution factor of 100, PEC values of 60 µg/L, 2.9 µg/L and

3.2 Effects on the environment

3.2.1 Aquatic effects

Table 1 indicates that glutaraldehyde is slightly toxic to crabs, shrimp and sewage micro-organisms, slightly to moderately toxic to fish and *Daphnia*, moderately toxic to oyster larvae, and moderately to highly toxic to algae. Glutaraldehyde loses its biological activity below about 10 mg/L.

Table 1: Aquatic toxicity of glutaraldehyde

Test	Species	Result
96h acute	Bluegill sunfish	LC_{50} = 11.2 mg/L
48h acute	Oyster larvae	LC_{50} = 2.1 mg/L
96h acute	Green crabs	LC_{50} = 465 mg/L
96h acute	Grass shrimp	LC_{50} = 41 mg/L
48h acute	*Daphnia magna*	LC_{50} = 0.35 mg/L
48h acute	*Daphnia magna*	LC_{50} = 16.3 mg/L
21d reproduction	*Daphnia magna*	LOEC = 4.3 mg/L NOEC = 2.1 mg/L
96h algal growth inhibition	*Selenastrum capricornutum*	ILm = 3.9 mg/L *
96h algal growth inhibition	*Scenedesmus subspicatus*	EC_{50} = 0.9 mg/L
Bacterial inhibition	Sewage microbes	IC_{50} = 25-34 mg/L

* ILm = median inhibitory limit

Acute data for bluegill sunfish, daphnids, oyster larvae, crabs, shrimp and algae are available. These indicate oyster larvae (48h LC_{50} = 2.1 mg/L) to be the most sensitive faunal species, disregarding one test for *Daphnia magna* in which poorly correlated data returned a 48h LC_{50} of 0.35 mg/L. For floral species, the alga *Scenedesmus subspicatus* is most sensitive (96h EC_{50} = 0.9 mg/L).

Additional summary data generated in Germany indicates slight to moderate acute toxicities under semi-static conditions to zebra fish (96h LC_{50} = 5.8 mg/L) and Daphnia (48h EC_{50} = 21.9 mg/L).

As a wide selection of species is available, a safety factor of 100 seems most appropriate, giving a PNEC of 2100/100 = 21 µg/L for faunal species and 900/100 = 9 µg/L for algae.

Note that these PNEC values are very much lower than measured no-effect concentrations, for example, the measured no-effect concentration for the alga *Scenedesmus subspicatus* is 0.3 mg/L. The no-effect concentration in 21d testing with *Daphnia magna* was 2.1 mg/L. Application of an assessment factor of 10 would give a PNEC of 30 µg/L based on the algal chronic value. [Note that the OECD *Provisional Guidance for the Assessment of Aquatic Effects* recommends that the PNEC should be derived using the chronic value where chronic data are available for the most sensitive species in acute testing.]

3.2.2 Terrestrial effects

Only avian data are available. Acute oral and dietary LD_{50}s for mallard duck are above 400 mg/kg. With a safety factor of 1000, the PNEC is above 400 µg/kg.

Table 2: Avian toxicity

Test	Species	Result
Acute oral	Mallard Duck	LD_{50} = 408 mg/kg
Acute oral	Mallard Duck	LD_{50} = 466 mg/kg
8d dietary	Mallard Duck	LC_{50} > 5000 ppm
8d dietary	Bobwhite quail	LC_{50} > 2500 ppm
8d dietary	Bobwhite quail	LC_{50} > 5000 ppm

3.3 Initial assessment for the environment

Application of a dilution factor of 2 to the predicted wastewater concentration of 40 µg/L to simulate discharge to inland waterways during drought provides a predicted environmental concentration of 20 µg/L. As this exceeds the acute PNEC of 9 µg/L, there may be some risk to algae, but only during drought conditions. A fivefold dilution factor would reduce the PEC below the acute PNEC. Reaction with proteinaceous constituents of raw sewage and biodegradation during sewage treatment will significantly reduce the PEC such that risk should not arise. Estimates from Sweden assume a fivefold reduction during 12 hours in an aerated basin, which would reduce the PEC below levels of concern.

The PEC is less than the acute PNEC for aquatic fauna, even without considering losses during sewage treatment, and also less than the PNEC based on algal chronic values. Therefore, glutaraldehyde is not expected to present a significant risk to the aquatic environment.

The above PEC values are based on the Australian situation where discharge to sewage treatment works allows large reductions through dilution. Estimates from Sweden indicate that concentrations in wastewater from on-site treatment plants (sedimentation and chemical precipitation only) serving fine paper mills may reach 6 mg/L, more than two orders of magnitude higher than predicted for municipal sewage treatment works. Hence concentrations of glutaraldehyde leaving specific facilities, such as paper mill effluents treated only by sedimentation and chemical precipitation, may be higher than concentrations leaving municipal sewage treatment works because of the absence of dilution by other waste streams.

For the terrestrial compartment, the PNEC is above 400 µg/kg, an order of magnitude above the predicted wastewater concentration. As glutaraldehyde is hydrophilic, biodegradable in soil and water and has no bioaccumulative properties, there is no apparent risk to the terrestrial compartment.

4. HUMAN HEALTH

4.1 Human Exposure

4.1.1 Occupational Exposure

Workers may be exposed to aqueous solutions of glutaraldehyde from 50% to less than 1% by skin contact and by inhalation of the vapours liberated from the solutions. Glutaraldehyde has a low vapour pressure over its aqueous solutions. The risk of exposure to glutaraldehyde vapours is enhanced at higher temperatures and/or concentrations and by use in spray form.

The occupational exposure standard for glutaraldehyde in most OECD member countries is 0.2 ppm (peak limitation) with a 'sensitiser' notation. The standard was recently lowered to 0.1 ppm (peak) in Australia and a similar reduction is proposed in Germany.

Manufacture of Glutaraldehyde

Exposure data is available for plant workers involved in the manufacture and drumming of glutaraldehyde. For 88 short-term (15 min.) exposure limit tests conducted between 1989-1992, the range was 0.01-0.34 ppm, with a mean of 0.06 ppm.

Formulation

The formulation of glutaraldehyde products is carried out by the dilution of aqueous concentrate (generally 25-50%) with water and the addition of other ingredients. Mixing is usually carried out in a sealed system, but handling and packaging of the formulated product is usually more open and workers may be exposed to glutaraldehyde. Atmospheric monitoring during a well-ventilated operation in Australia resulted in 15 minute glutaraldehyde concentrations in the range 0.02-0.10 ppm.

Cold Disinfection

The majority of exposure data for glutaraldehyde is related to its use in the health care industry. The number of workers potentially exposed is considerable due to growth in the use of endoscopy as a routine clinical procedure. A busy endoscopy unit in a general hospital could carry out several thousand examinations per year with the requirement for cleaning after each procedure. Workers in operating theatres, clinics, laboratories and dental departments may also be exposed.

Workplace monitoring has been conducted in Australian health care establishments, with glutaraldehyde concentrations of less than 0.1 ppm generally obtained in well ventilated workplaces. Results of up to 0.11 ppm were obtained with personal monitoring, and up to 0.49 ppm with area monitoring. Workplace monitoring in 6 Finnish health care establishments gave an average concentration of 0.1 ppm with a standard deviation of 0.1 ppm. Monitoring of levels in French workplaces found that the majority of samples were under 0.01 ppm. In the UK, personal monitoring results during endoscopy disinfection were up to 0.15 ppm, with a mean of 0.02 ppm for one set of results and 0.03 ppm for another.

Published monitoring results are available. In the disinfection of surfaces in operating theatres, use of a 0.5% solution gave personal exposures up to 0.03 ppm with a mean of 0.01 ppm, while use of a 3% solution resulted in exposures up to 0.57 ppm with a mean of 0.15 ppm. Use of a 2% solution for disinfection in endoscopy units gave a mean of 0.015 ppm, with the highest readings during decanting (max. 0.23 ppm).

In the USA, NIOSH has issued several reports on the atmospheric monitoring of glutaraldehyde in hospitals, with personal monitoring results up to 0.6 ppm and area monitoring results up to 0.3 ppm. The highest readings were for manual operations, for example, manual cleaning of endoscopes, filling tanks, cleaning surfaces.

X-Ray Film Processing

The introduction of automatic film processors has reduced exposure to glutaraldehyde during x-ray film processing, but it may be significant for those workers involved in manual processing and the mixing of solutions. Workplace atmospheric monitoring in Australian hospital x-ray facilities found that glutaraldehyde concentrations were generally less than 0.2 ppm, although concentrations up to 0.4 ppm

have been recorded. Monitoring in 2 Finnish workplaces found average concentrations of 0.65 ppm, with a standard deviation of 0.17 ppm.

Water Treatment

For a cooling tower where glutaraldehyde was injected into the sump, atmospheric concentrations during dosing at levels up to 1200 ppm were all below 0.024 ppm. Similar results were obtained during the dosing of an air washer at 1000 ppm and in the workplace near the air vent.

A theoretical calculation (by Sweden) showed that, for an initial concentration of 50 or 125 ppm in process water, the atmospheric concentration of glutaraldehyde would be 7 and 17.5 ppb respectively.

Exposure assessments performed at paper mills in Sweden, Scotland and Canada showed that the air concentration never exceeded the detection limit of 20 ppb or 1 ppb (Sweden). In Sweden, the initial dose in process water was 50 ppm glutaraldehyde.

Animal Health Industry

As the glutaraldehyde solution is generally applied in spray form during this use, full body protection is usually worn.

During the manual spraying of chicken houses with a 2% glutaraldehyde solution, a personal short-term (10-15 min.) sample gave an exposure measurement of 0.12 ppm and three static short-term readings were in the range 0.03-0.08 ppm. During automatic spraying, static short-term readings were in the range 0.02-0.05 ppm.

In Australia, an egg collector was exposed to an atmospheric concentration of < 0.1 ppm while using a solution containing 0.1-0.3% glutaraldehyde in spray form.

Other uses

Little information was available for occupational exposure to glutaraldehyde for its other uses, however, in general, exposure is expected to be low, for example, in microscopy, in aircraft and portable toilet sanitation, in tanning and in the paper and petroleum industries. In an ink formulating process in the UK, air concentrations up to 0.04 ppm glutaraldehyde were recorded.

In exposure information available for France, most atmospheric concentrations during control, disinfection, cleaning and repairing activities were < 0.005 ppm, with a peak of 17 ppm obtained for a non-specified activity. Levels up to 0.03 ppm were obtained in the agriculture/food industry, however, glutaraldehyde was not detectable in other industry activities monitored, for example, printing, water treatment, machining.

4.1.2 Consumer exposure

In general, public exposure to glutaraldehyde is minimal. The public is unlikely to be exposed during its routine importation, transportation and formulation, and during its use in most industrial applications. Direct exposure is a possibility in health care establishments if cleaning and rinsing is inadequate and if spillage occurs in patient areas. In the use of glutaraldehyde in water treatment, infrequent public exposure may occur from drift emanating from cooling water towers. Public exposure is also a possibility in premises after air duct disinfection if ventilation after the fogging process is inadequate.

Glutaraldehyde can be used in cosmetics at concentrations of up to 0.1% in Europe, however, no information was available on the current extent of use of glutaraldehyde in this application. Glutaraldehyde can be used in both rinse off and non-rinse off cosmetic products and the following exposures have been estimated (SCC, 1993).

For non-rinse off cosmetics (face cream, general purpose cream, body lotion, roll-on antiperspirant, hairstyling product), the mean total estimate of use for an individual was 20.3g (of product)/day, assuming that the person used all types extensively (rather than average use). The estimate for average use was 10.8 g/day. For rinse off cosmetics (make-up remover, shower gel, shampoo, hair conditioner), the corresponding estimate of extensive use was 17 g/day.

Using the EC algorithm method for estimating the average daily dermal exposure (E_d), and assuming that all products contained 0.1% glutaraldehyde, 10% of rinse off product is retained after rinsing, and 10% of glutaraldehyde is absorbed through the skin,

$$E_d = \frac{(20.3 \times 1 + 17 \times 0.1) \times 0.001 \times 0.1}{60} = 0.037 \text{ mg/kg/day.}$$

4.1.3 Indirect exposure via the environment

Due to relatively short residence time in the environment and a lack of bioaccumulation, indirect exposure via the environment is considered to be a minor route of exposure for humans.

4.2 Effects on Human Health

Human evidence has shown that glutaraldehyde is an irritant to the skin, eyes and respiratory system, with the effects consistent with those demonstrated in animal testing. Many cases of dermatitis have been reported for workers exposed to glutaraldehyde solutions, usually 2% or higher. Facial dermatitis has resulted from the use of glutaraldehyde in spray form. Irritation of the nose and throat and general tightness of the chest have been experienced by workers exposed to glutaraldehyde vapours. In a study of Swedish hospital workers, nose and throat irritation was experienced at vapour concentrations below 0.2 ppm. Eye irritation was observed in workers exposed to glutaraldehyde vapours above disinfectant solutions. Human evidence indicates that skin and respiratory irritant effects are exacerbated on repeated exposure to glutaraldehyde.

Case reports and patch testing in animals and volunteers have shown that glutaraldehyde is a skin sensitiser. Photosensitisation testing on volunteers did not produce a phototoxic or photoallergic response.

A number of reports of occupational asthma and/or rhinitis in workers exposed to glutaraldehyde have produced concern that glutaraldehyde may be a respiratory sensitiser. In the absence of adequate case reporting or an identified immune mechanism, it is difficult to say definitively that glutaraldehyde is a respiratory sensitiser, and there is debate on whether the symptoms are due to an irritant or an allergic respiratory response. However, in the United Kingdom, glutaraldehyde has been added to the indicative list of respiratory sensitisers.

Limited epidemiological data is available on the long-term effects of glutaraldehyde. A mortality study did not reveal any increased incidence of cancer deaths.

4.2.1 Results of Animal and In Vitro Testing

Several acute toxicity studies have been carried out in a variety of animal species. The oral LD_{50} of glutaraldehyde was 134-820 mg/kg in rats, 100-350 mg/kg in mice and 50 mg/kg in guinea-pigs. The

dermal LD_{50} was 640-2000 mg/kg in rabbits and > 2500 mg/kg in rats and mice, with skin absorption observed at high concentrations. Glutaraldehyde has a high acute inhalational toxicity in rats and mice, and lung damage has been reported. Four-hour LC_{50} values of 23.5 and 40.1 ppm have been obtained for male and female rats respectively, but the glutaraldehyde solution had to be heated in order to generate glutaraldehyde vapour at high enough concentrations.

Glutaraldehyde was corrosive to the skin and eyes of rabbits at high concentrations, with signs of skin irritation evident at 2%, and eye irritation at 0.2%. Exposure to glutaraldehyde vapours resulted in nasal irritation and respiratory difficulty. An RD_{50} of 13.8 ppm was obtained in mice, with the respiratory decrease 26% at 1.6 ppm, the lowest dose tested. Joint irritation was seen in rabbits after intra-articular administration. Glutaraldehyde was a skin sensitiser in guinea pigs.

Short term (9-day or 2-week) repeated dose inhalational rat studies resulted in significant mortality at approximately 2 ppm, and nasal irritation at levels down to approximately 0.2 ppm. Lesions of the nasal cavity and larynx were observed at 0.5 ppm and, in the 9-day study, atrophy of the liver was observed at 3.1 ppm. Signs of irritation included laboured breathing and discharge and encrustation around the eyes and nose.

In two subchronic (13-14 weeks) inhalational rat studies, signs of nasal irritation were observed at lower concentrations, with a NOAEL for nasal cavity lesions of 125 ppb in one study and a LOAEL of 194 ppb in the other. Slight nasal irritation was observed at 49 ppb in the second study. In corresponding 2-week and 13-week studies in mice, mortality occurred at 1.6 ppm and 500 ppb respectively, with lesions of the nasal cavity in females at the lowest dose (62.5 ppb) in the 13-week study.

In a short-term dermal study in male mice, cumulative toxicity and mortality occurred after repeated skin contact to aqueous solutions containing 25% and 50% glutaraldehyde, but there was no evidence of cumulative toxicity at 5% or less.

A subchronic drinking water study in rats indicated some toxicity at 1000 ppm, and a physiological response at 250 ppm. Reductions in food and water consumption and a dose-related effect in kidney weight were observed, but as drinking water studies at high concentrations are generally hampered by a natural aversion of the animals to the taste/odour of glutaraldehyde, the significance of these results is uncertain.

A 2-year drinking water study in rats resulted in an increased incidence of large granular lymphatic leukaemia (LGLL) in the liver and spleen of females only at all dose levels (50-1000 ppm), but the finding was not conclusive as the strain of rats used in the study has a high natural susceptibility to LGLL and variation in control data existed within the study laboratory.

Repeated oral doses given during pregnancy to rabbits, rats and mice caused embryotoxicity and foetoxicity, but only at maternally toxic doses. From a gavage study in the rabbit, the most sensitive species, a NOAEL of 15 mg/kg/d can be taken for the maternal and foetal organism. No teratogenic effects were observed in any of the studies.

Early mutagenicity studies were negative, but more recent studies have indicated that glutaraldehyde is mutagenic *in vitro* in bacterial assays and tests in mammalian cells. *In vivo* genotoxicity tests to date have proven negative.

4.3 Initial Assessment for Human Health

Humans may be exposed to glutaraldehyde by inhalation and skin contact.

4.3.1 Occupational Health

The critical effects are eye, skin and respiratory irritation, skin sensitisation and occupational asthma.

Nose and throat irritation has been observed in humans at vapour concentrations below 0.2 ppm. Occupational asthma has also been reported in workers exposed to dilute solutions of glutaraldehyde. In 9-day or 2-week rat studies, nasal irritation occurred at levels down to 0.2 ppm, and in 13 or 14-week sudies, a NOAEL of 125 ppb was obtained for nasal cavity lesions in rats and a LOAEL of 62.5 ppb in mice.

Atmospheric concentrations of glutaraldehyde > 0.1 ppm (peak) have been recorded during disinfection and x-ray film processing where control measures such as enclosure and local exhaust ventilation have not been installed, so the risk of respiratory irritant effects to workers in these situations is significant. The risk of respiratory irritant effects also may be significant where aerosols are generated, for example, in animal housing disinfection, however, from exposure information available, the risk is low for other uses of glutaraldehyde.

Glutaraldehyde is toxic by inhalation in animals, however, in an occupational setting, atmospheric concentrations are unlikely to be high enough to cause toxic effects in workers.

Contact dermatitis and eye irritation have been reported in workers using glutaraldehyde solutions, usually 2% or higher. Skin sensitisation has been confirmed in workers using dilute solutions. In rabbits, eye irritation was observed with a 0.2% solution and skin irritation with a 2% solution.

As exposure to glutaraldehyde solutions at 1% or higher is frequent, especially in the health care industry, the risk of dermatitis, eye irritation and skin sensitisation in workers is significant where skin and eye protection are not provided.

Risk Reduction Measures

Where occupational exposure may be significant, control measures are necessary to reduce the risk of adverse health effects. Operations involving glutaraldehyde should be enclosed as much as possible. In the health care industry, local exhaust ventilation is recommended for fixed work stations. Where this is not practical, mobile units with vapour extactors and adsorption filters can be used.

Recommended personal protective equipment includes safety eyewear, nitrile or butyl rubber gloves and protective clothing. Where glutaraldehyde is used in spray form, for example, in animal housing disinfection, a hood and respirator are also required.

Safe use guidelines, particularly for the health care industry, are worthwhile. They should include information about the health effects of glutaraldehyde and detailed guidance on the control measures available to minimise exposure.

4.3.2 Public Health

Due to low and intermittent exposure, the public health risk from the industrial use of glutaraldehyde is minimal.

For the use of glutaraldehyde in cosmetics, the average daily exposure from extensive use was estimated at 0.037 mg/kg/day. The critical NOAEL (for maternal toxicity and reproductive effects) is 15 mg/kg/day, giving a safety margin of 15/0.037 = 405, so the use of glutaraldehyde in cosmetics is of low concern.

5. CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

The health effects of glutaraldehyde in humans and animals are characterised by local irritation of the skin, eye and respiratory tract and skin sensitisation. The irritant effects are exacerbated by repeated exposure. Occupational asthma has been reported in workers exposed to glutaraldehyde. Consideration of the health effects data and current exposure levels indicates that some health concerns may arise during the use of glutaraldehyde in the health care industry (as a cold disinfectant) and during x-ray film processing in situations where control measures such as enclosure, local exhaust ventilation and skin and eye protection have not been implemented to minimise exposure. Similarly, in the use of glutaraldehyde in spray form during disinfection in the animal health industry, personal protective measures are necessary. However, it is expected that the necessary risk reduction techniques are available in member countries to adequately manage the risk.

In most situations, the risk to aquatic organisms is low. However, there may be some risk to aquatic organisms, specifically algae, under extreme environmental conditions, for example, during drought in Australia. Also, there may be a risk in situations such as paper mill effluent treated only by sedimentation and chemical precipitation and not discharged to sewer. The risk to terrestrial organisms is low.

The use of glutaraldehyde in cosmetics does not give cause for concern at the current maximum concentration of 0.1%.

5.2 Recommendations

There is no current priority for further testing, exposure analysis or an in-depth assessment. Risk reduction measures are recommended for the use of glutaraldehyde in a number of occupational settings to reduce the risk to human health. Further risk management action may be required in some situations to reduce the risk to the environment.

6. REFERENCES

National Industrial Chemicals Notification and Assessment Scheme, *Glutaraldehyde - Full Public Report*, AGPS, Canberra, Australia, July 1994.

National Chemicals Inspectorate, *Risk Assessment of Slimicides*, Sweden, 1995.

EC Scientific Committee on Cosmetics (SCC), *Opinion of the SCC Concerning Glutaraldehyde - Colipa no. P76*, June 1993.

APPENDIX A: SUMMARY OF USE DATA RECEIVED FROM MEMBER COUNTRIES

Country	Classification	Use of glutaraldehyde and quantity used	Other comments
Australia	R21-23-25-34-43	Over 100 te/yr imported. Used mainly in health care industry as disinfectant (55% of total) and in x-ray film processing (20%). Also used in water treatment (10%), tanning (5%), animal health (5%), and in small quantities in toilet disinfection, microscopy, aquaculture and air duct disinfection.	Exposure standard 0.1 ppm (peak), sens.
Austria	Corrosive, Harmful R20/22-34-43	Little information known.	Exposure standard 0.2 ppm.
Belgium		Open usage.	
Canada	Class E (Corrosive) Class B, division 1 (for serious toxic effects)	Not manufactured in Canada, imported by 11 facilities at a total volume between 33 and 333 te/year. Used as a drilling mud additive, oil recovery agent and in treating oil wells. Also used as a formulation component in pesticides and a processing aid. Classified as a 'fragrance, perfume, deodoriser and flavouring agent'. Used in the following industrial sectors: biotechnology, health and veterinary use, leather tanning, industrial chemical use, paints and coatings, petroleum and natural gas, photographic processing and photocopying, printing and publishing, and in rubber products.	
Denmark	Harmful, Corrosive, Sensitiser (skin)	More than 50 registered products (most contain 1-5% glutaraldehyde). Total volume in Danish products is approx 50 te/yr. Mainly used in the following industries: health sector (mainly hospitals), graphics and paper, film processing, agriculture, repair and service, iron and metals, petroleum processing, transport, food industry, tanning.	

Country	Classification	Use of glutaraldehyde and quantity used	Other comments
Finland	R22/38/41/43	Used in disinfection and x-ray film processing.	Workplace monitoring: disinfection of gastroscopes and bronchoscopes: mean 0.1 ppm; x-ray film processing: mean 0.65 ppm.
France		No major producer identified. Main importer < 1000 te/yr. Use pattern: 50% disinfection/biocidal control, 40% photographic industry, 5% leather industry, 5% paper industry. Industrial activities include: disinfection, cleaning, agriculture, food industry, printing, document reproduction, water treatment, and as biocide or preservative in a variety of other activities, eg machining, assembling, welding. Glutaraldehyde content of 8 products used in disinfection, control, cleaning and repairing was 0.024-6.5%.	Exposure standard 0.2 ppm (ceiling value). Monitoring of control, disinfection, cleaning, repairing activities gave concentrations mainly < 0.005 ppm (peak 17 ppm). In agriculture and food industries, levels up to 0.03 ppm. Not detected in other activities.
Germany		Open usage. Low exposure anticipated.	
Japan		Usage unknown. Occupational exposure managed voluntarily. Environmental exposure partly regulated.	
Norway	R21/22-36-43 S24-26-39	12 700 te of product consumed per year. 80% used in industrial cleaning agents in food, beverage, tobacco and paper manufacturing industries. 14% used in photocopying developers for use in the printing and publishing industry.	Exposure standard 0.2 ppm.

Country	Classification	Use of glutaraldehyde and quantity used	Other comments
Sweden	Corrosive Harmful	Total volume used approx. 165 te/yr. Used mainly in water treatment in the pulp and paper industry. Also used in photographic chemicals, agriculture, fish farming, metals industry, and disinfection in the health care industry. In the agricultural sector, used with high pressure cleaners and fog generators at 2-5% glutaraldehyde.	Exposure standard 0.2 ppm (ceiling).
Switzerland	Toxic	326 products registered, with approx. 50% being consumer products. Mainly used in disinfection (concentration 0.01-20%). Also used in washing agents for textiles and dishes, and in photographic products. Consumer exposure expected to be low and intermittent.	MAK 0.2 ppm, sens. No monitoring data available.
UK		Used mainly as disinfectant in health care industry and as biocide in off-shore operations. Also used in water treatment, animal health, paper manufacture, cosmetics, cleaning agents, and in smaller quantities in x-ray film processing and histology.	Exposure standard 0.2 ppm (10 min.) Monitoring data: disinfection of endoscopes 0.002-0.15 ppm, animal housing 0.02-0.08 ppm, water treatment < 0.024 ppm, ink formulation 0.04 ppm (mean).
USA		Used in disinfection, oil industry, tissue fixation, tanning, chemical manufacture, printing, agriculture, paper manufacture, cleaning.	TLV 0.2 ppm C, sens.

APPENDIX B

NIOSH NATIONAL OCCUPATIONAL EXPOSURE SURVEY
Number of Workers and Facilities Reporting Glutaraldehyde

Industry	No. of workers	No. of facilities
Agricultural services	570-3200	1-680
Oil and gas extraction	220-2500	1-120
Textile mill products	1-49	1-49
Paper and allied products	470-2600	1-250
Printing, publishing and allied industries	20 000 (3700)[1]	190-2100
Chemicals and allied products	190-2170	1-480
Industrial and commercial machinery	1-140	1-66
Electrical equipment and components	1-130	1-58
Transportation equipment	1-550	1-58
Measuring equipment and photographic, medical and optical goods	1-650	1-230
Air transport	1-290	1-26
Wholesale trade - non-durable goods	850-4800	1-410
Personal services	15 000 (3000) [1]	740-4200
Business services	2130-7140	150-1700
Health services	320 000 (25 000)[1]	1800-6000
TOTAL	260 000 - 380 000	5100-8200

[1] Standard error

SIDS DOSSIER ON GLUTARALDEHYDE

1. GENERAL INFORMATION

1.01 SUBSTANCE INFORMATION

A. **Cas-number** 111-30-8

B. **Name** *(IUPAC name)* 1,5-PENTANEDIAL.

C. **Name** *(OECD name)* GLUTARALDEHYDE

D. **CAS Descriptor** *(where applicable for complex chemicals)*
.....

E. **EINECS-Number** 203-856-5

F. **Molecular Formula** $C_5H_8O_2$

G. **Structural Formula** (CHO) CH_2 CH_2CH_2 (CHO)

H. **Substance Group**

I. **Substance Remark**

J. **Molecular Weight** 100.11

1.02 OECD INFORMATION

A. **Sponsor Country:** AUSTRALIA

B. **Lead Organisation**

Name of Lead Organisation: Worksafe Australia
National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
Contact person: Ms Lesley Onyon
Address:
Street: 92 Parramatta Road
Town: CAMPERDOWN
SYDNEY
State/Territory: NSW
Postcode: 2050

Tel: (02) 565 9417 Fax: (02) 565 9465

C. **Name of responder**

Name: Union Carbide Chemicals (Australia) Pty Ltd
Address**:** Suite 1, 1st floor

Street:	1-7 Jordan St Gladesville		
Town:	Sydney, New South Wales		
Country:	Australia	Postcode:	2111
Tel:	(02) 879 6066	Fax:	(02) 817 3318

D. Other participating companies

BASF Australia Ltd
500 Princes Highway, Noble Park, Victoria, Australia 3174

AGFA-Gevaert Ltd
372 Whitehorse Rd, Nunawading, Victoria 3131

Du Pont (Australia) Ltd
168 Walker St, North Sydney, NSW 2060

Hanimex Pty Ltd
108 Old Pittwater Rd, Brookvale, NSW 2100

ICI Australia Operations Pty Ltd
1 Nicholson St, Melbourne, Victoria 3000

Ilford (Australia) Pty Ltd
cnr Ferntree Gully & Foster Rd, Mt Waverley, Victoria 3149

Johnson & Johnson Medical Pty Ltd
1-5 Khartoum Rd, North Ryde NSW 2113

Kodak (Australasia) Pty Ltd
173 Elizabeth St, Coburg, Victoria 3058

Pfizer Agricare Pty Ltd
38-42 Wharf Rd, West Ryde, NSW 2114

T R (Chemicals Australia) Ltd
195 Briens Rd, Northmead, NSW 2152

Whiteley Chemicals Australia Pty Ltd
82-84 Ivy St, Chippendale, NSW 2008

1.1 GENERAL SUBSTANCE INFORMATION

A. Type of Substance

element [ ]; inorganic [ ]; natural substance [ ]; organic [X]; organometallic [ ]; petroleum product [ ]

B. Physical State *(at 20°C and 1.013 hPa)*

gaseous [ ]; liquid [X]; solid [ ]

C. Purity Usually supplied as a 50%$^{w}/_{w}$ aqueous solution.

1.2 SYNONYMS

glutardialdehyde
glutaral
1,3-diformylpropane
glutaric dialdehyde

1.3 IMPURITIES The dimer and trimer may be present in aqueous solution.

1.4 ADDITIVES Additives such as sodium bicarbonate may be added to commercial preparations.

1.5 QUANTITY

Remarks: In Australia, no manufacture - with approx. 100 te of 12-50% aqueous glutaraldehyde imported in 1992.
Two (2) main global producers (Union Carbide, BASF) - quantity not known

1.6 LABELLING AND CLASSIFICATION

Labelling

Type:		NOHSC Approved Criteria (same as 67/548/EEC)
Specific limits:		.....
Symbols:		T,C
Nota:		.....
R-phrases:	(50%)	R21, R23, R25, R34, R37, R41, R43
S-phrases:	(50%)	S26, S36/37/39, S51
Text of S-phrases:		.....
Remarks:		Note that glutaraldehyde is not included on Annex 1 of 67/548/EEC Proposed labelling and classification

Classification

Type		NOHSC Approved Criteria (same as 67/548/EEC)
Category of danger:		Toxic, Corrosive
R-phrases:	(50%)	R21, R23, R25, R34, R37, R41, R43
Remarks:		(see comments above for labelling)

*1.7 USE PATTERN

A. General

	Type of Use:	Category:
	(a) main industrial use	Wide dispersive use, Health care, Cold disinfectant
	(b) main industrial use	Wide dispersive use, Radiography/Health care, X-ray film processing

Remarks: (a) approx. 55% as disinfectant in Australia
(b) approx. 20% in x-ray film processing
(c) Also used in water treatment (10%), tanning (5%), animal housing (5%), toilet sanitation, microscopy, oil biocide

Reference: NICNAS Glutaraldehyde Report 1994

B. Uses in Consumer Products

	Function	Amount present	Physical state
	Biocide/Disinfection	2%	liquid

Remarks: Product usually sold within Health Care Industry

Reference: NICNAS Glutaraldehyde Report 1994

1.8 OCCUPATIONAL EXPOSURE LIMIT VALUE

Exposure limit value

Type:	Exposure Standard (Australia)
Value:	0.2 ppm (0.82 mg/m^3) - peak limitation No TWA value set.
: Remarks:	Exposure Standard is under review
Reference	NOHSC Exposure Standards 1991

1.9 SOURCES OF EXPOSURE

About 100 tonnes of 12-50% glutaraldehyde are imported into Australia annually.

The largest and most concentrated source of environmental exposure is disposal of spent cold chemical sterilant solutions. These are disposed of when the concentration in the sterilant bath drops below about 10-15 000 mg/L. Disposal generally entails flushing to sewer with copious quantities of water.

Glutaraldehyde is used in medical facilities across Australia. Discharge to sewer is assumed to occur throughout the year. Other uses include X-ray film processing, tanning, water treatment (cooling towers, air washers, pasteurisers), disinfection of animal housing, portable toilet sanitation, biocidal oil treatment, microscopy (tissue fixation) and farming of finfish.

Occupational exposure (to vapours and by skin contact). is mainly during the use of 1% and 2% aqueous solutions in disinfection in the health care industry. Exposure may also be significant during the use of x-ray film processing solutions and, to a lesser extent, during its use as a disinfectant in the animal health industry. Exposure in other industries is usually minor or sporadic.

Public exposure is minimal, with possible exposure to humans from portable toilet use and from vapour drift from water cooling towers.

1.10 ADDITIONAL REMARKS

Aside from dilution, glutaraldehyde solutions may be deactivated before disharge to sewer, for example by treatment with dibasic ammonium phosphate or caustic hydrolysis. Deactivation is recommended before discharge to septic systems. Incineration is recommended for concentrated solutions.

Significant discharge of free glutaraldehyde from X-ray film processors is not expected because of reaction with sulphite from the fixer.

Similarly, free glutaraldehyde is not expected to be present in tannery effluent at significant concentrations because of the large quantities of dissolved proteins present in such waste streams.

A preliminary study indicates that glutaraldehyde is rapidly reduced (half-life about a day) to 1,5-pentanediol in anaerobic water/sediment systems.

2. PHYSICAL-CHEMICAL DATA

2.1 MELTING POINT *(if more than one, identify the recommended value)*

Value:	-14°C	[50% aqueous solution: 21°C]
Decomposition:	Yes [ ] No [X]	Ambiguous [ ]
Sublimation:	Yes [ ] No [X]	Ambiguous [ ]
Method:		
GLP:	Yes [ ] No [ ]	? [X]
Remarks:	.....	
Reference:	Condensed Chemical Dictionary, 1981	

2.2 BOILING POINT

Value:	188°C	[50% aqueous solution: 101°C]
Pressure:	at 1002hPa	
Decomposition:	Yes [X] No [ ]	Ambiguous [ ]
Method:		
GLP:	Yes [ ] No [ ]	? [X]
Remarks:	.....	
Reference:	The Merck Index, 1983	

2.3 DENSITY (Relative density)

Type:	Bulk density [ ]; Density [ ]; Relative Density [X]
Value:	0.72 [50% aqueous solution: 1.13]

Temperature:	20°C
Method:	
GLP:	Yes [ ] No [ ] ? [X]
Remarks;	.....
Reference:	Condensed Chemical Dictionary, 1981

2.4 VAPOUR PRESSURE

Value:	2.03 Pa [for a 50% aqueous solution]
Temperature:	20°C
Method:	calculated [ ]; measured [X]
GLP:	Yes [ ] No [ ] ? [X]
Remarks:	In the absence of any experimental data for 100% glutaraldehyde, a value of about 60 Pa was estimated using the Antoine equation (method error about 85%).
Reference:	Union Carbide Corporation, 1993

2.5 PARTITION COEFFICIENT $\log_{10} P_{ow}$

$Log_{10} P_{ow}$:	- 0.01
Temperature:	.....°C
Method:	calculated [ ]; measured [X]
GLP:	Yes [X] No [ ] ? [ ]
Remarks:	a 50% aqueous solution was used in the study
Reference:	Speigell, Nov. 1981

2.6 WATER SOLUBILITY

A. Solubility

Value:	miscible
Temperature:	20-21°C
Description:	Miscible [X]; Of very high solubility [ ]; Of high solubility [ ]; Soluble [ ]; Slightly soluble [ ]; Of low solubility [ ]; Of very low solubility [ ]; Not soluble [ ]
Method:	US FIFRA guidelines 1993
GLP:	Yes [X] No [ ] ? [ ]
Remarks:	mean of 18 replicates
Reference:	SLI report, Feb. 1994

B. pH Value, pKa Value

pH Value:	.....
Concentration:	.....
Temperature:	.....°C
Method:	
GLP:	Yes [ ] No [ ] ? [ ]
pKa value:	..... at 25°C
Remarks:	The 50% aqueous solution is mildly acid
Reference:	Russell & Hopwood, 1976

2.7 FLASH POINT *(liquids)*

Value:	.....°C
Type of test:	Closed cup [ ]; Open cup [ ]; Other [ ]
Method:	
GLP:	Yes [ ] No [ ] ? [ ]
Remarks:	No data available
Reference:	.....

2.8 AUTO FLAMMABILITY *(solid/gases)*

Value:	.....°C
Pressure:	.....hPa
Method:	
GLP:	Yes [ ] No [ ] ? [ ]
Remarks:	No data available
Reference:	.....

2.9 FLAMMABILITY

Results:	Extremely flammable [ ]; Extremely flammable-liquefied gas [ ]; Highly flammable [ ]; Flammable [ ]; Non flammable[ ]; Spontaneously flammable in air [ ]; Contact with water liberates highly flammable gases [ ]; Other
Method:	
GLP:	Yes [ ] No [ ] ? [ ]
Remarks:	No data available. Handled exclusively as an aqueous solution.
Reference:	.....

2.10 EXPLOSIVE PROPERTIES

Results:	Explosive under influence of a flame [ ]; More sensitive to friction than m-dinitrobenzene [ ] More sensitive to shock than m-dinitrobenzene [ ]; Not explosive[ ]; Other [ ]
Method:	
GLP:	Yes [ ] No [ ] ? [ ]
Remarks:	No data available. Handled exclusively as an aqueous solution.
Reference:	.....

2.11 OXIDISING PROPERTIES

Results:	Maximum burning rate equal or higher than reference mixture [ ]; Vigorous reaction in preliminary test [ ]; No oxidising properties [ ]; Other [ ]
Method:	
GLP:	Yes [ ] No [ ] ? [ ]
Remarks:	.....
Reference:	

2.12 OXIDATION: REDUCTION POTENTIAL

Value:	.....mV
Method:	
GLP:	Yes [ ] No [ ] ? [X]
Remarks:	Glutaraldehyde is oxidised to glutaric acid.
Reference:	Beauchamp, 1992

2.13 ADDITIONAL DATA

A. Partition coefficient between soil/sediment and water (Kd)

Value:	.....
Method:	
GLP:	Yes [ ] No [ ] ? [ ]
Remarks:	see 3.3.1
Reference:	.....

B. Solubility in other solvents

Value:	acetone:	miscible
	dichloromethane:	36 mg/100 mL
	ethyl acetate:	30 mg/100 mL
	isopropanol:	miscible
	n-hexane:	0.096 mg/mL
	toluene:	4.4 mg/100mL

Temperature:	20-21°C
Method:	US FIFRA guidelines 1993
GLP:	Yes [X] No [ ] ? [ ]
Remarks:	mean of 6 replicates
Reference:	SLI report, Feb. 1994

3. ENVIRONMENTAL FATE AND PATHWAYS

3.1 STABILITY

3.1.1 PHOTODEGRADATION

Type:	Air [ ]; Water [X]; Soil [ ]; Other [ ]
Light source:	Sunlight [X]; Xenon lamp [ ]; Other [ ]
Direct photolysis:	
Degradation:	no statistical change after 24 hours
Method:	US FIFRA guidelines 1993
GLP:	Yes [X]; No [ ]; ? [ ]
Test substance:	UCARCIDE Antimicrobial 250, a 50% aqueous solution
Remarks:	This recent study was not reviewed. Aldehydes (eg formaldehyde, furfural) are known to be unstable in air when exposed to sunlight.
Reference:	SLI report, Jan 1994

3.1.2 STABILITY IN WATER

(a)

Type: Abiotic (hydrolysis) [X]; biotic (sediment) [ ].

Half-life: 508 days at pH 5 at 25°C;
102 days at pH 7 at 25°C;
46 days at pH 9 at 25°C.

Method: US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate, Series 161-1, 1982.

GLP: Yes [X]; No [ ]; ? [ ].

Test substance: [1,5-^{14}C]-Glutaraldehyde (radiochemical purity 97.8%).

Remarks: The hydrolysis product is 3-formyl-6-hydroxy-2-cyclohexene-1-propanal (CAS No 130434-30-9).

Reference: PTRL Report 284W-1, Dec. 1992

(b)

Type: Abiotic (hydrolysis) [ ]; biotic (sediment) [X]
river water and sediment (ratio 5:1) from Sacramento River Delta (Antioch, California).

Half-life: 10.6 hours at 25°C

Method: US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate, Series 162-4, 1982.

GLP: Yes [X]; No [ ]; ? [ ].

Test substance: [1,5-^{14}C]-Glutaraldehyde (radiochemical purity 97.8%) at 10 ppm in the water.

Remarks: Metabolises aerobically to glutaric acid (CAS no. 110-94-1) which is itself completely metabolised within 48 h. Production of carbon dioxide (CAS no 124-38-9) reached 80% by the end of the 30 day study. 14% of applied radiolabel was found in sediment after 30 days, with around 90% being in the form of bound residues.
The half-life reflects primary degradation, although mineralisation was significant..

References: Esser, PTRL Report 364W-1, Nov. 1993
Esser, amended report, May 1994

(c)

Type: Abiotic (hydrolysis) [ ]; biotic (sediment) [X]
river water and sediment (ratio 5:1) from Sacramento River Delta (Antioch, California).

Half-life: 7.7 hours at 25°C.

Method: US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate, Series 162-4, 1982.

GLP: Yes [X]; No [ ]; ? [ ].

Test substance: [1,5-^{14}C]-Glutaraldehyde (radiochemical purity 97.8%) at 10 ppm in the water.

Remarks: Metabolises anaerobically to 1,5-pentanediol (CAS no. 110-94-1) (up to 78%), 5-hydroxypentanal (35-39%) and a glutaraldehyde dimer (12-23%). The radiocarbon in the sediment remained below 10% throughout 4 months, with about 30% in the form of bound residues. The half-life reflects primary degradation.

Reference:: Esser, PTRL Report no. 365W-1, June 1994

3.1.3 STABILITY IN SOIL

No specific tests were performed. However, significant losses of glutaraldehyde to metabolism (generally 15-40%, but >80% in loamy sand) occurred during 24 h of equilibration in soil adsorption testing (see 3.3.1).

3.2 MONITORING DATA

No formal data are available. However, water authorities report that glutaraldehyde has never impacted on sewage treatment processes.

3.3 TRANSPORT AND DISTRIBUTION

Because of the use pattern of glutaraldehyde in Australia, the main exposure is aquatic (sewer) with some atmospheric.

Significant transport is not expected because of limited persistence in air, soil and water.

Concentrations likely to arise in sewage treatment works were estimated by diluting the average daily disposal from sterilant baths (assumed to be 75% of average daily use) and assuming dilution in the daily sewage flow, without degradation or sorption. Estimated concentrations in city and rural treatment works were about 50 and 200 µg/L, well below biocidal concentrations. The concentration likely to enter receiving waters is therefore low.

3.3.1 TRANSPORT

Type: Adsorption [X]: Desorption [X]; Volatility [ ]: Other [ ]

Method: US EPA Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate, Series 163.1, 1982.

GLP: Yes [X]; No [ ]; ? [ ].

Test substance: [1,5-^{14}C]-Glutaraldehyde (radiochemical purity 96.5%).

Concentration: 0-10 ppm in aqueous phase.

Soil class'n: DIN19863 [ ]; NF X31-107 [ ], USDA [X]; Other [ ]

Soil types:	Sandy loam, pH 6.8, 1.0% organic carbon, 10% clay, 23% silt, 67% sand, cation exchange capacity 5.5 meq/100 g; Silty clay loam, pH 5.7, 1.0% organic carbon, 29% clay, 55% silt, 16% sand, cation exchange capacity 19.7 meq/100 g; Silt loam, pH 6.7, 1.4% organic carbon, 21% clay, 62% silt, 17% sand, cation exchange capacity 16.8 meq/100 g; Loamy sand, pH 5.8, 0.24% organic carbon, 0% clay, 17% silt, 83% sand, cation exchange capacity 2.9 meq/100 g; Sediment, pH 8.1, 0.5% organic carbon, 0% clay,7% silt, 93% sand, cation exchange capacity 4.3 meq/100 g.
Adsorption:	Soil organic carbon partition coefficients were 210, 500, 340, 460 and 120, respectively.
Remarks:	Equilibration times for adsorption were reduced to 24 h to minimise degradation. The water/soil ratio varied between 1.5 and 3, depending on the soil. Sorption coefficients were determined using the Freundlich equation. Desorption isotherms could not be obtained because of degradation.
Reference:	Skinner, PTRL Report 363W-1, Mar. 1994

3.3.2 THEORETICAL DISTRIBUTION (FUGACITY CALCULATION)

No fugacity calculations were performed as glutaraldehyde has limited persistence. Its environmental fate is primarily determined by degradation rather than equilibration between compartments.

3.4 MAIN MODE OF DEGRADATION IN ACTUAL USE

No studies were located. However, because of the use pattern of glutaraldehyde in Australia, biodegradation in the sewer and at the treatment works is the main mode of degradation.

3.5 BIODEGRADATION

(a)

Type:	Aerobic [X]; anaerobic [ ].
Inoculum:	Adapted [ ]; non-adapted [X] activated bacterial sludge from a Swiss domestic wastewater plant (ARA Sissach).
Concentration:	0.1 g/L related to COD [ ]; DOC [ ]; test substance [X].
Medium:	water [ ]; water-sediment [ ]; soil [ ]; sewage treatment [X].
Degradation	0% in 3 days (BOD/COD) 13% in 5 days

23% in 6 days
30% in 7 days
35% in 15 days
80% in 15 days (DOC)

Results: Readily biodegradable [ ]; Inherently biodegradable [ ]; under test condition no biodegradation observed [ ]; other [X].

Method: OECD Guideline for Testing of Chemicals No 301C: "Ready biodegradability: Modified MITI Test (I)", 1981.

GLP: Yes [X]; no [ ]; ? [ ].

Remarks: The concentration tested is likely to have been inhibitory to microorganisms in the sludge. Because of the stringency of this test, the failure to achieve 60% BOD does not necessarily mean that the test substance would not be biodegradable under environmental conditions, but indicates that more work is necessary to establish biodegradability. The DOC result suggests ready biodegradability, as do the aquatic metabolism results [3.1.2(b)].

Reference: Ritter, RCC project 245327, May 1990

(b)
Type: Aerobic [X]; anaerobic [ ]

Inoculum: not stated

Concentration: 2-5 mg/L related to COD [ ]; DOC [ ]; test substance [X]

Medium: water [ ]; water-sediment [ ]; soil [ ]; sewage treatment [X]

Degradation: 74% of ThOD

Results: Readily biodegradable [X]; Inherently biodegradable [ ]; under test condition no bioddegradation observed [ ]; other [ ]

Method: Off. J. European Communities vol.27, 19 Sep 1984, no.L 251/188 (Closed Bottle Test OECD TG 301D)

GLP: Yes [ ]; no [ ]; ? [X]

Remarks: An inhibitory threshold of about 100 mg/L was determined separately [see 4.4(b)]

Reference: Gerike & Gode, 1990

3.6 BOD_5, COD OR RATIO BOD_5/COD

BOD_5

Method: "Standard Methods for the Examination of Water and Wastewater", 14 Ed, American Public Health Assoc, Washington DC, 1975.

Concentration: 0.9 mg/L related to COD [ ]; DOC [ ]; test substance [X];
1.7 mg/L related to COD [ ]; DOC [ ]; test substance [X];
3.3 mg/L related to COD [ ]; DOC [ ]; test substance [X];
5.0 mg/L related to COD [ ]; DOC [ ]; test substance [X];
10 mg/L related to COD [ ]; DOC [ ]; test substance [X].

Result: See ratio BOD_5/COD

GLP: Yes [ ]; no [ ]; ? [X].

COD

Method: "Standard Methods for the Examination of Water and Wastewater", 14 Ed, American Public Health Assoc, Washington DC, 1975.

Result: 1.88 mg O_2/mg glutaraldehyde (measured)
1.92 mg O_2/mg glutaraldehyde (calculated)

GLP: Yes [ ]; no [ ]; ? [X].

RATIO BOD_5/COD

Result: 71% at 0.9 mg/L;
55% at 1.7 mg/L;
11% at 3.3 mg/L;
12% at 5.0 mg/L;
7% at 10.0 mg/L.

Remarks: Note inhibitory effects at higher concentrations.

Reference: Union Carbide R & D project 515GO2, Oct. 1981.

3.7 BIOACCUMULATION

No tests conducted. As glutaraldehyde is hydrophilic and nonpersistent, significant bioaccumulation potential is not expected.

3.8 ADDITIONAL REMARKS

As well as undergoing rapid biodegradation in aquatic media (including sewage effluent), glutaraldehyde reacts with proteinaceous constituents of sewage.

4 ECOTOXICOLOGICAL DATA

4.1 ACUTE TOXICITY TO FISH

Type of test:	static [X]; semi-static [ ]; flow-through [ ]; other [ ]; open-system [ ]; closed-system [X]
Species:	Bluegill sunfish
Duration:	96 hours
Result:	24 h LC50 = 14.9 mg/L; 48 h LC50 = 11.8 mg/L; 96 h LC50 = 11.2 mg/L; NOEC = 10 mg/L.
Monitoring:	Yes [ ]; no [X].
Method:	Committee on Methods for Toxicity Tests with Aquatic Organisms. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. US EPA-660/3-75-009.
GLP:	Yes [ ]; no [ ]; ? [X].
Test substance:	50% solution (results expressed in terms of glutaraldehyde).
Remarks:	No replicates were used. The close similarity of 48 and 96 hour end-points suggests that glutaraldehyde degraded during the test. A similar end-point is reported for rainbow trout, but lacks a confirmatory test report.
Reference:	Union Carbide Environmental Services project 11506-61-06, Jan. 1978.

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

A. Daphnia

(a)

Type of test:	static [X]; semi-static [ ]; flow-through [ ]; other [ ]; open-system [ ]; closed-system [X]
Species:	*Daphnia magna*
Duration:	48 hours
Result:	48 h LC50 = 0.35 mg/L;
Monitoring:	Yes [ ]; no [X].
Method:	Committee on Methods for Toxicity Tests with Aquatic Organisms. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. US EPA-660/3-75-009.

GLP: Yes [ ]; no [ ]; ? [X].

Test substance: 50% solution (results expressed in terms of glutaraldehyde).

Remarks: Tests were conducted on four replicates, each containing 5 daphnids. Mortality was complete within 24 h at the highest dose tested (nominally 0.5 mg/L) but no deaths occurred at lower concentrations. By 48 h, mortality reached 5 and 10%, respectively, at 0.025 and 0.045 mg/L, but daphnids exposed to 0.08 and 0.14 mg/L all survived. The erratic results should be treated with caution.

Reference: Union Carbide Environmental Services project 11506-61-04, Jan. 1978.

(b)

Type of test: static [X]; semi-static [ ]; flow-through [ ]; other [ ]; open-system [ ]; closed-system [X]

Species: *Daphnia magna*

Duration: 48 hours

Result: 24 h LC50 > 25 mg/L;
48 h LC50 = 16.3 mg/L;
NOEC = 8 mg/L.

Monitoring: Yes [ ]; no [X].

Method: Committee on Methods for Toxicity Tests with Aquatic Organisms,1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians.
US EPA-660/3-75-009.

GLP: Yes [ ]; no [ ]; ? [X].

Test substance: 25% solution (results expressed in terms of glutaraldehyde).

Remarks: Tests were conducted on four replicates, each containing 5 daphnids. At 24 h, only one daphnid had deceased, at the highest concentration tested. By 48 h, mortality was complete at this concentration, and reached 25% at 14 mg/L.

Reference: Union Carbide Environmental Services project 11506-61-03, Dec. 1977

B. Other Aquatic Organisms

(a)

Type of test: static [X]; semi-static [ ]; flow-through [ ]; other [ ]; open-system [ ]; closed-system [X]

Species: Oyster larvae (*Crassostrea virginica*)

Duration:	48 hours
Result:	48 h LC50 = 2.1 mg/L; NOEC = 0.32 mg/L.
Monitoring:	Yes [ ]; no [X].
Method:	Committee on Methods for Toxicity Tests with Aquatic Organisms, 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. US EPA-660/3-75-009.
GLP:	Yes [ ]; no [ ]; ? [X].
Test substance:	25% solution (results expressed in terms of glutaraldehyde).
Remarks:	The bioassay was terminated after 48 hours as veligers would not survive without feeding beyond that period.
Reference:	Union Carbide Aquatic Env. Services, Dec. 1975.

(b)

Type of test:	static [X]; semi-static [ ]; flow-through [ ]; other [ ]; open-system [ ]; closed-system [X]
Species:	Green Crabs (*Carcinus maenas*)
Duration:	96 hours
Result:	48 h LC50 = 1100 mg/L; 96 h LC50 = 465 mg/L;
Monitoring:	Yes [X]; no [ ].
Method:	Committee on Methods for Toxicity Tests with Aquatic Organisms. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. US EPA-660/3-75-009.
GLP:	Yes [ ]; no [ ]; ? [X].
Test substance:	25% solution (results expressed in terms of glutaraldehyde).
Remarks:	No significant difference in analyses at 48 and 96 hours.
Reference:	Union Carbide Aquatic Env. Services, Dec 1975.

(c)

Type of test:	static [X]; semi-static [ ]; flow-through [ ]; other [ ]; open-system [ ]; closed-system [X]
Species:	Grass Shrimp (*Palaemonetes vulgaris*)
Duration:	96 hours
Result:	48 h LC50 = 400 mg/L;

96 h LC50 = 41 mg/L;

Monitoring: Yes [X]; no [ ].

Method: Committee on Methods for Toxicity Tests with Aquatic Organisms. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. US EPA-660/3-75-009.

GLP: Yes [ ]; no [ ]; ? [X].

Test substance: 25% solution (results expressed in terms of glutaraldehyde).

Remarks: No significant difference in analyses at 48 and 96 hours.

Reference: Union Carbide Aquatic Env. Services, Dec. 1975.

(d)

Type of test: static [ ]; semi-static [X]; flow-through [ ]; other [ ]; open-system [ ]; closed-system [ ]

Species: Marine amphipod (*Chaetogammarus marinus*)

Duration: 96 hours

Result:
24 h LC50 = 582 mg/L
48 h LC50 = 304 mg/L
72 h LC50 = 208 mg/L
96 h LC50 = 191 mg/L
96 h NOEC = 56 mg/L

Monitoring: Yes [ ]; no [X]

Method: Not stated

GLP: Yes [ ]; no [ ]; ? [X]

Test substance: 25% solution (Fluka AG)

Remarks: pH 8, salinity 28%

Reference: Adema & Bakker, May 1984

4.3 TOXICITY TO AQUATIC PLANTS eg Algae

(a)

Species: *Selenastrum capricornutum*

End-point: Biomass [X]; Growth Rate [ ]; Other [ ]

Duration: 96 hours

Results: Median inhibitory limit = 3.9 mg/L.

Monitoring:	Yes [ ]; no [X].
Method:	US EPA, "Algal Assay Procedure: Bottle Test", National Eutrophication Research program, Corvallis, Oregon, 1969, 1971.
GLP:	Yes [ ]; no [ ]; ? [X].
Test substance:	25% solution (results expressed in terms of glutaraldehyde).
Remarks:	The biomass was monitored by direct cell count and absorbance.
Reference:	Union Carbide Aquatic Env. Services, Dec. 1974.

(b)

Species	*Scenedesmus supspicatus*
End-point:	Biomass [X]; Growth Rate [ ]; Other [ ]
Duration:	96 hours
Results:	96 h EC50 = 2.1 mg/L LOEC = 1.25 mg/L NOEC = 0.625 mg/L
Monitoring:	Yes [X]; no [ ].
Method:	OECD Guideline for Testing of Chemicals No 201: "Alga, Growth Inhibition Test", 1984.
GLP:	Yes [X]; no [ ]; ? [ ].
Test substance:	50% solution (results expressed in terms of glutaraldehyde).
Remarks:	The biomass was monitored by direct cell count, and the end-point was determined from the area under the curve. End-points are expressed as nominal concentrations. Analytical measurements indicated that actual concentrations were in the order of 20% of nominal initially, declining to 5% or less after 96 h.
Reference:	RCC project 245340, May 1990.

4.4 TOXICITY TO BACTERIA

(a)

Type:	Aquatic [ ]; Field [ ]; Soil [ ]; Other [X]
Species	Various (unacclimated sewage microorganisms)
End-point:	Biomass [X]; Growth Rate [ ]; Other [ ]
Duration:	Not known (method specifies 16 hours)

Results:	IC50 = 25, 34 mg/L NOEC = 5, 10 mg/L
Monitoring:	Yes [ ]; no [X].
Method:	G M Alsop, G T Waggy and R A Conway, "Bacterial Growth Inhibition Test", *Journal WPCF*, 1980, **52**, 2452-2456.
GLP:	Yes [ ]; no [ ]; ? [X].
Test substance:	Not known.
Remarks:	The microbial population density was determined by turbidity measurement at 530 nm. This is a preliminary study only. A definitive study is in progress.

(b)

Type:	Aquatic [ ]; Field [ ]; Soil [ ]; Other [X]
Species:	*Pseudomonas putida*
End-point:	Biomass [ ]; Growth rate [ ]; Other [X]
Duration:	not stated
Results:	Inhibitory limit 130 mg/L
Monitoring:	Yes [ ]; no [ ]
Method:	OECD TG 209 (respiration inhibition - using above species in place of activated sludge)
GLP:	Yes [ ]; no [ ]; ? [X]
Test substance:	not known
Remarks:	The inhibitory limit measured in an OECD Confirmatory Test unit was 90 mg/L
Reference:	Gerike & Gode, 1990

4.5 CHRONIC TOXICITY TO AQUATIC ORGANISMS

4.5.1 CHRONIC TOXICITY TO FISH

No tests performed.

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

Type of test:	static [ ]; semi-static [X]; flow-through [ ]; other [ ]; open-system [ ]; closed-system [X]

Species:	*Daphnia magna*
Duration:	21 days
Result:	21 day LC50 > 4.3 mg/L; LOEC = 4.3 mg/L; NOEC = 2.1 mg/L.
Monitoring:	Yes [X]; no [ ].
Method:	OECD Guideline for Testing of Chemicals No 202: "*Daphnia* sp., Acute Immobilisation Test and Reproduction Test", 1984.
GLP:	Yes [X]; no [ ]; ? [ ].
Test substance:	50% solution (results expressed in terms of glutaraldehyde).
Remarks:	Test solutions were renewed three times per week, with concentrations measured for the initial and final renewal. Results are expressed as nominal concentrations, and should be treated with caution as measured concentrations were extremely erratic, ranging from 99.3% of nominal to below the limit of detection, and not correlated with nominal concentration or exposure period. The NOEC and LOEC reflect number of offspring per adult.
Reference:	Cytotest Cell Research project 164002, Mar. 1990.

4.6 TOXICITY TO TERRESTRIAL ORGANISMS

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

No tests available

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

No tests available.

4.6.3 TOXICITY TO OTHER NON-MAMMALIAN TERRESTRIAL SPECIES (INCLUDING AVIAN).

(a)

Species	Mallard duck
End-point:	Mortality [X]; Reproduction Rate [ ]; Weight[ ]; Other [ ]
Duration:	Acute oral administration, 8 days observation.
Results:	LC50 = 408 mg/kg;
Method:	Not specified.

GLP:	Yes [ ]; no [ ]; ? [X].
Test substance:	25% solution (results expressed in terms of glutaraldehyde).
Remarks:	Ducklings were 14 days old at study initiation.
Reference:	Wildlife project 142-114, Jan. 1978.

(b)

Species	Mallard duck
End-point:	Mortality [X]; Reproduction Rate [ ]; Weight[ ]; Other [ ]
Duration:	Acute oral administration, 8 days observation.
Results:	LC50 = 466 mg/kg;
Method:	Not specified.
GLP:	Yes [ ]; no [ ]; ? [X].
Test substance:	50% solution (results expressed in terms of glutaraldehyde).
Remarks:	Ducklings were 14 days old at study initiation.
Reference:	Wildlife project 142-111, Feb. 1978.

(c)

Species	Mallard duck
End-point:	Mortality [X]; Reproduction Rate [ ]; Weight[ ]; Other [ ]
Duration:	5 days dietary administration followed by 3 days observation.
Results:	LC50 > 5000 mg/kg;
Method:	Not specified.
GLP:	Yes [ ]; no [ ]; ? [X].
Test substance:	50% solution (results expressed in terms of glutaraldehyde) dissolved in corn oil and added to standard game bird starter ration.
Remarks:	Ducklings were 14 days old at study initiation. Reductions in feed consumption occurred at concentrations of 2320 mg/kg and above.
Reference:	Wildlife project 142-110, Jan. 1978.

(d)

Species:	Bobwhite quail
End-point:	Mortality [X]; Reproduction Rate [ ]; Weight[ ]; Other [ ]

Duration:	5 days dietary administration followed by 3 days observation.
Results:	LC50 > 2500 mg/kg;
Method:	Not specified.
GLP:	Yes [ ]; no [ ]; ? [X].
Test substance:	25% solution (results expressed in terms of glutaraldehyde) dissolved in corn oil and added to standard game bird starter ration.
Remarks:	Hatchlings were 14 days old at study initiation. There were no overt symptoms of toxicity or behavioural abnormalities.
Reference:	Wildlife project 142-112, Jan. 1978.

(e)

Species:	Bobwhite quail
End-point:	Mortality [X]; Reproduction Rate [ ]; Weight[ ]; Other [ ]
Duration:	5 days dietary administration followed by 3 days observation.
Results:	LC50 > 5000 mg/kg;
Method:	Not specified.
GLP:	Yes [ ]; no [ ]; ? [X].
Test substance:	50% solution (results expressed in terms of glutaraldehyde) dissolved in corn oil and added to standard game bird starter ration.
Remarks:	Hatchlings were 14 days old at study initiation. No overt symptoms of toxicity were apparent, but there was a reduction in body weight gain at the highest dose tested.
Reference:	Wildlife project 142-112, Jan. 1978.

4.7 BIOLOGICAL EFFECTS MONITORING

No reports.

4.8 BIOTRANSFORMATION AND KINETICS

No data. Glutaraldehyde would be expected to be rapidly metabolised in and excreted from living organisms.

4.9 ADDITIONAL REMARKS

None

5. TOXICITY

5.1 ACUTE TOXICITY

5.1.1 ACUTE ORAL TOXICITY

(a)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rat (Sprague-Dawley)
Value:	male 246 mg/kg b.w.: female 154 mg/kg
Method:	US EPA, 40 CFR, parts 158 & 798
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	50% aqueous solution
Remarks:	5 animals/sex/dose. Males administered (by gavage) 100, 200 or 400 mg/kg, females 100, 140 or 200 mg/kg. Dissection revealed damage and discolouration of lungs, stomach and intestines, with kidney damage in 2 females. All survivors recovered within 4-5 days.
Reference:	Bushy Run RC report 54-145, Jan 1992

(b)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rat (Sprague-Dawley)
Value:	male 316 mg/kg b.w.: female 285 mg/kg
Method:	OECD 401
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	50% aqueous solution
Remarks:	5 animals/sex/dose. Animals administered (by gavage) 215, 316, 464 or 1470 mg/kg. Dissection revealed acute congestion, damage and discolouration of stomach and intestines. Symptoms observed during exposure included breathing difficulty, apathy, piloerection and unsteadiness.
Reference:	BASF, 22 Dec 1981

(c)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rat (Wistar)
Value:	male 362 mg/kg b.w.: female 418 mg/kg
Method:	US EPA, 40 CFR 163.81-1
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	50% aqueous solution
Remarks:	5 animals/sex/dose were administered (by gavage) 226, 339, 565, 1130 or 1920 mg/kg. Dissection revealed damage to the lungs, stomach, intestines, liver and spleen. All survivors appeared healthy.
Reference:	Product Safety Labs, 22 June 1982

(d)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rat (albino) - males only
Value:	male 1330 mg/kg b.w.
Method:	.....
GLP:	Yes [ ] No [X] ? [ ]
Test substance:	45% aqueous solution
Remarks:	5 animals/dose were administered (by gavage) 560, 1120 or 2240 mg/kg. Dissection revealed congestion of the lungs.
Reference:	Mellon Institute report 27-137, Sep. 1964

(e)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rat (Wistar) - males only
Value:	male 1.47 g/kg b.w.
Method:	.....
GLP:	Yes [ ] No [X] ? [ ]
Test substance:	50% aqueous solution
Remarks:	5 animals/dose were administered (by gavage) 0.56, 1.13, 2.26, 4.52 or 9.0 g/kg. Dissection revealed damage to the liver, kidneys, adrenals, stomach and intestines. Some liver changes were observed in survivors.
Reference:	Chemical Hygiene Fellowship report 40-50, April 1977

(f)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rat (Wistar) - males only
Value:	male 1.98 g/kg b.w.:
Method:	.....
GLP:	Yes [ ] No [X] ? [ ]
Test substance:	25% aqueous solution
Remarks:	5 animals/dose were administered (by gavage) 1.1, 2.1 or 4.2 g/kg. Dissection revealed damage to the lungs, liver, adrenals, stomach, intestines, kidneys and spleen.
Reference:	Chemical Hygiene Fellowship report 40-120, Sep. 1977

(g)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rat (Wistar)
Value:	(i) male and female > 16 g/kg b.w. (ii) m 12.3, f 9.85 g/kg; (iii) m 3.32, f 1.33 g/kg; (iv) m 1.67, f 1.10 g/kg
Method:	OECD 401
GLP:	Yes [ ] No [ ] ? [X]
Test substance:	(i) 0.5% aqueous solution; (ii) 1.0%; (iii) 5.0%; (iv) 10%
Remarks:	5 animals/sex/dose were administered (by gavage) 3-6 doses between 0.5 and 16 mL/kg, except for 0.5% solution (16 mL/kg only). Gross pathology observations in victims included damage to the lungs, liver, stomach, intestines, kidneys and

spleen. Observations in survivors included discolouration of the lungs, liver and kidneys.

Reference: Bushy Run RC report 45-124, May 1990

(h)

Type: LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain: Rat (Wistar)
Value: male 1217 mg/kg b.w.: female 919 mg/kg
Method: US FIFRA 1982 guidelines
GLP: Yes [X] No [ ] ? [ ]
Test substance: 14.5% aqueous solution

Remarks: 5 animals/sex/dose were administered (by gavage) 325, 650, 1300 or 2600 mg/kg. Dissection revealed discolouration of the lungs, stomach and intestines. All survivors appeared healthy.

Reference: Bushy Run RC report 47-166, Nov. 1984

5.1.2 ACUTE INHALATION TOXICITY

(a)

Type: LC_0 [ ]; LC_{100} [ ]; LC_{50} [X], LCL_0 [ ]; Other [ ]
Species/strain: Rat (Fischer 344)
Exposure time: 4 hours
Value: male 96 µg/L (23.5 ppm $^{v}/_{v}$); female 164 µg/L (40.1 ppm)
Method: OECD 403
GLP: Yes [X] No [ ] ? [ ]
Test substance: Vapours generated by metering 5% aqueous solution into rotating evaporator tube, where hot air (65oC) exhausted into inhalation chamber.

Remarks: Dynamic study; 6/sex/dose exposed to 10.6, 23.0 or 42.7ppm $^{v}/_{v}$. Mortality: 42.7 ppm - 1 during exposure, 4 on day 1 after exposure, 2 on day 2 , 2 on day 3; 23.5 ppm - 3 on day 1, 1 on day 7. Animals died of lung damage. Signs of toxicity during exposure included excess lacrimation and salivation, audible and mouth breathing, and encrustation around nose and mouth. The study report attributed the high toxicity to the presence of more toxic higher molecular weight species formed during vapour generation at 65°C, but this was not substantiated.

Reference: Bushy Run RC report 44-96, Jan 1982

(b)

Type: LC_0 [ ]; LC_{100} [ ]; LC_{50} [X], LCL_0 [ ]; Other [ ]
Species/strain: Rat (Sprague-Dawley)
Exposure time: 4 hours
Value: male 0.35 mg/L; female 0.28 mg/L
Method: OECD 403
GLP: Yes [X] No [ ] ? [ ]
Test substance: 50% aqueous solution - aerosol

Remarks:	10 animals/sex/dose were exposed to 0.10, 0.18, 0.28, 0.39 or 0.44 mg/L. Animals died of acute congestion of the lungs. Signs of toxicity during exposure included excitation and discharge from the eyes and nose. Breathing difficulties persisted after exposure. The surviving animals showed no abnormalities after 5-9 days.
Reference:	BASF, 18 June 1982

(c)

Type:	LC_0 [ ]; LC_{100} [ ]; LC_{50} [X], LCL_0 [ ]; Other [ ]
Species/strain:	Rat (Wistar)
Exposure time:	4 hours
Value:	0.80 mg/L (male & female)
Method:	.....
GLP:	Yes [ ] No [ ] ? [X]
Test substance:	25% aqueous solution - aerosol
Remarks:	10 animals/sex/dose exposed to 0.51, 0.68 or 1.1 mg/L.
Reference:	BASF, 21 Jan. 1985 (in German)

(d)

Type:	LC_0 [ ]; LC_{100} [ ]; LC_{50} [X], LCL_0 [ ]; Other [ ]
Species/strain:	Rat (Sprague-Dawley)
Exposure time:	4 hours
Value:	male 0.52 mg/L; female 0.45 mg/L
Method:	.....
GLP:	Yes [ ] No [ ] ? [X]
Test substance:	50% aqueous solution - aerosol
Remarks:	10 animals/sex/dose exposed to 0.22, 0.31 or 0.63 mg/L.
Reference:	BASF, 24 Jan. 1985 (in German)

(e)

Type:	LC_0 [ ]; LC_{100} [ ]; LC_{50} [X], LCL_0 [ ]; Other [ ]
Species/strain:	Rat (Sprague-Dawley)
Exposure time:	4 hours
Value:	No mortality, so no LC_{50} determined
Method:	OECD 403
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	50% aqueous solution - open tray for static study, and air bubbler generation (at ambient temperature) for dynamic studies
Remarks:	In static study, 5 animals/sex exposed to mean vapour concentration of 3 ppm glutaraldehyde- no mortality In dynamic studies, 5 animals/sex exposed to mean vapour concentration of 16.3 ppm or 14.5 ppm- no mortality. No gross lesions observed at necropsy.
Reference:	Bushy Run RC report 53-8, Nov. 1991

5.1.3 ACUTE DERMAL TOXICITY

(a)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rat (Sprague-Dawley)
Value:	> 2000 mg/kg b.w.
Method:	OECD 402
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	50% aqueous solution
Remarks:	5 animals/sex/dose. Dose of 200, 1000 or 2000 mg/kg applied under an adhesive bandage to the clipped skin of the back and flank. One female at 2000 mg/kg died within 7 days and another within 14 days. Signs of systemic toxicity included breathing difficulty and apathy at 1000 and 2000 mg/kg, unsteadiness at the high dose, and excitation at all doses.
Reference:	BASF, 22 Dec 1981

(b)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rabbit (albino) - males only
Value:	(i) 1.80 g/kg b.w.; (ii) 8.5 g/kg; (iii) > 16.3 g/kg
Method:	Similar to OECD 402
GLP:	Yes [ ] No [ ] ? [X]
Test substance:	(i) 50% aqueous solution; (ii) 25%; (iii) 5%
Remarks:	50% - 4 animals/dose at 0.5, 1.0, 2.0 or 4.0 mL/kg applied under a bandage to the clipped skin of the trunk. 25% - 4 animals/dose at 2, 4, 8 or 16 mL/kg. 5% - 6 animals dosed at 16.0 mL/kg - no mortality. Gross pathology in victims revealed damage to the liver, kidneys, spleen, lungs and stomach.
Reference:	Bushy Run RC report 44-65, June 1981

(c)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rat (New Zealand White)
Value:	(i) males 2.24 g/kg b.w., females 3.04 g/kg (ii) > 16.6 g/kg; (iii) > 16.5 g/kg
Method:	OECD 402
GLP:	Yes [ ] No [ ] ? [X]
Test substance:	(I) 45% aqueous solution; (ii) 15%; (iii) 10%
Remarks:	45% - 5 animals/sex/dose at 1.0, 2.0 or 4.0 mL/kg applied under a bandage to the clipped skin of the trunk; also 5 females at 2.8 mL/kg, and .2 males at 8.0 or 16.0 mL/kg 15% - 5 animals/sex/dose at 16 mL/kg, and 5 females at 8.0 mL/kg - 1 female died at 16 mL/kg, no other mortality 10% - 5 animals/sex/dose at 16.0 mL/kg - no mortality. Gross pathology observations in victims included mottled and red lungs and subcutaneous oedema of the abdominal area.
Reference:	Bushy Run RC report 48-51, June 1985

(d)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other []
Species/strain:	Rabbit (New Zealand albino)
Value:	617 mg/kg b.w.
Method:	.....
GLP:	Yes [ ] No [X] ? [ ]
Test substance:	45% aqueous solution
Remarks:	4 animals/dose at approx. 0.6, 1.3 or 2.8 mL
Reference:	Mellon Institute report 27-137, Sep. 1964

(e)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other []
Species/strain:	Rabbit (albino) - males only
Value:	2.87 g/kg b.w.
Method:	.....
GLP:	Yes [ ] No [X] ? [ ]
Test substance:	50% aqueous solution
Remarks:	4 animals/dose at 0.90, 1.8, 3.6 or 7.2 g/kg. Gross pathology observations in victims included damage to lungs, liver, spleen and kidneys. In survivors, kidneys were mottled.
Reference:	Chemical Hygiene Fellowship report 40-50, April 1977

(f)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other []
Species/strain:	Rabbit (albino) - males only
Value:	13.6 g/kg b.w.
Method:	.....
GLP:	Yes [ ] No [X] ? [ ]
Test substance:	25% aqueous solution
Remarks:	4 animals/dose at 6.8 or 13.6 g/kg, 2 animals at 0.85 or 3.4 g/kg. Only 2/4 deaths at highest dose, so high degree of uncertainty in value. Gross pathology observations in victims included mottled liver and congested kidneys.
Reference:	Chemical Hygiene Fellowship report 40-120, Sep. 1977

(g)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other []
Species/strain:	Rabbit (New Zealand White)
Value:	> 2 g/kg b.w.
Method:	US FIFRA 1982 guidelines
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	14.5% aqueous solution
Remarks:	1.0 or 2.0 g/kg was applied (under gauze) to the clipped trunk of 5 animals/sex/dose. Only one male death at 2g/kg occurred. Gross pathology revealed discoloured lungs in 3 males.
Reference:	Bushy Run RC report 47-166, Nov. 1984

(h)

Type:	LD_0 [ ]; LD_{100} [ ]; LD_{50} [X], LDL_0 [ ]; Other [ ]
Species/strain:	Rabbit (.....)
Value:	male (i) 900 mg/kg b.w.: (ii) 1430 mg/kg b.w.
Method:	
GLP:	Yes [ ] No [ ] ? [X]
Test substance:	50% aqueous solution,
Remarks:	.....
Reference:	Ballantyne, 1986

5.1.4 ACUTE TOXICITY, OTHER ROUTES OF ADMINISTRATION
(e.g. subcutaneous, intravenous etc.)

No studies available.

5.2 CORROSIVENESS/IRRITATION

5.2.1 SKIN IRRITATION/CORROSION

(a)

Species/strain:	Rabbit (New Zealand White)
Results:	50% aqueous solution: Corrosive [X] 25%: Highly irritating [X] 2%: Slightly irritating [X] 1%: Not irritating [X]
Classification:	> 25%: Corrosive (caused burns) [X] 2% and up to 25%: Irritating [X]
Method:	OECD 404
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	1% to 50% aqueous solutions
Remarks:	3 male and 3 females treated with 0.5 mL solution, which was kept in contact for 4 hours under an occlusive dressing. 45 and 50% solutions corosive - moderate to severe erythema, slight to severe oedema and spots of necrosis; 25% solution a severe irritant; 2% a slight irritant; no significant effects for a 1% solution.
Reference:	Bushy Run RC report 47-33, Nov 1984

(b)

Species/strain:	Rabbit (New Zealand White)
Results:	Highly irritating [X]
Classification:	Highly corrosive (causes severe burns) [ ]; Corrosive (caused burns) [ ]; Irritating [X]; Not irritating [ ]
Method:	USA FIFRA 1982 guidelines
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	14.5% aqueous solution
Remarks:	3 male and 3 females treated with 0.5 mL solution, which was kept in contact for 4 hours under an occlusive dressing. Resulted in moderate to severe erythema, moderate oedema and necrosis.
Reference:	Bushy Run RC report 47-166, Nov. 1984

5.2.2 EYE IRRITATION/CORROSION

(a)

Species/strain:	Rabbit (New Zealand White)
Results:	5% solution: Highly irritating [X] 2%: Irritating [X] 1%: Moderate irritating [X]
Classification:	Irritating [X]; Not irritating [ ]; Risk of serious damage to eyes [ ]
Method:	OECD 405
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	1, 2 and 5% aqueous solutions
Remarks:	In this study, 6 rabbits/dose were treated with 0.01 mL or 0.1mL of solution, resulting in: 5% (0.1 mL) - severe corneal injury, moderate iritis, severe and persistent conjunctival irritation and necrosis 2% - slight corneal injury, moderate iritis and moderate to severe conjunctival irritation 1% - slight corneal injury and iritis in 2/6 animals, moderate to severe conjunctival irritation in 3/6
Reference:	Bushy Run RC report 47-33, Nov 1984

(b)

Species/strain:	Rabbit (albino) - males only
Results:	Slightly irritating [X]
Classification:	Iritating [X]
Method:	OECD 405
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	0.1, 0.2 and 0.5% aqueous solutions
Remarks:	6 rabbits/dose were treated with 0.01 mL or 0.1mL of solution, resulting in slight redness of eyelids and conjunctival irritation for 0.2 and 0.5% (0.1 mL), but no effect at 0.1%.
Reference:	Bushy Run RC report 47-65, June 1981

(c)

Species/strain:	Rabbit (New Zealand White)
Results:	Corrosive [X]
Classification:	Iritating [ ]; Not irritating [ ]; Risk of serious damage to eyes [X}
Method:	US FIFRA 1982 guidelines
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	14.5% aqueous solution
Remarks:	3 male and 3 female rabbits were treated with 0.1 mL of solution, resulting in severe corneal injury, iritis and severe conjunctival irritation.
Reference:	Bushy Run RC report 47-166, Nov. 1984

5.3 SKIN SENSITISATION

(a)

Type:	Maximisation
Species/strain:	Guinea-pig (Dunkin Hartley)
Results:	Sensitising [X]; Not sensitising [ ]; ambiguous [ ]
Classification:	Sensitising [X]; Not sensitising [ ]
Method:	OECD 406
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	2% aqueous solution
Remarks:	A 2% aqueous solution was a moderate to strong skin sensitiser, and a 2% alkalinised solution was a weak to moderate skin sensitiser.
Reference:	Pharmaco LSR report 93-0793, Sept 1993

(b)

Type:	Buehler
Species/strain:	Guinea-pig (Hartley)
Results:	Sensitising [ ]; Not sensitising [X]; ambiguous [ ]
Classification:	Sensitising [ ]; Not sensitising [X]
Method:	OECD 406
GLP:	Yes [ ] No [ ] ? [X]
Test substance:	0.5% aqueous solution
Remarks:	A 0.5% aqueous solution did not produce skin sensitisation in 10 male animals.
Reference:	Product Safety Labs, 1 June 1982

(c)

Type:	Patch Test
Species/strain:	Human
Results:	Sensitising [ ]; Not sensitising [ ]; ambiguous [X]
Classification:	Sensitising [ ]; Not sensitising [ ]
Method:	Other
GLP:	Yes [ ] No [X] ? [ ]
Test substance:	2% + 5% aqueous solution
Remarks:	5% aqueous glutaraldehyde was applied to the skin of two groups of volunteers under an occluded patch for 24 hours, resulting in severe erythema and oedema. In the first group of 20 persons, a challenge dose of 2% solution produced six cases of slight erythema, but in the second group of 40 persons, no reaction was obtained with 2% and 5% challenge doses. There were no controls in the study.
Reference:	Shelanski, IBL report 4099, Aug 1966

(d)

Type:	Patch Test
Species/strain:	Human
Results:	Sensitising [X]; Not sensitising [ ]; ambiguous [ ]
Classification:	Sensitising [X]; Not sensitising [ ]
Method:	other

GLP:	Yes [ ] No [X] ? [ ]
Test substance:	0.1% to 0.5% aqueous solutions
Remarks:	Dilute aqueous glutaraldehyde (0.1, 0.2, 0.5%) was applied to the backs of 109 volunteers under an occluded patch for 48 hours, with 16 positive irritation reactions for 0.5%, and 3 cases for 0.1 and 0.2%. On challenge with the same dose, 2 positive reactions were noted for 0.5%, but none for 0.1 and 0.2%.
Reference:	Testkit Labs. report 80-39, Nov. 1980

5.4 REPEATED DOSE TOXICITY

(a)

Species/strain:	Rat (Fischer 344)
Sex:	Female [ ]; Male [ ]; Male/Female [X]
Route of Administration:	Oral feed (drinking water)
Exposure period:	90 days
Frequency of treatment:	7 days/week
Postexposure observ. period:	4 weeks
Dose:	males: 0, 5, 25, 100 mg/kg females: 0, 7, 35, 120 mg/kg (20m, 20f per group)
Control group:	Yes [X]; No [ ]; No data [ ], Concurrent no treatment [ ]; Concurrent vehicle [X]; Historical [ ]
NOEL:	5 mg/kg
LOEL:	25 mg/kg
Results:	A significant dose-related increase in relative kidney weight occurred for males and females in mid- and high-dose groups, but no changes evident on histological examination of tissues. Food and water consumption was also reduced in the same groups. As drinking water studies at high glutaraldehyde concentrations are generally hampered by a natural aversion of the animals to the taste/odour of glutaraldehyde, the significance of these results in uncertain.
Method:	OECD 408
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	50% aqueous solution
Reference:	Bushy Run RC report 48-107, Dec. 1985

(b)

Species/strain:	Mouse (C3H/HeJ)
Sex:	Female [ ]; Male [X]; Male/Female [ ]
Route of Administration:	Dermal
Exposure period:	10 days
Frequency of treatment:	one application per day
Postexposure observ. period:	.....
Dose:	50µl of solution
Control group:	Yes [X]; No [ ]; No data [ ]

	Concurrent no treatment [ ]; Concurrent vehicle [X]; Historical [ ]
NOEL:	.....
LOEL:	.....
Results:	All mice lost weight and died after 4-9 doses of the 25% or 50% solutions. For a 5% solution, the mice lost weight after 4-6 doses, but not thereafter. For 2.5% solutions and less, no signs of toxicity were observed.
Method:	.....
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	0.05, 0.25, 0.5, 2.5, 5.0, 25 and 50% aqueous solution
Reference:	Bushy Run RC report 44-107, Dec. 1981

(c)

Species/strain:	Rat (Fischer 344)
Sex:	Female [ ]; Male [ ]; Male/Female [X]
Route of Administration:	Dermal
Exposure period:	28 days
Frequency of treatment:	daily
Postexposure observ. period:	4 weeks
Dose:	2.0 mL/kg b.w./day of 0, 2.5, 5.0 or 7.5% of solution of test substance (0, 50, 100, 150 mg/kg b.w./day)
Control group:	Yes [X]; No [ ]; No data [ ] Concurrent no treatment [ ]; Concurrent vehicle [X]; Historical [ ]
NOEL:	not determined
LOEL:	50 mg/kg b.w./day (lowest dose)
Results:	15 animals/sex/dose for control and high doses, 10 for low and mid doses. No treatment-related mortality. Clinical signs of toxicity during study included slight erythema, little oedema and persistent skin colour change. Dose-related incidence of skin lesions confirmed by microscopic examination at necropsy. Reduced body weight gain in males, dose-related increase in platelet count in females.
Remarks:	This recent study was not reviewed.
Method:	OECD 410
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	UCARCIDE Antimicrobial 250, which is a 50% aqueous solution
Reference:	Bushy Run RC report 93U1252, May 1994

(d)

Species/strain:	Rat (Fischer 344)
Sex:	Female [ ]; Male [ ]; Male/Female [X];
Route of Administration:	inhalation
Exposure period:	9 days
Frequency of treatment:	6 hours/day
Post-exposure observ. period:	.....

Dose:	0, 0.2, 0.63, 2.1 ppm
Control group:	Yes [X]; No [ ]; No data [ ] Concurrent no treatment [X]; Concurrent vehicle Historical [ ]
NOEL:	.....
LOEL:	0.2 ppm
Results:	10 animals/sex/dose exposed to 0, 0.2, 0.63 or 2.1 ppm. in each group. At 2.1ppm, 9 of the males and 7 of the females died (days 3-9); at 0.63 ppm, one male died. Body weight and organ weight decreases occurred at 0.63 and 2.1 ppm, with respiratory irritation observed at all doses.
Method:	similar to OECD 412
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	Vapours generated from heated solution.
Reference:	Bushy Run RC report 46-95, Nov. 1983

(e)

Species/strain:	Rat (Fischer 344)
Sex:	Female [ ]; Male [ ]; Male/Female [X]
Route of Administration:	inhalation
Exposure period:	9 days
Frequency of treatment:	6 hours/day
Post-exposure observ. period:	.....
Dose:	0, 0.3, 1.1, 3.1ppm
Control group:	Yes [X]; No [ ]; No data [ ] oncurrent no treatment [ ]; Concurrent vehicle [ ]; Historical [ ]
NOEL:	.....
LOEL:	0.3 ppm
Results:	12 male and 12 females were in each group. At 3.1 ppm, 7 of the males and 6 of the females died (days 8 or 9). Nasal cavity lesions occurred at 1.1 and 3.1 ppm, atrophy of the liver at 3.1 ppm. Body weight decrease occurred at 1.1 and 3.1 ppm, where signs of respiratory irritation were also observed. Significant weight decreases were noted for the liver, heart, lungs, kidney and testes at 3.1 ppm, smaller decreases at 1.1 ppm for the liver, heart, kidney and testes, and a small increase in lung weight for males at 0.3 ppm.
Method:	OECD 412
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	Vapours generated at ambient temperature.
Reference:	Bushy Run RC report 46-63, Nov. 1983

(f)

Species/strain:	Rat (F344/N)
Sex:	Female [ ]; Male [ ]; Male/Female [X]
Route of Administration:	inhalation
Exposure period:	2 weeks

Frequency of treatment:	6 hours/day, 5 days/week
Postexposure observ. period:	.....
Dose:	0, 0.16, 0.5, 1.6, 5, 16 ppm
Control group:	Yes [X]; No [ ]; No data [ ] Concurrent no treatment [ ]; Concurrent vehicle [ ]; Historical [ ]
NOEL:	0.16 ppm
LOEL:	0.5 ppm
Results:	Five animals per sex were in each group. All animals at 5 and 16ppm died of respiratory distress, with lesions of the nasal cavity and larynx observed. At necropsy, histological examination of the tissues revealed damage to the nasal cavity and larynx at 0.5ppm and above.
Method:	Similar to OECD 412
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	
Reference:	NTP, March 1993

(g)

Species/strain:	Mouse ($B6C3F_1$)
Sex:	Female [ ]; Male [ ]; Male/Female [X]
Route of Administration:	inhalation
Exposure period:	2 weeks
Frequency of treatment:	6 hours/day, 5 days/week
Postexposure observ. period:	.....
Dose:	0, 0.16, 0.5, 1.6, 5 and 16ppm
Control group:	Yes [X]; No [ ]; No data [ ] Concurrent no treatment [ ]; Concurrent vehicle [ ]; Historical [ ]
NOEL:	0.16 ppm
LOEL:	0.5 ppm
Results:	Five animals per sex were in each group. All mice at 1.6 ppm and above died of respiratory distress. At necropsy, histological examination of tissues revealed damage to the nasal cavity at 1.6 ppm and above, and damage to the larynx at 0.5 ppm and above.
Method:	Similar to OECD 412
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	
Reference:	NTP, March 1993

(h)

Species/strain:	Rat (Fischer 344)
Sex:	Female [ ]; Male [ ]; Male/Female [X]
Route of Administration:	inhalation
Exposure period:	14 weeks
Frequency of treatment:	6 hours/day, 5 days/week
Postexposure observ. period:	.....
Dose:	0, 21, 49, 194ppb
Control group:	Yes [X]; No [ ]; No data [ ]

	Concurrent no treatment [ ]; Concurrent vehicle [ ]; Historical [ ]
NOEL:	21 ppb
LOEL:	49 ppb
Results:	20 animals per sex were in each group, and all survived. Respiratory irritation was observed at 49 and 194 ppb. Body weight decreases in males occurred at 49 and 194 ppb, and for females at 194 ppb. No lesions of the nasal cavity were observed.
Method:	OECD 413
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	
Reference:	Bushy Run RC Report 46-101, Dec. 1983

(i)

Species/strain:	Rat (F344/N)
Sex:	Female [ ]; Male [ ]; Male/Female [X]
Route of Administration:	inhalation
Exposure period:	13 weeks
Frequency of treatment:	6 hours/day, 5 days/week
Postexposure observ. period:	.....
Dose:	0, 62.5, 125, 250, 500, 1000 ppb
Control group:	Yes [X]; No [ ]; No data [ ] Concurrent no treatment [ ]; Concurrent vehicle [ ]; Historical [ ]
NOEL:	125 ppb
LOEL:	250 ppb
Results:	Ten animals per sex were in each group, with no exposure-related mortality. Dose-related lesions of the nasal cavity were observed at 250 ppb and above. The body weight gain was reduced in males at 1000 ppb, and in females at 500 and 1000 ppb. Histoaudioradiographic studies indicated that the nasal lesions were different from those observed with formaldehyde.
Method:	Similar to OECD 413
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	
Reference:	NTP, March 1993

(j)

Species/strain:	Mouse ($B6C3F_1$)
Sex:	Female [ ]; Male [ ]; Male/Female [X]
Route of Administration:	inhalation
Exposure period:	13 weeks
Frequency of treatment:	6 hours/day, 5 days/week
Postexposure observ. period:	.....
Dose:	0, 62.5, 125, 250, 500, 1000ppb
Control group:	Yes [X]; No [ ]; No data [ ] Concurrent no treatment [ ]; Concurrent vehicle [ ]; Historical [ ]
NOEL:	.....

LOEL: 62.5 ppb
Results: Ten animals per sex were in each group, with mortality of all mice at 1000 ppb, and 2 females at 500 ppb. Lesions of the nasal cavity were observed in all females, and at 250 ppb and above in males. Lesions of the larynx were revealed at 1000 ppb. The body weight gain was reduced in males at all doses, and in females at 250 and 500 ppb. Histoaudioradiographic studies indicated that the nasal lesions were different from those observed with formaldehyde.

Method: Similar to OECD 413
GLP: Yes [X] No [ ] ? [ ]
Test substance:

Reference: NTP, March 1993

5.5 GENETIC TOXICITY IN VITRO

A. BACTERIAL TEST

Type: Bacterial reverse mutation assay
System of testing: Species/strain: S. typhimurium TA98, TA100, TA102, TA104, TA1535, TA1537
Concentration: 0, 300, 333, 3333 µg/plate
Metabolic activation: With [ ]; Without [ ]; With and Without [X]; No data [ ]
Results:
Cytotoxicity conc:
With metabolic activation: .....
Without metabolic activation: .....
Precipitation conc: .....
Genotoxic effects: + ? -
With metabolic activation: [X] [ ] [ ] to TA100, TA102, TA104
Without metabolic activation: [X] [ ] [ ] to TA100, TA102, TA104
Method: Similar to OECD 471
GLP: Yes [X] No [ ] ? [ ]
Test substance:
Remarks: Activation system: rat liver S9

Reference: NTP, March 1993

B. NON-BACTERIAL IN VITRO TEST

(a)
Type: Cytogenetic assay
System of testing: Chinese hamster ovary cells
Concentration: 0.03 - 30 µg/mL
Metabolic activation: With [ ]; Without [ ]; With and Without [X]; No data [ ]
Results:
Cytotoxicity conc:
With metabolic activation: 300 µg/mL
Without metabolic activation: 30 µg/mL

	Precipitation conc:	.....
	Genotoxic effects:	+ ? -
	With metabolic activation:	[ ] [ ] [X]
	Without metabolic activation:	[ ] [ ] [X]
Method:	OECD 473	
GLP:	Yes [X] No [ ] ? [ ]	
Test substance:	50% aqueous solution	
Remarks:	The controls tested positive in this chromosomal aberrations assay.	
Reference:	Bushy Run RC report 54-101, Sept. 1991	

(b)

Type:	Cytogenetic assay	
System of testing:	Chinese hamster ovary cells	
Concentration:	0.3 - 16 µg/mL	
Metabolic activation:	With [ ]; Without [ ]; With and Without [X]; No data [ ]	
Results:		
	Cytotoxicity conc:	
	With metabolic activation:	.....
	Without metabolic activation:	.....
	Precipitation conc:	.....
	Genotoxic effects:	+ ? -
	With metabolic activation:	[ ] [ ] [X]
	Without metabolic activation:	[X] [ ] [ ]
Method:	Similar to OECD 473	
GLP:	Yes [X] No [ ] ? [ ]	
Test substance:		
Remarks:	In these chromosomal aberration assays, one laboratory obtained negative results with and without S9 metabolic activation. In the second laboratory, the result was negative with S9, and positive without S9.	
Reference:	NTP, March 1993	

(c)

Type:	Sister chromatid exchange assay	
System of testing:	Chinese hamster ovary cells	
Concentration:	0.36 - 16 µg/mL	
Metabolic activation:	With [ ]; Without [ ]; With and Without [X]; No data [ ]	
Results:		
	Cytotoxicity conc:	
	With metabolic activation:	.....
	Without metabolic activation:	.....
	Precipitation conc:	.....
	Genotoxic effects:	+ ? -
	With metabolic activation:	[X] [ ] [ ]
	Without metabolic activation:	[X] [ ] [ ]
Method:	Similar to OECD 479	
GLP:	Yes [X] No [ ] ? [ ]	
Test substance:		
Remarks:	In one laboratory, sister chromatid exchanges were induced, with and without S9 metabolic activation. In the second laboratory, the result was negative without S9, and weakly positive with S9.	

Reference: NTP, March 1993

(d)

Type: Sister chromatid exchange assay
System of testing: Chinese hamster ovary cells
Concentration: 0.01 - 0.3 µg/mL
Metabolic activation: With [ ]; Without [ ]; With and Without [X]; No data [ ]
Results:

Cytotoxicity conc:
With metabolic activation: 0.30 mg/mL
Without metabolic activation: 0.10 mg/mL
Precipitation conc: .....
Genotoxic effects: + ? -
With metabolic activation: [ ] [X] [ ]
Without metabolic activation: [ ] [X] [ ]

With metabolic activation, statistically significant increases were observed at 0.1 and 1 µg/mL, but not at 0.3 µg/mL. Without metabolic activation, statistically significant increases were observed at 0.03 and 0.1 µg/mL, but not at 0.3 µg/mL.

Method: OECD 479
GLP: Yes [X] No [ ] ? [ ]
Test substance: UCARCIDE Antimicrobial 250, a 50% aqueous solution
Remarks: This recent study was not reviewed.

Reference: Bushy Run RC report 92U1180, April 1994

(e)

Type: HGPRT forward mutation assay
System of testing: Chinese hamster ovary cells
Concentration: 0.10 - 30 µg/mL
Metabolic activation: With [ ]; Without [ ]; With and Without [X]; No data [ ]
Results:

Cytotoxicity conc:
With metabolic activation: 30 µg/mL
Without metabolic activation: 6 µg/mL
Precipitation conc: .....
Genotoxic effects: + ? -
With metabolic activation: [ ] [ ] [X]
Without metabolic activation: [ ] [ ] [X]

Method: .....
GLP: Yes [X] No [ ] ? [ ]
Test substance: UCARCIDE Antimicrobial 250, a 50% aqueous solution
Remarks: This recent study as not reviewed,

Reference: Bushy Run RC report 92U1179, April 1994

(f)

Type: Mouse lymphoma assay
System of testing: Mouse lymphoma L5178Y cells
Concentration: 0 - 16 µg/mL
Metabolic activation: With [ ]; Without [X]; With and Without [ ]; No data [ ]
Results:

Cytotoxicity conc:
With metabolic activation: .....

Without metabolic activation: 16 µg/mL
Precipitation conc: .....
Genotoxic effects: + ? -
With metabolic activation: [ ] [ ] [ ]
Without metabolic activation: [X] [ ] [ ]
Method: Similar to OECD 476
GLP: Yes [X] No [ ] ? [ ]
Test substance:
Remarks: Mutations were induced at the TK locus of cells at 8 µg/mL, but no significant increase was observed at concentrations up to 4 µg/mL.

Reference: NTP, March 1993

5.6 GENETIC TOXICITY IN VIVO

(a)
Type: Micronucleus assay
Species/strain: Mouse (Swiss-Webster)
Sex: Female [ ]; Male [ ]; Male/Female [X]; No data [ ]
Route of Administration: gavage
Exposure period: .....
Doses: 0, 80, 160, 250 mg/kg
Results:
Effect on mitotic index or P/N ratio: no change in P/N ratio
Genotoxic effects: + ? -
[ ] [ ] [ ]
Method: similar to OECD 474
GLP: Yes [X] No [ ] ? [ ]
Test substance: 50% aqueous solution
Remarks: Five animals per sex per group were dosed except for 250 mg/kg, where 8 per sex were dosed. No females died, but 2 mice at 250 mg/kg and one each at 80 and 160 mg/kg died. No induction of micronuclei in the polychromatic erythrocytes in the peripheral blood was observed.

Reference: Bushy Run RC report 91U0101, Feb. 1993

(b)
Type: Cytogenetic assay
Species/strain: Rat (Sprague-Dawley)
Sex: Female [ ]; Male [ ]; Male/Female [X]; No data [ ]
Route of Administration: gavage
Exposure period: .....
Doses: males: 0, 25, 60, 120 mg/kg bw; females: 0, 15, 40, 80 mg/kg
Results:
Effect on mitotic index or P/N ratio: .....
Genotoxic effects: + ? -
[ ] [ ] [X]
Method: similar to OECD 475
GLP: Yes [X] No [ ] ? [ ]
Test substance: 50% aqueous solution
Remarks: Five animals per sex per group were dosed, with one male at 120 mg/kg dying. The number off aberrant

cells in bone marrow were similar to the vehicle controls for each time period (12, 24, 48h), so no evidence of clastogenicity was observed.

Reference: Ballantyne, Bushy Run RC draft report 91U0139, Dec. 1992

(c)

Type: Drosophila SLRL test
Species/strain: Drosophila melanogaster
Sex: Female [ ]; Male [X]; Male/Female [ ]; No data [ ]
Route of Administration: injection and oral feed
Exposure period: .....
Doses: .....
Results:

Effect on mitotic index or P/N ratio: .....
Genotoxic effects: + ? -
[ ] [ ] [X]

Method: similar to OECD 477
GLP: Yes [ ] No [ ] ? [ ]
Test substance:
Remarks: Male Canton-S wild-type flies were injected with glutaraldehyde solution, with the number of lethal mutations from the mating of newly-emerged flies determined. The results were negative. In a second series of tests, the eggs of mated Canton-S flies were exposed to cornmeal containing glutaraldehyde, with the results also negative.

Reference: NTP, March 1993

5.7 CARCINOGENICITY

Species/strain: Rat (Fischer 344)
Sex: Female [ ]; Male [ ]; Male/Female [X]; No data [ ]
Route of Administration: Drinking water
Exposure period: 2 years
Frequency of treatment: .....
Postexposure observation period: .....
Doses: males: 0, 4, 17, 64 mg/kg bw; females: 0, 6, 25, 86 mg/kg bw
Control group: Yes [X]; No [ ]; No data [ ];
Concurrent no treatment [ ]; Concurrent vehicle [X]; Historical [ ]

Results: Groups of 100 males and 100 females were treated , with 10 animals per sex per dose sacrificed at 52 and 78 weeks, and the remainder at 104 weeks. The main finding was a statistically significant increase in large granular cell lymphatic leukaemia (LGLL) in the liver and spleen of females only at all doses at 104 weeks; LGLL was also observed in males at all doses (including controls), but the increase was not statistically significant. No LGLL at 52 weeks and 4 (at 50 ppm only) at

78 weeks. Fischer 344 rats have a high historical susceptibility to LGLL (NTP data: 10-72% in males, 6-31% in females), so the study was inconclusive.

Method: .....
GLP: Yes [ ] No [ ] ? [X]
Test substance:
Remarks: .....
Reference: Ballantyne, Bushy Run RC draft report 91U0012, Apr. 1993, and report Mar. 1994

5.8 TOXICITY TO REPRODUCTION

(a)

Type: Fertility [X]; One generation study [ ]; Two generation study [ ]; Other [ ]
Species/strain: Rat (F344/N)
Sex: Female [ ]; Male [ ]; Male/Female [X]; No data [ ]
Route of Administration: inhalation
Exposure period: 13 weeks
Frequency of treatment: 6 hours/day, 5 days/week
Postexposure observation period: .....
Premating exposure period: male: ....., female: .....
Duration of test: .....
Doses: 0, 62.5, 250, 1000 ppb
Control group: Yes [X]; No [ ]; No data [ ];
Concurrent no treatment [ ]; Concurrent vehicle [ ]; Historical [ ]
.....
NOEL Parental: .....
NOEL F1 Offspring: .....
NOEL F2 Offspring: .....
Results: Sperm morphology measurements for the males were normal. Estrous cycle lengths for the females were normal.

Method: .....
GLP: Yes [ ] No [ ] ? [X]
Test substance:
Remarks: .....
Reference: NTP, March 1993

(b)

Type: Fertility [X]; One generation study [ ]; Two generation study [ ]; Other [ ]
Species/strain: Mouse ($B6C3F_1$)
Sex: Female [ ]; Male [ ]; Male/Female [X]; No data [ ]
Route of Administration: inhalation
Exposure period: 13 weeks
Frequency of treatment: 6 hours/day, 5 days/week
Postexposure observation period: .....
Premating exposure period: male: ....., female: .....
Duration of test: .....

Doses:	0, 62.5, 250, 500 ppb
Control group:	Yes [X]; No [ ]; No data [ ]; Concurrent no treatment [ ]; Concurrent vehicle [ ]; Historical [ ]
	.....
NOEL Parental:	.....
NOEL F1 Offspring:	.....
NOEL F2 Offspring:	.....
Results:	Sperm morphology measurements for the males were normal. There were significant differences in estrous cycle length for females at 250 and 500ppb.
Method:	.....
GLP:	Yes [ ] No [ ] ? [X]
Test substance:	
Remarks:	.....
Reference:	NTP, March 1993

(c)

Type:	Fertility [ ]; One generation study [ ]; Two generation study [X]; Other [ ]
Species/strain:	Rat (CD)
Sex:	Female [ ]; Male [ ]; Male/Female [X]; No data [ ]
Route of Administration:	oral (drinking water)
Exposure period:	20 weeks
Frequency of treatment:	.....
Postexposure observation period:	.....
Premating exposure period:	10 weeks
Duration of test:	9 months
Doses:	0, 50, 250, 1000 ppm
Control group:	Yes [X]; No [ ]; No data [ ]; Concurrent no treatment [ ]; Concurrent vehicle [X]; Historical [ ]
NOEL Parental:	50 ppm
NOEL F1 Offspring:	offspring effects: 250 ppm reproductive effects: > 1000 ppm
NOEL F2 Offspring:	(as for F1)
Results:	Minimal parental effects (body weight) at 250 ppm. No adverse effects on reproductive performance.
Method:	.....
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	UCARCIDE Antimicrobial 250, which is a 50% aqueous solution
Remarks:	This recent study was not reviewed. Dose concentrations expressed as w/v glutaraldehyde.
Reference:	Bushy Run RC report 92U1059, March 1994

5.9 DEVELOPMENTAL TOXICITY/ TERATOGENICITY

(a)

Species/strain:	Rat (Wistar)
Sex:	Female [X]; Male [ ]; Male/Female [ ]; No data [ ]
Route of Administration:	Drinking water
Duration of test:	sacrifice at 20 days
Exposure period:	days 6 to 16 post coitum
Frequency of treatment:	.....
Doses:	0, 5, 36, 68 mg/kg bw (25 per group)
Control group:	Yes [X]; No [ ]; No data [ ]; Concurrent no treatment [ ]; Concurrent vehicle [X]; Historical [ ]
NOEL Maternal Toxicity:	5 mg/kg
NOEL teratogenicity:	.....
Results:	A dose-related decrease in water consumption occurred for dams at 26 and 68 mg/kg. For foetuses, no significant findings were observed in the sex distribution, placental weight or foetal weight. No significant malformations or variations were noted in soft tissue and skeletal examination of the foetuses.
Method:	OECD 414
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	.....
Remarks:	.....
Reference:	BASF project report 33R0599/89025, 1991

(b)

Species/strain:	Rabbit(Himalayan)
Sex:	Female [X]; Male [ ]; Male/Female [ ]; No data [ ]
Route of Administration:	gavage
Duration of test:	sacrifice at day 29
Exposure period:	days 7 to 19 post insemination
Frequency of treatment:	daily
Doses:	0, 5, 15, 45 mg/kg bw (15 per group)
Control group:	Yes [X]; No [ ]; No data [ ]; Concurrent no treatment [ ]; Concurrent vehicle [X]; Historical [ ]
NOEL Maternal Toxicity:	15 mg/kg
NOEL teratogenicity:	.....
Results:	Five of the 15 does died at 45 mg/kg, with only 4 live foetuses produced (from one doe). In the does, food consumption and body weight gain were reduced, and at necropsy, irritation of the gastrointestinal tract was noted. No significant effects were observed for does or foetuses at 5 and 15 mg/kg. There was no evidence of teratogenicity at any dose.
Method:	OECD 414
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	.....
Remarks:	.....
Reference:	BASF project report 40R0599/89026, 1991

5.10 OTHER RELEVANT INFORMATION

A. Specific toxicities

(a)

Type:	Respiratory irritation
Species/strain:	Mouse (Swiss Webster) - males only
Results:	Irritating at the lowest dose (1.64 ppm) RD50 13.8 ppm
Classification:	Irritating
Method:	ASTM E981-84
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	Vapour generated by passing air (at ambient temperature) through a bubbler containing 50% aqueous solution - a second bubbler required for the higher vapour concentrations
Remarks:	4 animals/dose exposed (head only) for 30 minutes to 1.64, 3.21, 4.65, 5.80, 7.47, 20.4 or 36.7 ppm to give % respiratory decrease 26.4, 30.2, 41.5, 39.6, 41.1, 57.1 and 59.0 respectively. No mortality and no clinical signs of toxicity observed.
Reference:	Bushy Run RC report 91U0123, Dec. 1993 (draft)

(b)

Type:	Respiratory hypersensitivity
Species/strain:	Guinea pig (Hartley) - males only
Results:	Sensitising [ ]; Not sensitising [X]; ambiguous [ ]
Classification:	Sensitising [ ]; Not sensitising [X]
Method:	.....
GLP:	Yes [X] No [ ] ? [ ]
Test substance:	Vapour generated by passing air (at ambient temperature) through bubbler containing 50% aqueous solution
Remarks:	8 animals exposed (head only) to 14 ppm for 1h/day for 5 days, followed by challenge with 4-5 ppm on days 19, 26, 40. No change in respiratory waveform, and respiratory rate decrease in exposed animals similar to controls in each challenge phase.
Reference:	Bushy Run RC report 92U1193, Sep. 1993 (draft)

(c)

Type:	Phototoxicity
Results:	not phototoxic in humans
Remarks:	Dilute aqueous glutaraldehyde (0.005, 0.01, 0.02, 0.05%) was applied to 2 sites on the backs of 52 volunteers for 24 hours, with one of the sites irradiated with UV light. A third site was irradiated with UV light. Two subjects experienced very slight erythema with 0.05% glutaraldehyde/UV light.
Reference:	TKL study 906001, April 1990

(d)

Type:	Photoallergy
Results:	No evidence of photoallergic response in humans

Remarks: Dilute aqueous glutaraldehyde (0.0005, 0.01, 0.02, 0.05%) was applied to 2 sites on the backs of 99 volunteers 2/week for 3 weeks, with one of the sites irradiated with UV light 24 hours after each application. On challenge testing, no significant erythema or oedema was noted.

Reference: TKL study 907001, April 1990

B. Toxicodynamics, toxicokinetics

Type: Toxicokinetics

Results: Dermal and intravenous studies in the rat with dilute aqueous glutaraldehyde solutions (0.075-7.5%) showed that , in dermal tests, approx 5% was absorbed in the rat, and 30-50% in the rabbit. In the intravenous injection tests, approx 12% was absorbed in the rat and approx 33% in the rabbit. There were no significant differences between males and females in the study. The dermal absorption rate constant was low (0.2-2 hours) in each species. The elimination times were long for both intravenous injection ($t_{0.5}$ for the rat 10h, rabbit 15-30h) and dermal application ($t_{0.5}$ for the rat 40-110h, rabbit 20-100h), possibly due to the binding of glutaraldehyde to protein and the slow excretion of metabolites. The principal metabolite in both species was CO_2 with other metabolites not identified. The report proposed that the metabolism probably involved initial oxidation to corresponding carboxylic acids by aldehyde dehydrogenase, and then further oxidation to CO_2. (Reference: Ballantyne, 1986)

Other studies:
In vitro studies using human skin tissue showed that glutaraldehyde did not penetrate the thick skin of the sole, but 3-14% penetrated the stratum corneum of the chest and abdomen and 3-4% penetrated the epidermis. (Ref. Reifenrath, 1985)
In a study in humans, rats, mice, rabbits and guinea-pigs, less than 1% of applied glutaraldehyde penetrated the skin. (Ref. Beauchamp, 1992)

5.11 EXPERIENCE WITH HUMAN EXPOSURE

(a)

Results: No. of deaths in a mortality study was less than expected, as was the incidence of cancer deaths.

Remarks: The incidence of death and incidence of cancer deaths in 186 male employees at a glutaraldehyde production unit were compared to those of US white males and to 29,000 other chemical workers during the period 1959 - 1978. All subjects were observed for 10 years.

Reference: Teta et al, 1992[1]

(b)

Results: The incidence of sensitisation in glutaraldehyde workers was inconclusive.

Remarks: The medical records of 210 workers at a glutaraldehyde production unit were screened with the assistance of an occupational physician to identify any symptoms of sensitisation which may correlate with

exposure to glutaraldehyde. Six possible cases were noted, but these workers were also exposed to other chemicals in the workplace.

Reference: Teta et al, 1992[2]

(c) Case reports

(i) Skin irritation

Dermatitis of the hands in 18 of 39 (46%) Swedish hospital workers using aq. glutaraldehyde, compared with 16% in controls. (Ref. Norback, *Scand. J. Work Env. Hlth* vol 14, 366-371, 1988)

Increased incidence of skin disease in 541 hospital cleaners compared with 157 controls. (Ref. Hansen, *Cont. Derm.* vol9, 343-351, 1983)

Facial dermatitis in 3 of 9 staff in an endoscopy unit. (Ref. Jachuck et al, *J. Soc. Occup. Med.* vol 39, 69-71, 1989)

Skin irritation in 14 of 44 hospital workers exposed to 2% solution. (Ref. NIOSH HETA report 86-226-1769, Jan. 1987)

(ii) Eye irritation

Eye irritation in 28 of 44 hospital workers exposed to 2% solution. (Ref. NIOSH HETA report 86-226-1769, Jan. 1987)

(iii) Respiratory irritation

Nose and throat irritation in Swedish hospital workers using aq. glutaraldehyde. (Ref. Norback, *Scand. J. Work Env. Hlth* vol 14, 366-371, 1988)

Nose and throat irritation in hospital workers using 2% aq. glutaraldehyde. (Ref. D'Arcy,. *J. Pharmac. Belg.* vol 45, 47, 1989)

(iv) Skin sensitisation

Dermatitis of hands and fingers and around eyes and mouth in hospital cleaner exposed to 2% glutaraldehyde solution. Patch testing positive. (Ref. Di Prima et al, *Cont. Derm.* vol 9 (3), 219-220, 1988)

Dermatitis of hands in hospital nurses. Patch test positive. (Ref. Bardazzi et al, *Cont. Derm.* vol 14 (5), 319-320, 1986)

Dermatitis of hands, arms face and neck in hospital maintenance employee. Patch testing positive. (Ref. Fowler, *J. Occup. Med.* vol 31 (10), 852-853, 1989)

Dermatitis of the hands in 13 health care workers exposed regularly to glutaraldehyde solution. Positive patch test in 9 workers after 48h and positive in all after 96h. (Ref. Nethercott et al, *Cont. Derm.* vol 18, 193-196, April 1988)

Dermatitis in funeral service workers; 6/34 tested positive to glutaraldehyde compared 0/38 controls. (Ref. Nethercott et Holness, *Cont. Derm.* vol 18, 263-267, May 1988)

Dermatitis on hands and forearms in 5 hospital workers. Patch testing positive. (Ref. Goncalo et al, *Cont. Derm.* vol 10, 183-184, 1984)

Dermatitis on fingers of a radiologist and an x-ray technician. Patch testing positive. (Ref. Fisher, *Cutis* vol 28, 113-122, 1981)

Dermatitis of hands and fingers in three dental assistants and two patients being treated therapeutically with glutaraldehyde. Patch testing positive. (Ref. Jordan et al, *Arch. Dermatol. Res.* vol 105, 94-95, 1972)

Dermatitis of scalp from hair conditioner containing glutaraldehyde. Positive patch test. (Ref. Jaworsky et al, *Cleveland Clinic J. Med.* vol 54 (5), 443-444, 1987)

(v) Occupational asthma and/or rhinitis

Asthma-like symptoms in endoscopy unit sister; peak-flow measurements improved over weekend. (Ref. Benson, *J. Soc. Occup. Med.* vol 34, 63-64, 1984)

Asthma in 4 endoscopy nurses, including 3 atopics. Adverse reaction in 2 cases on provocation testing with glutaraldehyde. (Ref. Corrado et al, *Human Toxicol.* vol 5, 325-327, 1986)

Rhinitis in 6 of 9 staff in an endoscopy unit and one case of asthma; no history of atopy. (Ref. Jachuck et al, *J. Soc. Occup. Med.* vol 39, 69-71, 1989)

Asthma in respiratory technologist in bronchoscopy unit. Positive challenge testing. (Ref. *J. Allergy Clin. Immunol.* vol 91 (5), 974-978, 1993)

Asthma in two radiographers with history of hay-fever. Only one positive to challenge testing. (Ref. Cullinan, *The Lancet*, vol 340, 1477, 12 Dec1992)

Asthma-like symptoms in endoscopy nurse; improved over weekend and holidays. (Ref. Caswell, *Australian Doctor*, 10 Sep 1993, 53-54)

Asthma, nasal congestion and watering of eyes in respiratory technician, with frequency and severity gradually increasing. Delayed response on challenge test, but IgE and IgG levels normal. (Ref. Nicewicz et al, *Immunol. Allergy Pract.* vol 8 (8), 272-278, 1986)

Additional information on workplace exposure in Australia and information on human health effects are detailed in the NICNAS Glutaraldehyde Report 1994.

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EXTRACT FROM IRPTC LEGAL FILE

File: 17.01 LEGAL **rn : 100246**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : ARG type : REG

subject	specification	descriptor
AIR	OCC	MPC

8H-TWA : 0.7 MG/M3 (0.2 PPM)
entry date: OCT 1991 effective date: 29MAY1991

title: LIMIT VALUES FOR CHEMICAL SUBSTANCES IN THE WORKING ENVIRONMENT-RESOLUTION NO. 444/1991 OF THE MINISTRY OF WORK AND SOCIAL SECURITY (AMENDING REGULATION DECREE NO. 351/1979 UNDER LAW NO. 19587/1972: HYGIENE AND SAFETY AT WORK)
original : ARGOB*, BOLETIN OFICIAL DE LA REPUBLICA ARGENTINA(ARGENTIAN OFFICIAL BULLETIN), 24170 , I , 1 , 1979
amendment: ARGOB*, BOLETIN OFICIAL DE LA REPUBLICA ARGENTINA(ARGENTIAN OFFICIAL BULLETIN), 27145 , I , 4 , 1991

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File: 17.01 LEGAL **rn : 300074**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : CAN type : REG

subject	specification	descriptor
AIR	OCC	TLV

TWA: ceiling limit - 0.2 ppm, 0.7 mg/m3. Prescribed by the Canada Occupational Safety and Health Regulations, under the Canada Labour Code(administered by the Department of Employment and Immigration). The regulations state that no employee shall be exposed to a concentration of an airborne chemical agent in excess of the value for that chemical agent adopted by ACGIH (American Conference of Governmental Industrial Hygienists) in its publication entitled: "Threshold Limit Value and Biological Exposure Indices for 1985-86". The regulations also state that the employer shall, where a person is about to enter a confined space, appoint a qualified person to verify by means of tests that the concentration of any chemical agent or combination of chemical agents will not result in the exposure of the person to a concentration in excess of the value indicated above. These regulations prescribe standards whose enforcement will provide a safe and healthy workplace.
entry date: OCT 1994 effective date: 24MCH1994

amendment: CAGAAK, CANADA GAZETTE PART II, 128 , 7 , 1513 , 1994

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File: 17.01 LEGAL **rn : 301027**

systematic name:Pentanedial
common name :glutaraldehyde

reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : CAN type : REG

subject	specification	descriptor
PACK	AGRIC	CLASS
LABEL	PESTI	
USE		

Formulations containing this active ingredient are approved for commercial, manufacturing use as slimicide, hard-surface desinfectant. (Formulations: solution). Code GLT. The Pest Control Products Act and Regulations are administered by the Department of Agriculture. These establish a registration, classification, packaging and labelling system for pest control products. Only pest control products that are currently registered with the department of agriculture and products that have been removed from that list since 1983 are included; other historical records are excluded.
entry date: JAN 1993 effective date: 19NOV1992

amendment: CAGAAK, CANADA GAZETTE PART II, 126 , 25 , 4701 , 1992

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File: 17.01 LEGAL **rn : 303083**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : CAN type : REG

subject	specification	descriptor
USE	OCC	RQR
STORE		
LABEL		

Ingredient Disclosure List - Concentration: 1% weight/weight. The Workplace Hazardous Materials Information System (WHMIS) is a national system providing information on hazardous materials used in the workplace. WHMIS is implemented by the Hazardous Products Act and the Controlled Products Regulations (administered by the Department of Consumer and Corporate Affairs). The regulations impose standards on employers for the use, storage and handling of controlled products. The regulations also address labelling and identification, employee instruction and training, as well as the upkeep of a Materials Safety Data Sheet (MSDS). The presence in a controlled product of an ingredient in a concentration equal to or greater than specified in the Ingredient Disclosure List must be disclosed in the Safety Data Sheet.
entry date: APR 1991 effective date: 31DEC1987

amendment: CAGAAK, CANADA GAZETTE PART II, 122 , 2 , 551 , 1988

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File: 17.01 LEGAL **rn : 500736**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :Glutardialdehyde
cas no :111-30-8 rtecs no :MA2450000
area : DEU type : REC

subject	specification	descriptor
AQ USE	INDST	CLASS RQR

THIS SUBSTANCE IS CLASSIFIED AS HAZARDOUS TO WATER (WATER-HAZARD CLASS: WGK 2). (THE DIFFERENT CLASSES ARE: WGK 3 = VERY HAZARDOUS; WGK 2 = HAZARDOUS; WGK 1 = SLIGHTLY HAZARDOUS; WGK 0 = IN GENERAL NOT HAZARDOUS.) THE CLASSIFICATION FORMS THE BASIS FOR WATER-PROTECTION REQUIREMENTS FOR INDUSTRIAL PLANTS IN WHICH WATER-HAZARDOUS SUBSTANCES ARE HANDLED.
entry date: JAN 1995

title: Administrative Rules concerning Substances Hazardous to Water (Verwaltungsvorschrift wassergefaehrdende Stoffe)
original : GMSMA6, Gemeinsames Ministerialblatt, , 8 , 114 , 1990

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File: 17.01 LEGAL **rn : 503348**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :Glutardialdehyde
cas no :111-30-8 rtecs no :MA2450000
area : DEU type : REC

subject	specification	descriptor
AIR	OCC	MAK

8h-TWA: 0.1 ml/m3 (ppm); 0.4 mg/m3 (20C, 101.3 kPa). Local irritant. 5min-STEL: 0.2 ml/m3 (ppm); 0.8 mg/m3; ceiling value; 8x/shift. Danger of sensitization. Pregnancy group C: There is no reason to fear a risk of damage to the developing embryo or fetus when MAK and BAT values are adhered to.
entry date: FEB 1996 effective date: 01JUL1995

title: Maximum Concentrations at the Workplace and Biological Tolerance Values for Working Materials (Maximale Arbeitsplatzkonzentrationen und Biologische Arbeitsstofftoleranzwerte)
original : MPGFDF, Mitteilung der Senatskommission zur Pruefung gesundheitsschaedlicher Arbeitsstoffe, 31 , , , 1995

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File: 17.01 LEGAL **rn : 601734**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : GBR type : REC

subject	specification	descriptor
SAFTY MONIT	INDST	RQR

The code of practice gives practical guidance on how to protect workers from the ill-effects of respiratory sensitisers including glutaraldehyde. Assessment of risk, control measures, monitoring

exposure and health surveillance are discussed.
entry date: MCH 1995 effective date: APR1994

title: Preventing Asthma at Work: How to Control Respiratory Sensitisers.
original : GBCOP*, APPROVED CODES OF PRACTICE, L 55 , , , 1994

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File: 17.01 LEGAL **rn : 606850**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : GBR type : REG

subject	specification	descriptor
TRNSP	MARIN	RQR
AQ	MARIN	RSTR
AQ	EMI	RSTR

CATEGORY D SUBSTANCE: DISCHARGE INTO THE SEA IS PROHIBITED; DISCHARGE OF RESIDUAL MIXTURES IS SUBJECT TO RESTRICTIONS. (APPLIES TO GLUTARALDEHYDE SOLUTIONS OF 50% OR LESS).
entry date: 1992 effective date: 06APR1987
title: THE MERCHANT SHIPPING (CONTROL OF POLLUTION BY NOXIOUS LIQUID SUBSTANCES IN BULK) REGULATIONS 1987, SCHEDULE 1
original : GBRSI*, STATUTORY INSTRUMENTS, 551 , , 15 , 1987
amendment: GBRSI*, STATUTORY INSTRUMENTS, 2604 , , 2 , 1990

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File: 17.01 LEGAL **rn : 1010024**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : MEX type : REG

subject	specification	descriptor
AIR	OCC	MXL

AT ANY WORKPLACE WHERE THIS SUBSTANCE IS PRODUCED, STORED OR HANDLED A CONCENTRATION OF 0.7MG/M3 (0.2PPM) SHOULD NEVER BE EXCEEDED AT ANY TIME.
entry date: DEC 1991 effective date: 28MAY1984

title: INSTRUCTION NO.10 RELATED TO SECURITY AND HYGIENIC CONDITIONS AT WORKPLACES. (INSTRUCTIVO NO. 10, RELATIVO A LAS CONDICIONES DE SEGURIDAD E HIGIENE DE LOS CENTROS DE TRABAJO).
original : DOMEX*, DIARIO OFICIAL, , , , 1984

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File: 17.01 LEGAL **rn : 1122493**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000

area : RUS type : REG

subject	specification	descriptor
AIR	OCC	MAC CLASS

CLV: 5.0MG/M3 (VAPOUR) HAZARD CLASS: III
entry date: MAY 1990 effective date: 01JAN1989

amendment: GOSTS*, GOSUDARSTVENNYI STANDART SSSR(STATE STANDARD OF USSR), 12.1.005 , , , 1988

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File: 17.01 LEGAL **rn : 1143332**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : RUS type : REG

subject	specification	descriptor
AQ	SURF	MAC CLASS

0.07MG/L HAZARD CLASS: II
entry date: JUL 1990 effective date: 1JAN1989

amendment: SPNPV*, SANITARNYE PRAVILA I NORMY OKHRANY POVERKHNOSTNYKH VOD OT ZAGRIAZNENIA (HEALTH REGULATION AND STANDARDS OF SURFACE WATER PROTECTION FROM CONTAMINATION), 4630-88 , , , 1988

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File: 17.01 LEGAL **rn : 1200258**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : SWE type : REG

subject	specification	descriptor
AIR	OCC	HLV

CLV: 0.8MG/M3 (0.2PPM) (15MIN-TWA). SENSITIZING.
entry date: 1992 effective date: 01JUL1991

title: HYGIENIC LIMIT VALUES.
original : AFS***, ARBETARSKYDDSSTYRELSENS FOERFATTNINGSSAMLING, 1990:13, , 5-64 , 1990

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File: 17.01 LEGAL **rn : 1248487**

systematic name:Pentanedial
common name :glutaraldehyde

reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : SWE

subject	specification	descriptor
USE	PESTI	PRMT

Approved for use as pesticide. Approved pesticide product(s) containing this substance assigned to Class 2. (Class 1: Pesticide products that may only be used in the course of business activities by someone holding a special permit; Class 2: Pesticide products that may only be used in the course of business activities; Class 3: Pesticide products that may be used by anyone.)
entry date: JAN 1996 effective date: 1995

title: The National Chemicals Inspectorate's List of Approved Pesticides etc. 1995. Kemikalieinspektionens f”rteckning ”ver bek„mpningsmedel m.m.1995.
original : KIFS**, KEMIKALIE INSPEKTIONENS FOR FATTNINGSSAMLING(STATUTE-BOOK OF THE NATIONAL CHEMICALS INSPECTORATE (SWEDEN)), 1993:5 , , , 1993
amendment: KIFS**, KEMIKALIE INSPEKTIONENS FOR FATTNINGSSAMLING(STATUTE-BOOK OF THE NATIONAL CHEMICALS INSPECTORATE (SWEDEN)), 1994:15 , , , 1994

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File: 17.01 LEGAL **rn : 1302296**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : USA type : REG

subject	specification	descriptor
FOOD	ADDIT	RSTR
TRANS		RSTR
STORE		RSTR
PACK		RSTR

; Summary - THIS SUBSTANCE IS INCLUDED ON A LIST OF SUBSTANCES USED TO PREPARE ADHESIVES WHICH MAY BE SAFELY USED AS COMPONENTS OF ARTICLES INTENDED FOR USE IN PACKAGING, TRANSPORTATION, OR HOLDING FOOD IN ACCORDANCE WITH THE FOLLOWING PRESCRIBED CONDITIONS: SUBSTA NCE MUST BE SEPARATED FROM THE FOOD BY A FUNCTIONAL BARRIER, MUST NOT EXCEED LIMITS OF GOOD MANUFACTURING PRACTICE USED WITH DRY FOODS, OR NOT EXCEED TRACE AMOUNTS AT SEAMS AND EDGE EXPOSURES WHEN USED WITH FATTY AND AQUEOUS FOODS. ALSO REGULATED BY SEA M INTEGRITY, LABELING STANDARDS, AND ANY PROVISION UNDER 21 CFR 175
entry date: NOV 1991 effective date: 1977

title: SUBSTANCES FOR USE ONLY AS COMPONENTS OF ADHESIVES
original : FEREAC, FEDERAL REGISTER, 42 , , 14534 , 1977
amendment: CFRUS*, CODE OF FEDERAL REGULATIONS, 21 , 175 , 105 , 1988

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File: 17.01 LEGAL **rn : 1318062**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE

cas no :111-30-8 rtecs no :MA2450000
area : USA type : REG

subject	specification	descriptor
FOOD	ADDIT	RSTR
MANUF		RSTR
STORE		RSTR
PACK		RSTR

FOR USE ONLY AS AN ANTIMICROBIAL AGENT IN PIGMENT AND FILLER SLURRIES USED IN THE MANUFACTURE OF PAPER AND PAPERBOARD AT LEVEL NOT TO EXCEED 300 PARTS PER MILLION BY WEIGHT OF THE SLURRY SOLIDS.; Summary - THIS SUBSTANCE IS INCLUDED ON A LIST OF SUBSTANCES WHICH HAVE BEEN CONDITIONALLY APPROVED TO BE USED AS COMPONENTS OF THE UNCOATED OR COATED FOOD-CONTACT SURFACE OF PAPER AND PAPERBOARD FOR USE WITH MANUFACTURING, PACKING, PROCESSING, PREPARING, TREATING , TRANSPORTING OR HOLDING AQUEOUS AND FATTY FOODS. THESE ARE EXEMPTED FROM EXTRACTION ANALYSIS IN 21 CFR 176.170(C).
entry date: NOV 1991 effective date: 1977

title: INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS-COMPONENTS OF PAPER AND PAPERBOARD IN CONTACT WITH AQUEOUS AND FATTY FOODS
original : FEREAC, FEDERAL REGISTER, 42 , , 14554 , 1977
amendment: CFRUS*, CODE OF FEDERAL REGULATIONS, 21 , 176 , 170 , 1988

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File: 17.01 LEGAL **rn : 1321097**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : USA type : REG

subject	specification	descriptor
CLASS	PESTI	RQR
MANUF	PESTI	PRMT
FOOD	ADDIT	RQR
AQ	GRND	RQR
SAFTY	OCC	RQR

CASE NAME GLUTARALDEHYDE; Summary - THIS SUBSTANCE IS INCLUDED ON A LIST OF ACTIVE INGREDIENTS CONTAINED IN A PRODUCT FIRST REGISTERED BEFORE NOVEMBER 1, 1984, FOR WHICH A REGISTRATION STANDARD HAS NOT BEEN ISSUED. PUBLICATION OF THIS LIST INITIATES AN ACCELERATED REREGISTRATION AND DATA C ALL-IN FOR PRODUCTS CONTAINING THE LISTED ACTIVE INGREDIENTS. THE STATUTORY CRITERIA THAT EPA MUST INCLUDE IN SETTING PRIORITIES FOR INCLUSION ON LIST B ARE THOSE ACTIVE INGREDIENTS RELATING TO FOOD AND FEED USE, GROUNDWATER CONTAMINANTS, POTENTIAL RESID UES IN SHELLFISH, AND THOSE ACTIVE INGREDIENTS WITH SIGNIFICANT DATA GAPS AND THOSE OF CONCERN FOR WORKER EXPOSURE BECAUSE OF AGRICULTURAL, GREENHOUSE, OR NURSERY EXPOSURE.
entry date: JAN 1992 effective date: 1988

title: FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT: PESTICIDES REQUIRED TO BE REREGISTERED; LIST B
original : FEREAC, FEDERAL REGISTER, 54 , 100 , 22706 , 1989
amendment: FEREAC, FEDERAL REGISTER, 54 , 100 , 22706 , 1989

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File: 17.01 LEGAL **rn : 1340157**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : USA type : REC

subject	specification	descriptor
AIR	OCC	TLV

Ceiling Limit 0.2 ppm, 0.82 MG/M3; Summary - THIS THRESHOLD LIMIT VALUE IS INTENDED FOR USE IN THE PRACTICE OF INDUSTRIAL HYGIENE AS A GUIDELINE OR RECOMMENDATION IN THE CONTROL OF POTENTIAL HEALTH HAZARDS.
entry date: DEC 1991 effective date: 1989

title: THRESHOLD LIMIT VALUES
original : ACGIH*, AMERICAN CONFERENCE OF GOVERNMENT INDUSTRIAL HYGIENISTS, , , 11 , 1989
amendment: ACGIH*, AMERICAN CONFERENCE OF GOVERNMENT INDUSTRIAL HYGIENISTS, , , 11 , 1991

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File: 17.01 LEGAL **rn : 1408109**

systematic name:Pentanedial
common name :glutaraldehyde
reported name :GLUTARALDEHYDE
cas no :111-30-8 rtecs no :MA2450000
area : EEC type : REG

subject	specification	descriptor
GOODS	CSMET	PRMT
GOODS	CSMET	RQR
GOODS	CSMET	MXL

THE SUBSTANCE IS PRESERVATIVE WHICH COSMETIC PRODUCTS MAY CONTAIN WITHIN THE LIMIT AND UNDER THE CONDITIONS LAID DOWN. MXL: 0.1%. THE SUBSTANCE IS PROHIBITED IN AEROSOLS. WARNING WHICH MUST BE PRINTED ON THE LABEL IS GIVEN. MEMBER STATES SHALL TAKE ALL MEASURES NECESSARY TO ENSURE THAT THE COSMETIC PRODUCTS MAY BE MARKETED ONLY IF THEIR PACKAGING, CONTAINERS OR LABELS BEAR THE INFORMATION LAID DOWN.
entry date: SEP 1995 effective date: 27MCH1978

title: COUNCIL DIRECTIVE OF 27 JULY 1976 ON THE APPROXIMATION OF THE LAWS OF THE MEMBER STATES RELATING TO COSMETIC PRODUCTS (76/768/EEC)
original : OJEC**, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, L262 , , 169 , 1976
amendment: OJEC**, OFFICIAL JOURNAL OF THE EUROPEAN COMMUNITIES, L181 , , 31 , 1994