FOREWORD INTRODUCTION

ETHYLENE GLYCOL PHENYL ETHER

CAS N°: 122-99-6

SIDS Initial Assessment Report

For

SIAM 18

Paris, France, 20-23 April 2004

1. Chemical Name:	ETHYLENE GLYCOL PHENYL ETHER
2. CAS Number:	122-99-6
3. Sponsor Country:	USA U.S. Environmental Protection Agency Mr. Oscar Hernandez, Director Risk Assessment Division (7403M) 1200 Pennsylvania Ave., NW Washington, DC 20460 Phone: 202-564-7641
4. Shared Partnership with:	No partner, single sponsor
5. Roles/Responsibilities of the Partners:	Not applicable
• Name of industry sponsor /consortium	ACC Ethylene and Propylene Glycol Ethers Panel CEFIC Oxygenated Solvents Producers Association
• Process used	The single U.S. manufacturer of EGPhE keeps up with the published literature on EGPhE with periodically updated literature searches for all important toxicological and environmental endpoints and adds any new studies to its files. All such published studies were provided for compiling the SIDS dossier, as well as pertinent unpublished data from the manufacturer. In addition, the summaries compiled in the IUCLID dossier published by the European Chemicals Bureau were merged with the current dossier
6. Sponsorship History	
• How was the chemical or category brought into the OECD HPV Chemicals Programme ?	The Ethylene Glycol Ethers and Propylene Glycol Ethers Panels of the American Chemistry Council notified the Environmental Protection Agency that they wished to volunteer to sponsor a number of ethylene glycol ethers in SIDS program, including ethylene glycol phenyl ether. Originally this chemical was to be part of a category of low boiling ethylene glycol ethers, but the EPA and the sponsors later agreed that ethylene glycol phenyl ether should be sponsored as an individual chemical, with the remainder of these ethers handled as one or more categories.
7. Review Process Prior to	SIDS Dossier and Testing Plan were reviewed by the US EPA

the SIAM: and the following SIDS Testing Plan was recommended:

no testing (X)

testing ( )

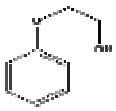
8. Quality check process: On completing the data collection, important and significant studies were identified for all endpoints. These studies were reviewed and summarized following current guidelines for robust summaries. Reliability ratings were assigned following the Klimisch rating system. Studies assigned ratings of 1 or 2 were considered to be acceptable. The key studies were identified based on completeness, protocol and GLP use and other quality factors. These were flagged as critical studies. The summaries were compiled using the IUCLID program.

9. Date of Submission: 8 August 2003

10. Date of last Update: 23 January 2004

11. Comments: This is the final version of the SIAR, which addresses any outstanding issues raised at SIAM 18.

SIDS INITIAL ASSESSMENT PROFILE

CAS No.	122-99-6
Chemical Name	Ethylene Glycol Phenyl Ether
Structural Formula	

SUMMARY CONCLUSIONS OF THE SIAR

Human Health

Studies in rats and rabbits indicate that ethylene glycol phenyl ether (EGPhE) is rapidly absorbed after oral administration and excreted in the urine, either as unchanged material or 2-phenoxyacetic acid. The most reliable LD50 values for the rat after oral administration are 1,386 and 2,563 mg/kg bw in fasted males and females (respectively), and 2,937 and 4,013 mg/kg bw in fed males and females, (respectively). isSigns of acute toxicity include a slight to severe reduction of activity, decreased reflexes and labored respiration. Rats treated with high doses appeared comatose before death or recovery. A dermal LD50 value of 14,300 mg/kg bw was observed in rats. EGPhE is not irritating to human skin, but is slightly irritating to rabbit skin, and irritating to rabbit eyes. Contact with up to 5% EGPhE in petrolatum is not sensitizing to human skin.

Dermal administration of up to 500 mg/kg bw/day EGPhE (the highest dose tested) for 90 days had no effect in rabbits other than erythema at the test site. The oral (gavage), repeated-dose 90 day NOAEL in rats is 80 mg/kg bw/day. In this study, 400 mg/kg bw/day for 90 days was associated with kidney toxicity and changes in grooming behavior. Rats orally administered 2000 mg/kg bw/day exhibited toxicity to red blood cells and other effects associated with this phenomenon (decreased number of circulating red blood cells, decreased red blood cell hemoglobin, and kidney inflammation). Compared to the rat, the rabbit is more sensitive to the hemolytic effects of EGPhE (hemolysis is noted in rabbits orally treated with $\geq$ 100 mg/kg bw/day EGPhE for 10 days).

EGPhE tested negative for mutagenicity in an Ames test conducted in *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 (in the absence and presence of metabolic activation). EGPhE also tested negative in an *in vivo* cytogenicity study in the rat and a mouse micronucleus test. Other *in vitro* chromosomal aberrations and gene mutation assays were also negative.

Minimal tubular atrophy of the testes was observed in 1/15 control male and 3/15 male rats orally treated with 2000 mg/kg bw/day EGPhE for 90 days. Moderate tubular atrophy associated with a reduction of spermatozoa in the epididymal tubules also was found in one high dose male. . The ability of EGPhE to cause testicular toxicity in 6-week old male mice was also reported. The animals were administered up to 2000 mg/kg of EGPhE by gavage, 5 days/week for 5 weeks. EGPhE had no effect on weights of testes, combined weights of the seminal vesicles and coagulating gland, or morphology of the testes, seminal vesicles or coagulating gland.

A 2-generation continuous breeding, oral feeding study in CD-1 mice with EGPhE resulted in NOAELs of 400 mg/kg bw/day for both parental animals and offspring. EGPhE was associated with decreased body weight (in males at 4000 mg/kg/day and in both males and females at 2000 mg/kg/day) and increased liver weight (males and females at both 2000 and 4000 mg/kg/day). Decreased absolute weight of seminal vesicles was noted in males treated with 2,000 mg/kg bw/day, but not 4,000 mg/kg bw/day. Developmental toxicity was seen in offspring of mice treated with 2,000 mg/kg bw/day, which had lower birth weights, and F1 weanlings exposed to 4,000 mg/kg bw/day test material, which had lower birth, weaning and mating weights than controls and high lethality rates. Decreased numbers of live pups per litter as well as decreased proportion of live pups were born. A lower percent of the high dose animals (60%) had a fifth litter compared with 90% in the controls.

A developmental toxicity study in rabbits resulted in no teratogenicity or developmental toxicity when

administered dermally at doses up to 600 mg/kg bw/day from gestation days 6-18. This concentration induced hemolysis and death in 5/25 dams, but appeared to have no adverse effect on the remaining maternal animals. Two other studies showed some evidence of developmental toxicity; in one of the studies, the dose was administered subcutaneously and the reliability of the second study (an oral study) could not be verified.

Environment

EGPhE is a high boiling liquid (boiling point 245.2°C) with a very low vapor pressure (0.000134 hPa at 20°C). It has a melting point of 14°C, a water solubility of 28.9 g/l and a log octanol/water partition coefficient of 1.16. The photodegradation half-life is 3.9 hrs. Like other glycol ethers, EGPhE possesses no functional groups in its molecular structure that are readily subject to hydrolysis in the presence of water. The Henry's law constant is calculated to be 1.55 x 10^{-8} atm.m^3/mole at 25°C. Level III fugacity modeling assuming equal distribution to the various compartments indicates mass balances of 0.685% to air, 46.3% to water, 53.0% to soil and 0.0867% to sediment compartments. Although the material preferentially partitions to water and soil when released into the aqueous environment, it is readily biodegradable, and based on the log partition coefficient of 1.16, has a very low potential to bioaccumulate.

Adequate acute toxicity tests in fish and aquatic invertebrates show that EGPhE is of low toxicity to these species (LC/EC50 values are 344 and 488 mg/l, respectively). The 16-hr IC_{50} value for bacteria (sewer microorganisms) is 1,650 mg/l. Since the highest concentration used in the algal toxicity test (500 mg/l) did not have an effect on cell biomass, the EC50 value in algae is greater than this value.

There are no data on chronic toxicity of EGPhE to aquatic organisms or toxicity of EGPhE to terrestrial plants.

Exposure

In the U.S., EGPhE is produced by a single manufacturer using a continuous reactor, distillation column and storage tanks. Annual production is about 6.4 thousand metric tons in the U.S. EGPhE is used primarily as both a solvent and as an industrial intermediate, but it also has other uses in cosmetics as an antibacterial agent and some consumer products. Exposure is limited during manufacture by the enclosed nature of the process and the low volatility of EGPhE. Because the material is transported, used in product formulations and industrial application, used as a solvent, and may be present in some consumer products, there is some potential for widespread exposure. The material has been detected in the effluents of sewage treatments and effluents from chemical manufacturing facilities. Exposure can occur via ingestion, dermal absorption, and inhalation (to a lesser extent based on low volatility). Because EGPhE biodegrades and photodegrades readily it is not expected to persist in the environment and remain present in significant concentrations, thereby contributing significantly to environmental exposure.

RECOMMENDATION

Environment: The chemical is currently of low priority for further work.

Human Health: This chemical is a candidate for further work.

RATIONALE FOR THE RECOMMENDATION AND NATURE OF FURTHER WORK RECOMMENDED

Human Health: The chemical possesses properties indicating a hazard for human health (eye irritation – which is reversible - and developmental toxicity at high doses associated with maternal toxicity). Based on data presented by the Sponsor country, exposure is controlled in the occupational setting. Due the wide dispersive use, member countries are invited to perform an exposure assessment and if then indicated, a risk assessment, especially for consumers. Countries may desire to investigate any exposure scenarios that were not presented by the Sponsor country.

Environment: This chemical is currently of low priority for further work because of its low hazard profile.

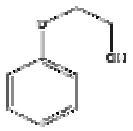
Note: EGPhE may be evaluated further under the EU Biocides Directive. This will include exposure assessment on operators (occupational) and by-standers (consumers)

SIDS Initial Assessment Report

1 IDENTITY

1.1 Identification of the Substance

CAS Number: 122-99-6
IUPAC Name: Ethylene glycol phenyl ether
Molecular Formula: C8 H10 O2
Structural Formula:



Molecular Weight: 138.17
Synonyms: (2-hydroxyethoxy)benzene
beta-Hydroxyethyl phenyl ether
beta-Phenoxyethanol
2-Hydroxyethyl phenyl ether
2-phenoxyethanol
ethyleneglycol monophenyl ether
DOWANOL®EPH Glycol Ether

1.2 Physicochemical properties

Table 1 Summary of Physicochemical Properties

Property	Value	Method/Reference
Physical state	liquid	
Melting point	14 °C	Windholz et al., 1983
Boiling point	245.6°C at 1013 hPa	Windholz et al., 1983
Relative density	1.1094 g/cm3 at 20°C	Windholz et al., 1983
Vapour pressure	0.013 hPa at 20°C	IPCS INCHEM, 2005
Water solubility	28.9 g/l	Windholz et al., 1983
Partition coefficient n-octanol/water (log value)	1.16	Hansch and Leo, 1979
Henry's law constant	1.55 E-8 atm-m^3/mole @25°C	Estimated using EPIWIN

2 GENERAL INFORMATION ON EXPOSURE

2.1 Production Volumes and Use Pattern

Ethylene glycol phenyl ether (EGPhE) is produced by one U.S. manufacturer at one production site. Annual production volume in 1999 in the U.S. was reported to be about 6.4 thousand metric tons

(Chinn, 2000). Producers, if any, outside of the U.S. have not been identified. EGPhE is produced by reacting ethylene oxide with phenol in an alkaline medium using a continuous closed reactor column (Budavari, 1989). The product is purified by passing the crude reaction mixture through a continuous distillation column. The purified product is then transferred through a closed line to a storage tank. Most of the product is sold and transported in bulk (tank car or tank truck), and a portion of it is drummed for sales in smaller quantities.

EGPhE has the following reported uses: solvent for cellulose acetate, dyes, inks, resins, organic synthesis of plasticizers, germicides, and pharmaceuticals, and as a preservative for human anatomical specimens for dissection (Sax and Lewis, 1987). It is reportedly used as a fixative for perfumes, in organic synthesis, as a bactericide and insect repellent (Budavari, 1989). It has also reportedly been used as a fixative for cosmetics and soaps, a textile dye carrier, a chemical intermediate, a solvent for cleaners, and as a solvent for stamp pads, specialty inks and ball points (HSDB, 2003).

The Environmental Protection Agency (EPA) has provided the following reported uses of EGPhE in consumer products: various soaps (including shower/hand soaps), oven cleaner, heavy duty floor finish stripper, hair conditioner/gel, microemulsion sheen activator/moisturizer, hot oil treatment, interior latex primer-sealer, paint and varnish removers (EPA, 2003). Some of these uses may be the same as those identified above (e.g., fixative for soaps and solvent for cleaners). In a project for the Consumer Product Safety Commission (CPSC), The American Chemistry Council Ethylene and Propylene Glycol Ethers Panel has tabulated uses of various ethylene glycol ethers in consumer products. This unpublished tabulation provides the following information on EGPhE:

Table 2 Percentage of EGPhE Production Used For Consumer Products

Types of Consumer End Products	Consumer Products Vol (metric tons)	Consumer Products % Production	Consumer Products Approx. Weight %	Percent Industrial/ Consumer Use
Paints/coatings	< 4,500	37.5%	5-15%	
Cleaners	< 2,300	19.0%	5-15%	37/63
Dyes	< 450	6.5%	5-15%	

No further details were provided about the uses reported by the EPA or in the above table.

According to the SPIN database, the following uses have been reported in 2002 for the EU Nordic countries: cleaning/washing agents, paints lacquers and varnishes, cutting fluids, non-agricultural pesticides and preservatives, reprographic agents, surface active agents, in cosmetics and softeners, adhesive/binding agents, surface treatment, welding and soldering agents, pharmaceuticals, colouring agents, corrosion inhibitors, lubricant and additives, stabilizers, solvent and “other”.

2.2 Environmental Exposure and Fate

Table 3 Summary of Environmental Fate Properties for EGPhE

Photodegradation OH radical rate constant	Predicted Environmental Distribution (Level III fugacity model)			
	Air (%)	Water (%)	Soil (%)	Sed. (%)
32.67 E-12 cm^3/molecule-sec $t_{1/2}$ = 3.9 hrs	0.68	46.2	53.0	0.0866

All values were estimated using EPIWIN

2.2.1 Sources of Environmental Exposure

There is expected to be limited opportunity for environmental release during current U.S. manufacturing practices, because of the use of closed systems employed for this purpose by the single U.S. manufacturer. The chemical is stored in closed tanks and transported in tank cars and tank trucks, and smaller amounts are transported in drums. Environmental release during transport is possible in the event of a spill or accident. Through the use of this substance as a solvent, as a chemical intermediate and for other multiple, dispersive applications in industrial and consumer products, EGPhE may be released into the aquatic environment through industrial wastewater effluents or into the atmosphere by volatilization. Environmental monitoring information is largely not available, but ethylene glycol phenyl ether was detected qualitatively in 1976 in effluents from sewage treatments and chemical manufacturing facilities (Shackelford and Keith, 1976). If the substance is released to the air it will degrade relatively rapidly by reaction with photochemically-produced hydroxyl radicals (estimated half-life of 3.9 hours). Because the substance is relatively soluble in water, physical removal from air via wet deposition may occur. If released to soil or water, ethylene glycol phenyl ether is expected to biodegrade readily.

2.2.2 Photodegradation

The hydroxyl radical induced photodegradation rate constant and half-life for EGPhE were estimated using the EPIWIN AOP (v.1.90) Program (Table 3). The hydroxyl radical-induced photodegradation rate constant of 3.2 E-11 cm^3/molecule-sec and predicted half-life of 3.9 hours indicate that the substance photodegrades readily in the atmosphere.

2.2.3 Stability in Water

Although no quantitative rate constant has been determined for water hydrolysis of EGPhE, it is well known that ether groups are generally stable to water under neutral conditions and ambient temperatures (Fieser and Fieser, 1960). The ether function is readily hydrolyzed only by heating in the presence of halogen acids, particularly hydrogen iodide. The EPIWIN/Hydrowin program is not able to calculate a rate constant for water hydrolysis for ether functions.

2.2.4 Transport between Environmental Compartments

Level III Fugacity modeling has been conducted for EGPhE using the EPIWIN Program (Table 3). Measured inputs to the EPIWIN program are a melting point of 14°C, a boiling point of 245.2°C, a water solubility of 28,900 mg/l and a vapor pressure of 0.00975 mm Hg. The Fugacity model, assuming equal releases to air, water and soil, predicts that the substance partitions preferentially to water and soil about equally, with limited partitioning to air and sediment. The mass percentages in each medium are given in Table 3. The predicted half-lives in hours are: air = 7.858, water = 360, soil = 360, and sediment = 1440; with a BIOWIN ultimate estimate range of weeks.

2.2.5 Biodegradation

Results of an OECD Guideline 301 F “Ready Biodegradability: Manometric Respirometry Test” indicate that 90% of EGPhE degrades within 28 days (Goodwin, 1999). An additional study performed according to APHA guidelines shows 60% biodegradation of EGPhE after 20 days (Waggy, 1987). Three additional studies for which the reliability could not be verified also reported that EGPhE is biodegradable.

2.2.6 Bioaccumulation

A bioconcentration factor (BCF) of 0.3493 (log BCF = -0.457) estimated by EPIWIN BCF (v2.14) indicates that EGPhE has a low potential to bioaccumulate.

2.3 Human Exposure

2.3.1 Occupational Exposure

Occupational exposure to the ethylene glycol ethers occurs through inhalation of vapour and dermal contact (Parmeggiani, 1983). Inhalation exposure is limited by the substance's low vapour pressure (0.0053 hPa at 20°C). NIOSH has estimated that 96,814 workers are potentially exposed to ethylene glycol phenyl ether in the USA (NOES, 1983). Exposure is more likely to occur during processing and use as a solvent, since manufacture takes place in a closed system.

2.3.2 Consumer Exposure

The general population can be exposed through dermal contact and inhalation of vapour through ethylene glycol phenyl ether's use as a perfume fixative or solvent for inks, resins and cellulose acetate (Sax and Lewis, 1987). Table 2 above lists a number of reported uses of EGPhE in consumer products, and indicates that about 63% of total manufacturing volume goes into consumer products, and that such products may contain 5-15% by weight EGPhE. The most likely routes of exposure are dermal and inhalation, and the latter route is limited by the low vapour pressure of EGPhE.

3 HUMAN HEALTH HAZARDS

3.1 Effects on Human Health

3.1.1 Toxicokinetics, Metabolism and Distribution

Studies in Animals

In vitro studies

The dermal absorption of EGPhE in methanol through unoccluded rat skin was tested in vitro (Roper et al., 1997). Approximately 43-64% of the material was absorbed by 24 hours. Qualitatively, the study showed that first-pass metabolism of EGPhE to phenoxyacetic acid was not detected during percutaneous penetration through viable rat skin in a flow-through system. However, the postmitochondrial fraction of the skin metabolized EGPhE to phenoxyacetic acid at 5% of the rate for liver. Metabolism by the postmitochondrial fraction was inhibited by 1 mM pyrazole, suggesting involvement of alcohol dehydrogenase. It is possible that use of methanol in this study may have affected the absorption of EGPhE but it is not known whether it would have resulted in greater or less absorption.

In vivo Studies

In rabbits given a single oral dose of 800 mg/kg bw EGPhE, parent material (up to 25 micrograms/ml) and phenoxyacetic acid (PAA) were identified in serum samples taken up to 24 hours after dosing. Peak PAA concentrations (1452 micrograms/ml) occurred 3 hr after administration (Breslin et al., 1991).

After oral administration of 15.6 to 160.7 mg/kg bw to four rats, between 95-98% of the EGPhE was recovered, of which 91-94% was in the urine, 0.8-1.3% in the feces and 1.3-2.2% was exhaled as carbon dioxide. With dermal application (6.2-24 mg/kg bw), the recovery rate was between 65-99%; the major portion also was in the urine and only small amounts were in the feces. After either oral or dermal application, unchanged test substance, 2-phenoxyacetic acid (>75%) and small amounts of two further metabolized products were found in urine (Howes, 1988).

Studies in Humans

In vitro Studies

The dermal absorption of EGPhE in methanol through unoccluded human skin was tested in vitro. (Roper *et al*., 1997). Approximately 60% of the material was absorbed by 6 hours. As noted above, it is not clear whether use of methanol as a solvent had an effect on the absorption of EGPhE.

3.1.2 Acute Toxicity

Studies in Animals

Inhalation

In studies that were not conducted according to GLP, groups of 6 male albino rats and quail exposed to room –temperature vapor substantially saturated with EGPhE for 7 to 8 hours exhibited no signs of toxicity, survived the 14 day observation period and gained weight normally (Union Carbide, 1949, American Cyanamid Co., 1966).

Dermal

A dermal LD_{50} value of 14.3 g/kg bw was obtained in an adequate study in rats (Davies, 1970). The period of contact with the skin was 24 hours. Hemorrhagic lungs were noted at necropsy. It is not known if this only occurred in animals that died. Skin reactions were not described. . Adequate, earlier studies conducted in male rabbits indicate lower LD_{50} values (2,251 and 3,815 mg/kg bw) (Union Carbide, 1949; American Cyanamid Co., 1966). It is not known if the lower LD_{50} values in the rabbit (compared to the rat) are due to greater species sensitivity or use of material with lower purity. Additional dermal toxicity studies for which the reliability could not be verified reported LD_{50} values of 2,250 – 5,545 mg/kg bw in rabbits and > 22,180 mg/kg bw in guinea pigs.

Oral

A sufficient oral toxicity study reported LD_{50} values of 1,386 and 2,563 mg/kg bw for EGPhE of at least 92% purity in fasted male and female Sprague-Dawley rats, respectively (Hill Top Research, 1980). An oral LD_{50} value of 2,563 mg/kg bw also was obtained in a non-GLP study conducted in fasted, male CF Nelson rats (American Cyanamid, 1966). Signs of toxicity these studies included a slight to severe reduction of activity, weakness, decreased reflexes and labored respiration. Rats treated with high doses appeared comatose before death or recovery. No lesions were found in survivors. The results of the GLP cytogenicity study conducted with fed Sprague-Dawley rats indicated LD_{50} values of 2937 and 4013 mg/kg bw for males and females, respectively (Gollapudi et al., 1988). Additional studies that were reviewed reported LD_{50} values of 1,260 and 2,580 mg/kg bw for fed male rats (Smyth et al. 1941, Union Carbide, 1949). These studies are not considered to be as reliable as more current studies, since the studies were not conducted according to GLP and the purity of the material was not listed. Oral LD_{50} values for rats in a number of other studies for which reliability ratings could not be assigned ranged from 1,260 – 7,500 mg/kg bw (European Chemicals Bureau, 2000).

A preliminary acute oral toxicity study designed to indicate the MTD in fasted mice indicated that the LD_{50} value in this species was > 1000 and < 1500 mg/kg bw. Symptoms of toxicity in animals dosed with concentrations > = 2000 mg/kg bw were lethargy, ataxia and body tremors, which occurred within 6-8 hours of dosing. Lethargy also was noted in animals treated with 1000 or 1500 mg/kg bw. Most deaths occurred within 8 hours of dosing. Postmortem examinations of all dead mice revealed no abnormalities (Richold *et al*., 1982b).

Studies in Humans

Three cases of acute and chronic toxicity were reported in women who tagged and/or trimmed fish in Oregon from 1983 to 1985 (Morton, 1990). Each tagger put about 80 fingerlings into a small dishpan about half full of water, added several "squirts" of 2-phenoxyethanol to partially anesthetize the fish, then picked up the fish bare-handed for tagging. For fish trimming, larger pans and more 2-phenoxyethanol were used. The three taggers/trimmers handled about 4000 to 8000 fish per day. After skin contact over a time period of 5 months to 2 years headaches, general weakness and tiredness was experienced after the beginning of the exposure, and after 1-2 years cognitive disturbances were observed. The relationship of exposure to 2-phenoxyethanol and the symptoms is tenuous, since the concentration of phenoxyethanol (or other chemicals) that the subjects were exposed to were not listed, neurologic function prior to employment was not assessed, use of alcohol and other substances that could have influenced the results was not listed, a detailed work history prior to employment at the hatchery was not obtained, control incidences of similar toxicities were not examined, numbers of workers who performed the same job but did not experience symptoms were not noted, and the contribution of a highly repetitive, tedious task to reported signs was not considered. Existing animal data do not indicate any nervous system effects other than possible, reversible depression of the CNS.

3.1.3 Irritation

Skin Irritation

Studies in Animals

Results of an occlusive patch study conducted in six rabbits that was described in a CIR Review (1990) indicated that slight, transient irritation occurred in two rabbits given 10% test material in acetone/water (10/90) and one rabbit given 2% test material in the same vehicle (Huntingdon Research, 1970). No irritation was noted in intact and abraded skin of 6 rabbits exposed to undiluted EGPhE for 24 hours under an impervious patch (American Cyanamid, 1966). A number of additional studies that were poorly described or were not available for review indicated that EGPhE was not irritating or was only slightly irritating to rabbit or guinea pig skin.

Studies in Humans

Results of a repeated insult patch test that was described in a CIR Review (1990) indicate that there was little indication of irritancy in 51 volunteers whose skin was in 24 hour covered contact with a 10% solution of EGPhE, three times weekly for 23 weeks (Hill Top Research, 1984). An additional study described in the CIR Review showed that of 2736 patients patch-tested with 1% EGPhE in petrolatum, none had signs of irritant reactions 2 and 4 days after application. Patch testing of 130 patients with 1, 5, and 10% EGPhE in petrolatum also resulted in no irritant reactions (Lovell *et al.,* 1984). Two additional studies in humans that were not available for review also indicate that EGPhE is not irritating to human skin.

Eye Irritation

Studies in Animals

Studies in rabbits show that undiluted EGPhE of unknown purity is highly irritating to eyes (Krasavage, 1981, American Cyanamid, 1966, Union Carbide, 1983). A number of additional studies for which the reliability could not be verified also indicated that EGPhE is irritating to rabbit eyes.

3.1.4 Sensitisation

Several studies described in a CIR Review (1990) indicate that EGPhE is not a sensitizer. For example, when patch tested with EGPhE (5% or 0.4% in petrolatum, respectively), one out of 3726 experienced an allergic reaction (Fuchs *et al*., 1991). No allergic reactions were reported in 2,736 subjects patch tested with 1% EGPhE in petrolatum (Lovell *et al*., 1984). One person out of 501 who were undergoing patch testing for suspected contact dermatitis experienced an allergic reaction (DeGroot *et al*., 1986). Several additional studies in humans and guinea pigs also show no sensitization.

3.1.5 Repeated-Dose Toxicity

Dermal and oral repeated-dose toxicity studies are summarized in the following sections. Two 90-day studies (one dermal and one oral) are described in addition to a 10-day oral study in rabbits. Only the 90-day studies are included in Table 4, given the short duration of the study in rabbits.

Studies in Animals

Dermal

In a 90-day repeated-dose dermal toxicity, rabbits were administered 50, 150, and 500 mg/kg bw/day EGPhE for 6 hrs/day for 5 days/week (Breslin *et al*. 1991). Examinations included those for clinical chemistry parameters, haematological parameters, and pathology. No effects other than erythema at the test site were observed. Therefore, 500 mg/kg bw/day was considered to be the NOAEL for systemic toxicity (see Table 4).

Oral

EGPhE was administered via gavage for 13 weeks to rats at doses of 80, 400, and 2000 mg/kg bw/day. The dose of 2000 mg/kg bw/day caused toxicity to red blood cells and other effects that are associated with this phenomenon (decreased number of circulating red blood cells, decreased red blood cell hemoglobin, and kidney inflammation) (Ben-Dyke, *et al.,* 1977).[1] Inflammation of the kidneys was also seen at 400 mg/kg bw/day. Minimal tubular atrophy of the testes was observed in 1/15 control males and 3/15 males treated with 2000 mg/kg bw/day EGPhE. Moderate tubular atrophy associated with a reduction of spermatozoa in the epididymal tubules also was found in one high dose male. These findings in the testes were considered by test personnel to be of equivocal toxicological significance. The tubular atrophy was not graded as severe, and there was no indication as to whether the lesions were unilateral or bilateral. The NOAEL in this study was 80 mg/kg bw/day.

[1] EGPhE is not as potent in causing red blood cell hemolysis in rats as ethylene glycol butyl ether (EGBE), as oral administration of approximately 90 mg/kg bw/day of EGBE for 13 weeks is associated with its development (Boatman and Knaak, 2001).

Another study administered doses of 100, 300, 600, and 1000 mg/kg bw/day for 10 consecutive days to three adult female rabbits per group (Breslin et al., 1991). Although none of the data from this study were statistically analyzed, compared to the rat, the rabbit appears to be more sensitive to the hemolytic effects of EGPhE since hemolysis was observed at doses ≥ 100 mg/kg bw/day EGPhE for 10 days.[2] Additional haematological effects were observed at all doses. Deaths occurred at doses of 300 mg/kg and higher; all rabbits in the 1000 mg/kg bw/day group were found dead or were killed moribund on day 2. In the 600 mg/kg bw/day group, one rabbit was found dead and two rabbits were terminated moribund on days 3 and 6, respectively. One rabbit in the 300 mg/kg bw/day group was found dead on day 10 after dosing. Other signs of toxicity included anorexia, lethargy, and excretion of dark-red urine. Body weights were decreased at all doses. Additional effects are discussed in the Dossier. Limitations of this study include the short duration and the lack of statistical analysis.

Table 4: Repeated-Dose Toxicity of EGPhE

Reference	Species/ Exposure	Dose (mg/kg bw/d) (deaths)	Gross Changes (per dose)	Histopathological Changes (per dose)	Clin. Chem/ Hemat. Changes
Breslin et al., 1991	Dermal NZW rabbit, 6 hr/d, 5 d/wk, 90 d, 10/sex/ group	50 150 500[a]	none none erythema at test site	none none none	none none none
Ben-Dyke et al., 1977	Gavage CD rat, daily for 13 weeks, 15/sex/group	80[a] 400 [b] 2,000 (5/30)	none no grooming ↓ bw, food, ↑ water, urine, liver, kidney, thyroid wt, no grooming	none distended tubules, inflamm in kidney distended tubules, inflamm in kidney	none ↑ ALP ↓ rbc, pcv, hb, ↑ urea, glucose, ALP, GPT

[a] NOAEL; [b] LOAEL

3.1.6 Mutagenicity

Adequate mutagenicity and *in vivo* cytogenicity tests have been performed with EGPhE.

Studies in Animals

In vitro Studies

EGPhE tested negative for mutagenicity in an Ames test conducted in *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 with concentrations up to 5,000 micrograms/plate in the absence and presence of a metabolic activation system (Richold *et al*., 1982a). The material (2000 – 3500 µg/ml, with and without metabolic activation) also tested negative for HGPRT mutants in Chinese Hamster Ovary cells (Dow Chemical Company, 1987).

[2]Additional studies performed by these investigators with rabbit erythrocytes in vitro showed that phenoxyacetic acid metabolites are not responsible for rabbit red blood cell hemolysis caused by EGPhE. The lack of in vitro hemolytic effects of the phenoxyacetic acid metabolite relative to EGPhE in rabbits is consistent with that reported for butoxyacetic acid and EGBE in rabbits, dogs and humans (Carpenter *et al*., 1956, Bartnik *et al*., 1987, and Hext, 1984). However, rat erythrocytes are reportedly more susceptible in vitro to the hemolytic effects of butoxyacetic acid (the oxy acetic acid metabolite of EGBE) than EGBE (Bartnik *et al.,* 1987, Hext, 1984). Breslin and coworkers (1991) hypothesized that the differences in species susceptibility between the rabbit and rat suggest that metabolism of EGPhE to phenoxyacetic acid is a deactivation pathway with regard to hemolysis in rabbits and metabolism of EGBE to butoxyacetic acid is an activation process in the rat.

In vivo Studies

EGPhE tested negative in a bone marrow cell cytogenicity test performed -in groups of five male and five female Sprague-Dawley rats given 280, 933 or 2,800 mg/kg bw by gavage (Gollapudi *et al*., 1988). Data on mitotic indices indicated that there was no excessive toxicity in cells from treated animals. There were no significant increases in total or specific types of cytogenetic anomalies at 933 or 2800 mg/kg bw and the overall results were negative.

A micronucleus test also has been conducted with EGPhE in the CD-1 mouse (Richlold *et al*., 1982b). Groups of 10 males and 10 females received total doses of 0, 300, 600 or 1200 mg/kg bw EGPhE in 1% methylcellulose by gavage in two divided doses within a 24 hour period (Richlold et al. 1982b). There was no effect of treatment on the number of micronucleated cells/1000 polychromatic erythrocytes (PCE) isolated from bone marrow. There also was no effect of treatment with EGPhE on the ratio of normochromatic/ polychromatic cells.

3.1.7 Carcinogenicity

No studies on carcinogenicity of EGPhE were located. FDA cancer models predict a negative result for EGPhE in male/female rats and male/female mice (Danish Environmental Protection Agency, 2004).

3.1.8 Toxicity for Reproduction

Studies in Animals

Effects on Fertility

CD-1 mice were administered 400, 2000 or 4000 mg/kg bw/day EGPhE via feed in a 2-generation, continuous breeding study. Doses of 2000 and 4000 mg/kg bw/day were associated with decreased parental body weight and increased relative liver weight. Decreased absolute weight of seminal vesicles was noted in F1 males treated with 2000 mg/kg bw/day. However, this effect appears to be a consequence of the reduced body weight, because when adjusted for body weight there was no difference between seminal vesicle weights of the animals and their respective controls. Offspring of rats treated with 2000 mg/kg bw/day had lower birth weights, and F1 weanlings exposed to 4000 mg/kg bw/day test material in feed had lower birth, weaning and mating weights than controls and high lethality rates (25/32 males and 21/24 females). At 4000 mg/kg bw/day, the number of live pups per litter and the proportion of pups born alive were decreased. A lower percent of the high dose animals (60%) had a fifth litter compared with 90% in controls. Effects on offspring such as increased fetal lethality and decreased birth weight were only observed at high concentrations (> = 2000 mg/kg bw/day) that caused parental toxicity (and were greater than the OECD-recommended high dose of 1000 mg/kg/day for repeated dose studies). Based on these results, the NOAELs for parental and fetal effects were both 400 mg/kg bw/day (Heindel *et al.,* 1990).

The ability of EGPhE to cause testicular toxicity was tested in a study conducted in 6-week old male mice (Nagano *et al*., 1984) that was described in an abstract. Groups of five animals were given 500, 1000, or 2000 mg/kg bw/day by gavage, 5 days/week for 5 weeks, after which the testes, seminal vesicles and coagulating gland were weighed and examined microscopically. EGPhE did not result in changes in any of these endpoints.

Developmental Toxicity

Results of a developmental toxicity study in New Zealand white rabbits indicate that EGPhE is not a teratogen or developmental toxicant when administered dermally from gestation days 6 to 18 (Scorticini et al., 1987). No effects on the fetus were noted (even at concentrations that produced

maternal toxicity). Although no effects were noted in offspring from the 5 surviving females treated with 1000 mg/kg bw/day, this value cannot be used as the NOAEL for developmental toxicity because the effect of this dose on the majority of the progeny from dams given 1000 mg/kg bw/day was not assessed (due to maternal death or termination before delivery). Therefore, the NOAEL for developmental toxicity in this study was 600 mg/kg bw/day.

A study for which the reliability could not be verified indicates that EGPhE is a developmental toxicant in Wistar rats at concentrations that cause maternal toxicity (BASF AG, 1992). Administration of 444 mg/kg bw/day subcutaneously, from gestation days 6-15, was associated with maternal toxicity (reduced weight gain and feed intake, and hemoglobinuria), embryolethality (an increased number of resorptions), and developmental toxicity (reduced weight and an increased incidence of unossified cervical centers). The parental and developmental NOAELs were determined to be 111 mg/kg bw/day, based on a reduction in maternal body weight from gestation days 11 to 15 and increased numbers of intrauterine resorptions and fetuses with unossified cervical centers that were observed at 222 mg/kg bw/day.

An additional study that was only described in an abstract (and therefore the information cannot be verified) indicated that EGPhE caused developmental toxicity at concentrations that did not cause maternal toxicity (as evidenced by no effect on weight or food consumption) (Mankes and Renak, 1987). At 300 mg/kg bw/day (the highest dose used in the study), "significant birthweight depression" was detected in male pups. Increased fetal anomalies such as hydronephrosis and variant ossification patterns of the skull appeared to correlate with the prevalence of males in the litter. Doses at which the anomalies occurred were not mentioned and the statistical method used to analyze data was not described. Although the authors mention that the correlation was significant to $p < 0.05$, they also mention that the correlation coefficient was 0.4. Since this correlation coefficient is very low, the statistical significance of the results is possibly suspect. Also, the study was apparently never published.

3.2 Initial Assessment for Human Health

Studies in rats and rabbits indicate that ethylene glycol phenyl ether (EGPhE) is rapidly absorbed after oral administration and excreted in the urine, either as unchanged material or 2-phenoxyacetic acid. The most reliable LD50 values for the rat after oral administration are 1,386 and 2,563 mg/kg bw in fasted males and females (respectively), and 2,937 and 4,013 mg/kg bw in fed males and females, (respectively). isSigns of acute toxicity include a slight to severe reduction of activity, decreased reflexes and labored respiration. Rats treated with high doses appeared comatose before death or recovery. A dermal LD50 value of 14,300 mg/kg bw was observed in rats. EGPhE is not irritating to human skin, but is slightly irritating to rabbit skin, and irritating to rabbit eyes. Contact with up to 5% EGPhE in petrolatum is not sensitizing to human skin.

Dermal administration of up to 500 mg/kg bw/day EGPhE (the highest dose tested) for 90 days had no effect in rabbits other than erythema at the test site. The oral (gavage), repeated-dose 90 day NOAEL in rats is 80 mg/kg bw/day. In this study, 400 mg/kg bw/day for 90 days was associated with kidney toxicity and changes in grooming behavior. Rats orally administered 2000 mg/kg bw/day exhibited toxicity to red blood cells and other effects associated with this phenomenon (decreased number of circulating red blood cells, decreased red blood cell hemoglobin, and kidney inflammation). Compared to the rat, the rabbit is more sensitive to the hemolytic effects of EGPhE (hemolysis is noted in rabbits orally treated with $\geq$ 100 mg/kg bw/day EGPhE for 10 days).

EGPhE tested negative for mutagenicity in an Ames test conducted in *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 (in the absence and presence of metabolic activation). EGPhE also tested negative in an *in vivo* cytogenicity study in the rat and a mouse micronucleus test. Other *in vitro* chromosomal aberrations and gene mutation assays were also negative.

Minimal tubular atrophy of the testes was observed in 1/15 control male and 3/15 male rats orally treated with 2000 mg/kg bw/day EGPhE for 90 days. Moderate tubular atrophy associated with a reduction of spermatozoa in the epididymal tubules also was found in one high dose male. . The ability of EGPhE to cause testicular toxicity in 6-week old male mice was also reported. The animals were administered up to 2000 mg/kg of EGPhE by gavage, 5 days/week for 5 weeks. EGPhE had no effect on weights of testes, combined weights of the seminal vesicles and coagulating gland, or morphology of the testes, seminal vesicles or coagulating gland.

A 2-generation continuous breeding, oral feeding study in CD-1 mice with EGPhE resulted in NOAELs of 400 mg/kg bw/day for both parental animals and offspring. EGPhE was associated with decreased body weight (in males at 4000 mg/kg/day and in both males and females at 2000 mg/kg/day) and increased liver weight (males and females at both 2000 and 4000 mg/kg/day). Decreased absolute weight of seminal vesicles was noted in males treated with 2,000 mg/kg bw/day, but not 4,000 mg/kg bw/day. Developmental toxicity was seen in offspring of mice treated with 2,000 mg/kg bw/day, which had lower birth weights, and F1 weanlings exposed to 4,000 mg/kg bw/day test material, which had lower birth, weaning and mating weights than controls and high lethality rates. Decreased numbers of live pups per litter as well as decreased proportion of live pups were born. A lower percent of the high dose animals (60%) had a fifth litter compared with 90% in the controls.

A developmental toxicity study in rabbits resulted in no teratogenicity or developmental toxicity when administered dermally at doses up to 600 mg/kg bw/day from gestation days 6-18. This concentration induced hemolysis and death in 5/25 dams, but appeared to have no adverse effect on the remaining maternal animals. Two other studies showed some evidence of developmental toxicity; in one of the studies, the dose was administered subcutaneously and the reliability of the second study (an oral study) could not be verified.

4 HAZARDS TO THE ENVIRONMENT

4.1 Aquatic Effects

Ecotoxicity data from robust study summaries are discussed below and listed in Table 5.

Acute Toxicity Test Results

An LC_{50} value of 344 mg/l was obtained for fathead minnows (*Pimephales promelas*) in a well-conducted flow-through test conducted following USEPA Guidelines (Veith, 1973). Other tests in fathead minnows that were poorly described reported 96-hour LC_{50} values of 366 and 478 mg/l. The 48-hour LC_{50} value for *Rasbora heteromorpha* was lower than the LC_{50} values reported for fathead minnows (135 mg/l) (Alabaster, 1969). This study is not considered to be as reliable as the study conducted by Veith, since water quality was not monitored during the test and raw data were not reported.

Adequate toxicity tests for Daphnia that were conducted according to EPA/ASTM and Richtlinie 79/831/EWG, C.2 report 48-hour LC_{50} values of 488 and > 500 mg/l (Waggy, 1987; BASF AG, 1988). In a test performed in algae (*Scenedesmus subspicatus*), the highest concentration tested (500 mg/l) had no effect on chlorophyll fluorescence, which is an indicator of biomass (BASF AG, 1989).

Although concentrations in some of the above studies were not analytically confirmed, it is well known that glycol ethers, including EGPhE, are stable in water.

The EPA ECOSAR model predicts a 96-hour LC50 value of 718 mg/l for fish, 48-hour LC50 value of 723 mg/l for Daphnia, and a 96-hour EC50 value of 429 mg/l for algae. These results are of the same order of magnitude as the measured LC50/EC50 values, and support the conclusion that EGPhE is of low acute toxicity to aquatic species.

Chronic Toxicity Test Results

There are no data on chronic toxicity of EGPhE to aquatic organisms.

Toxicity to Microorganisms

The 16-hr IC_{50} value for bacteria (sewer microorganisms) is 1,650 mg/l (Waggy, 1987).

Table 4 Aquatic Toxicity of EGPhE

Fish 96-hr LC_{50} (mg/l)	Invertebrate 48-hr EC_{50} (mg/l)	Algae 72-hr EC_{50} (mg/l)	Bacteria 16-hr EC50 (mg/l)
344[a] *(Pimephales promelas)* 718[b]	488[a] (*Daphnia magna*) 723[b]	>500[a] (*Scenedesmus subspicatus)* 429[b]	1,650[a]

[a]measured
[b]estimated

4.2 Terrestrial Effects

No data on terrestrial effects were located.

4.3 Other Environmental Effects

No other environmental data were found.

4.4 Initial Assessment for the Environment

EGPhE is a high boiling liquid (boiling point 245.2°C) with a very low vapor pressure (0.000134 hPa at 20°C). It has a melting point of 14°C, a water solubility of 28.9 g/l and a log octanol/water partition coefficient of 1.16. The photodegradation half-life is 3.9 hrs. Like other glycol ethers, EGPhE possesses no functional groups in its molecular structure that are readily subject to hydrolysis in the presence of water. The Henry's law constant is calculated to be 1.55×10^{-8} $atm.m^3$/mole at 25°C. Level III fugacity modeling assuming equal distribution to the various compartments indicates mass balances of 0.685% to air, 46.3% to water, 53.0% to soil and 0.0867% to sediment compartments. Although the material preferentially partitions to water and soil when released into the aqueous environment, it is readily biodegradable, and based on the log partition coefficient of 1.16, has a very low potential to bioaccumulate.

Adequate acute toxicity tests in fish and aquatic invertebrates show that EGPhE is of low toxicity to these species (LC/EC50 values are 344 and 488 mg/l, respectively). The 16-hr IC_{50} value for bacteria (sewer microorganisms) is 1,650 mg/l. Since the highest concentration used in the algal toxicity test (500 mg/l) did not have an effect on cell biomass, the EC50 value in algae is greater than this value.

There are no data on chronic toxicity of EGPhE to aquatic organisms or toxicity of EGPhE to terrestrial plants.

5 RECOMMENDATIONS

This chemical is a candidate for further work for human health. The chemical possesses properties indicating a hazard for human health (eye irritation – which is reversible – and developmental toxicity at high doses associated with maternal toxicity). Based on data presented in the Sponsor country, exposure is controlled in the occupational setting. Due to the wide dispersive use, member countries are invited to perform an exposure assessment and if then indicated, a risk assessment, especially for consumers. Countries may desire to investigate any exposure scenarios that were not presented by the Sponsor country.

Note: EGPhE may be evaluated further under the EU Biocides Directive. This will include exposure assessment on operators (occupational) and by-standers (consumers).

The chemical is currently of low priority for further work for the environment because of its low hazard profile.

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S I D S

Dossier

Existing Chemical	:	ID: 122-99-6
CAS No.	:	122-99-6
EINECS Name	:	2-phenoxyethanol
EINECS No.	:	204-589-7
Molecular Weight	:	138.17
Molecular Formula	:	C8H10O2

Producer Related Part

Company	:	PCA Services, Inc.
Creation date	:	07.02.2002

Substance Related Part

Company	:	PCA Services, Inc.
Creation date	:	07.02.2002
Memo	:	
Printing date	:	08.09.2005
Revision date	:	08.09.2005
Date of last Update	:	08.09.2005
Number of Pages	:	159
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 7
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 APPLICANT AND COMPANY INFORMATION

Type	:	lead organization
Name	:	ACC Ethylene and Propylene Glycol Ethers Panel; CEFIC Oxygenated Solvents Producers Association
Contact Person	:	Dr. Susan Lewis
Date	:	06-JAN-2005
Street	:	1300 Wilson Blvd
Post Code/Town	:	Arlington, VA
Country	:	United States
Phone	:	703 741 5635
E-mail	:	

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

Type	:	Manufacturer
Name of Plant	:	The Dow Chemical Company
Country	:	United States

1.0.3 IDENTITY OF RECIPIENTS

1.1.1 GENERAL SUBSTANCE INFORMATION

Substance type	:	Organic
Physical status	:	Liquid
Source	:	EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

1.1.0 DETAILS ON TEMPLATE

1.1.1 SPECTRA

1.2 SYNONYMS AND TRADENAMES

(2-hydroxyethoxy)benzene
Source : Seppic Paris
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

.beta.-Hydroxyethyl phenyl ether
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

.beta.-Phenoxyethanol
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

.beta.-Phenoxyethyl alcohol
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

1-Hydroxy-2-phenoxyethan

Source : Bayer AG Leverkusen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

1-Hydroxy-2-phenoxyethane
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

2-Hydroxyethyl phenyl ether
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

2-phenoxyethanol
Source : Seppic Paris
RHODIA GERONAZZO S.p.A OSPIATE
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

2-Phenoxyethanol
Source : BASF AG Ludwigshafen
TRANSOL Chemiehandel GmbH Essen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

2-Phenoxyethyl alcohol
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Arosol
Source : BASF AG Ludwigshafen
Haarmann & Reimer GmbH Holzminden
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

beta-Hydroxyethylphenylether
Source : Bayer AG Leverkusen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

beta-phenoxyethanol
Source : Seppic Paris
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Dalpad A
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

DALPAD* A
Remark : DALPAD is a Trademark of The Dow Chemical Company.
Source : Dow Benelux B.V. (Botlek) Botlek-Rotterdam
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Dowanol EP
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Dowanol EPh
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

DOWANOL* (R) EPH Glycol Ether
Remark : DOWANOL is a Trademark of The Dow Chemical Company.
Source : Dow Benelux B.V. (Botlek) Botlek-Rotterdam
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

ethanol, 2-phenoxy-
Source : Huels AG Marl
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Ethanol, 2-phenoxy-
Source : Haarmann & Reimer GmbH Holzminden
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Ethanol, 2-phenoxy- (6Cl, 7Cl, 8Cl, 9Cl)
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Ethyleen glycol monophenyl ether
Source : TRANSOL CHEMICALS BV RIDDERKERK
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Ethylene glycol monophenyl ether
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Ethylene glycol phenyl ether
Source : Dow Benelux B.V. (Botlek) Botlek-Rotterdam
BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Ethylene glycol monophenyl ether
Source : Huels AG Marl
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Ethyleneglycol monophenylether
Source : RHODIA GERONAZZO S.p.A OSPIATE
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Ethylenglykolmonophenylether
Source : Bayer AG Leverkusen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Ethylenglykolphenylether
Source : Bayer AG Leverkusen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

H 4644
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

MONOPHENYLGLYCOL
Source : TRANSOL CHIMICA ITALIA S.R.L. CASSINA DE PECCHI
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Monophenylglycol
Source : TRANSOL Chemiehandel GmbH Essen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Monophenylglykol
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

PHE-SS
Source : TRANSOL Chemiehandel GmbH Essen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Phenoxethol
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Phenoxetol
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Phenoxy ethyl alcohol
Source : Givaudan Roure SA Sant Celoni, Barcelona
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Phenoxyethanol
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Phenoxyethyl alcohol
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Phenyl cellosolve
Source : RHODIA GERONAZZO S.p.A OSPIATE
BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

phenylcellosolve
Source : Huels AG Marl
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

phenylglycol
Source : Huels AG Marl
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

phenylglycol ether

1.3 IMPURITIES

1.4 ADDITIVES

1.5 TOTAL QUANTITY

Produced : 6,400 metric tons
Year : 1999
Remark : The above reported manufacturing volume is for the U.S. only. Manufactures in other countries, if any exist, are not known to the U.S. sponsor.
: (43)

1.6.1 LABELLING

Labelling : as in Directive 67/548/EEC
Symbols : Xn

Nota : C
Specific limits : no data
R-Phrases : (22) Harmful if swallowed
(36) Irritating to eyes
S-Phrases : (2) Keep out of reach of children
(26) In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

1.6.2 CLASSIFICATION

Classification : as in Directive 67/548/EEC
Class of danger : corrosive
R-Phrases : (22) Harmful if swallowed
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Classification : as in Directive 67/548/EEC
Class of danger : irritating
R-Phrases : (36) Irritating to eyes
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

1.7 USE PATTERN

Type : Type
Category : Non dispersive use
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : Type
Category : Use in closed system
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : Type
Category : Wide dispersive use
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : Industrial
Category : Chemical industry: used in synthesis
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : Industrial
Category : Paints, lacquers and varnishes industry
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : industrial
Category : Personal and domestic use
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : industrial

Category : Textile processing industry
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : industrial
Category : other: Adhesives industry
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : industrial
Category : other: Cosmetics industry
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : industrial
Category : other
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Category : Cleaning/washing agents and disinfectants
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Category : Colouring agents
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Category : Cosmetics
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Category : Impregnation agents
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Category : Intermediates
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Category : Non agricultural pesticides
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Category : Odour agents
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Category : Solvents
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use

Category : other: Konservierungsmittel [preservative]
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Category : other: as reactive solvent or evaporation retardant in inks
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Category : other: coalescent solvent
Source : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability :

Type : use
Remark : According to the TOXNET Hazardous Substances Data Bank, EGPhE has the following reported uses: industrial intermediate used as a fixative for perfumes, bactericide, insect repellent, solvent for cleaners, fixative for soaps and cosmetics, textile dye carriers, solvent for stamp pads and inks, preservative for anatomical specimens, and solvent for cellulose acetate, dyes and resins.
(144)

Type : Use
Remark : According to the SPIN database, the following uses have been reported in 2002 for the EU Nordic countries: cleaning/washing agents, paints lacquers and varnishes, cutting fluids, non-agricultural pesticides and preservatives, reprographic agents, surface active agents, in cosmetics and softeners, adhesive/binding agents, surface treatment, welding and soldering agents, pharmaceuticals, colouring agents, corrosion inhibitors, lubricant and additives, stabilizers, and solvent.
(140)

1.7.1 DETAILED USE PATTERN

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

Type of limit : MAK (DE)
Limit value :
Remark : NO MAK value established
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
(145)

Type of limit : MAK (DE)
Limit value :
Remark : No MAK value established
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
13.03.2002 (146)

Type of limit : MAK (DE)
Limit value :
Country : Germany
Remark : not established
Source : Huels AG Marl
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

(91)

Remark : No occupational exposure levels have been set for this substance. Dow uses an internal Industrial Hygiene Guide of 25 ppm, with skin notation.

Source : Dow Benelux B.V. (Botlek) Botlek-Rotterdam
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2.1 MELTING POINT

Value : ca. 14 ° C
Decomposition : no at ° C
Sublimation : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 – 1.4
Reliability : (2) valid with restrictions. Data were obtained from peer reviewed references. Purity of material was not listed.
Flag : Critical study for SIDS endpoint
13.03.2002 (96) (193)

Value : ca. 11 ° C (freezing point)
Decomposition : no at ° C
Sublimation : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 – 1.4
Reliability : (4) not assignable. Data were obtained from the manufacturer's MSDS. Purity of material is 100%.
Flag :
13.03.2002 (53)

Value : = 13 ° C
Remark : Druck [Pressure]: 1013 hPa

Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002 (31)

Value : = 14 ° C
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002 (41)

Value : = 14 ° C
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of

material is unknown.
13.03.2002 (116)

Remark : Erstarrungstemperatur [Solidification temperature]: ca. 13 Grad C.

Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002 (28)

2.2 BOILING POINT

Value : = 245.2 ° C
Decomposition : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 – 1.4
Reliability : (2) valid with restrictions. Data came from peer reviewed references. Purity of material is unknown.
Flag : Critical study for SIDS endpoint
13.03.2002 (96)(193)

Value : = 245.6 ° C at 1013 hPa
Decomposition : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 – 1.4
Reliability : ((4) not assignable. Data were obtained from the manufacturer's MSDS. Purity of material is 100%.
Flag :
13.03.2002 (53)

2.3 DENSITY

Value : = 1.1094 g/cm3 at 20 degrees C
Decomposition : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 – 1.4
Reliability : (2) valid with restrictions. Value was obtained from a peer reviewed reference. Purity of material is unknown.
13.03.2002 (193)

Type : density
Value : = 1.108 - 1.111 g/cm3 at 20° C
Method : other: DIN 51757

Year :
GLP :
Test substance :
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002 (31)

Type : density
Value : = 1.1094 g/cm3 at 20° C
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002 (41)(116)

Type : density
Value : ca. 1.11 g/cm3 at 20° C
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002 (28)(29)

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value : = .013 hPa at 20° C
Decomposition : no
Method : other
Year :
GLP : no
Result : Value listed on ICSC was 0.0013 kPa at 20° C
Reliability : (2) valid with restrictions. Data came from a peer-reviewed reference. Purity of material was not listed.
Flag : Critical study for SIDS endpoint
31.01.2005 :
(96)

Value : = .0093 hPa at 25° C
Decomposition : no
Method : other

Year :
GLP : no
Test substance :
Decomposition : no
Source :
Reliability : (4) not assignable. Data came from a manufactuer's MSDS. Purity of material is 100%.
Flag :
13.03.2002 (53)

Value : = .04 hPa at 20° C
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002 (28)(29)

Value : = 999.76 hPa at 244.9° C
Decomposition :
Method other (measured): dynamisch unter Stickstoffatmosphäre [dynamic under nitrogen atmosphere]
Year : 1986
GLP : no
Test substance : as prescribed by 1.1- 1.4
Remark : nachvollziehbar und akzeptabel [reproducible and acceptable]

Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.
Result : Temperatur in Grad C/Dampfdruck in hPa (gemessen) [Temperature in degrees C/vapor pressure in hPa (measured)]: 6.34/1.004; 93.46/3.002; 115.20/10.037; 167.98/100.370; 30.68/699.940; 244.89/999.760; eßgenauigkeit [accuracy]: Druck [pressure] +/- 0.10%; Temperature: < +/- 0.15% at 00 - 300 degrees C
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : Purity: > 99.9%
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau.
13.03.2002 (18)

Value : = 1013 hPa at 244.9° C
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002 (31)

Value : = 1013.25 hPa at 245.3° C

Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Result : [Temperature in degrees C/vapor pressure in] hPa: 8/1.33; 121.2/13.3; 176.5/133;
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.

13.03.2002 (124)

Value : 1013.25 at 245.3° C
Method other (measured): Dynamisch unter Argon [dynamic under argon], GC
Year : 1993
GLP : no
Test substance :
Remark : [Calculated from measured values through regression].

nachvollziehbar und akzeptabel [reproducible and acceptable]

Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.
Result : Temperature in degrees C/vapor pressure in hPa (measured): 6.32/1.00; 102.40/5.00; 115.26/10.00; 150.10/50.00; 67.92/100.0; 218.2/500.0; 245.5/1013.5
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 99.1% purity
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau.

13.03.2002 (16)

2.5 PARTITION COEFFICIENT

Log pow : = 1.16 at ° C
Method other: measured
Year : 1979
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Reliability : (2) valid with restrictions. Study predates GLP and OECD Guidelines. Purity of material was not listed.
Flag : Critical study for SIDS endpoint

(76) (77)

13.03.2002

Log pow : = 1.13 at 25° C
Method other (measured)
Year : 1989
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : nachvollziehbar und akzeptabel [reproducible and acceptable]

Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Test substance : Purity: 100 %
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau.
13.03.2002 (13)

Log pow : = 1.1 at ° C
Method other: calculated
Year : 2001
GLP : no
Test substance : as prescribed by 1.1 –1.4
Reliability : (2) valid with restrictions. Data were obtained by modeling.
Source : EPIWIN KOWWIN (v1.66) program
13.03.2002

2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Value : = 28.9 g/l at 20 ° C

Method : other
Year : 1993
Test substance : as prescribed by 1.1 – 1.4,
Result : [Temperature in degrees C/Solubility in mass%] : 10.0/2.56; 20.0/2.89; 30.0/2.54; 40.0/2.97; 50.0/3.19; 60.0/3.57; 70.0/3.37; 80.0/4.54; 90.0/5.58;
Test Condition : Water and EGPhE were brought into equlibrium at a 20 degrees C in a thermostat and samples of each layer were removed with a syringe for analysis by gas chromatography. The EGPhE came from Aldrich or TCI America laboratory supply houses and had a purity of 98%.
Reliability : (1) valid without restriction. Study was well conducted, using standard analytical methods with the purity of the test material stated as being 98%.
Flag : Critical study for SIDS endpoint
30.03.2004 (141)

Value : = 23 g/l at 25 ° C
Qualitative :
Pka : at 25 ° C
PH : at and ° C
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 – 1.4
Reliability : (4)not assignable. Data were obtained from a manufactuer's MSDS. Purity of material is 100%.
13.03.2002 (53)
Value : = 26.7 g/l
Qualitative :
Pka :
PH :
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 – 1.4
Reliability : (2) valid with restrictions. Data were obtained from the Merck Index. Purity of material is unknown.
13.03.2002 (193)

Value : = 24 g/l at 20 ° C
Qualitative :

Pka : at 25 ° C
PH : ca. 7 at 10 g/l and 23 ° C
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.

13.03.2002 (28)(29)(31)

Value : 27 g/l at 25 ° C
Method : other
Year : 1976
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

The value listed here is in agreement with that listed on International Chemical Safety Card (ICSC) 0538, for Ethylene Glycol Phenyl Ether, online at http://www.inchem.org/documents/icsc/icsc/eics0538.htm
Test substance : Test substance was DOWANOL EPh. It contained 92% ethylene glycol phenyl ether and 8% diethylene glycol phenyl ether.
Reliability : (2) valid with restrictions. The study was not reviewed. The reliability rating of 2 (valid with restrictions) assigned in the original IUCLID document published by the European Chemicals Bureau is appropriate since it is in agreement with the value listed in a peer-reviewed reference

13.03.2002 (33)

Value : 27 g/l at 20 ° C
Test substance : as prescribed by 1.1 - 1.4
Remark :

Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
The value listed here is in agreement with that listed on International Chemical Safety Card (ICSC) 0538, for Ethylene Glycol Phenyl Ether, online at http://www.inchem.org/documents/icsc/icsc/eics0538.htm

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (2) valid with restrictions. The study was not reviewed. The reliability rating of 2 (valid with restrictions) assigned in the original IUCLID document published by the European Chemicals Bureau is appropriate since it is in agreement with the value listed in a peer-reviewed reference. Purity of material is unknown.

13.03.2002 (116)

2.6.2 SURFACE TENSION

See Section 2.13

2.7 FLASH POINT

Value : 121 ° C
Test substance : as prescribed by 1.1 – 1.4
Reliability : (2) valid with restrictions.
Data came from a standard reference source. Purity of material was not listed.
(193)

Value : 127 ° C
Type : closed cup
Test substance : as prescribed by 1.1 – 1.4
Reliability : (2) valid with restrictions
Data were obtained from the manufacturer's MSDS. However, a reliability rating of 2 is appropriate since the value is in agreement with that of a peer-reviewed reference. Purity of material is 100%
:
(53)

Value : 127 ° C
Test substance : as prescribed by 1.1 – 1.4
Reliability : (2) valid with restrictions.
Data came from a peer reviewed reference. Purity of material is unknown.
(96)

Value : > 100 ° C
Type :
Method : other: DIN 51 758
Year :
GLP :
Test substance :
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002
(28)

Value : ca. 120 ° C
Type :
Method : other: DIN 51 758
Year :
GLP :
Test substance :
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
(29)

Value : = 121 ° C
Type :
Method : other: DIN 51 758
Year :
GLP :
Test substance :

Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Method : Flammpunkt nach Pensky-Martens [Flash point according to Pensky-Martens method]
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
(31)

Value : = 126 ° C
Type :
Method : other: DIN 51 758
Year :
GLP :
Test substance :
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
(7)

2.8 AUTO FLAMMABILITY

Value : 500 degrees C
Method : other
Test substance : as prescribed by 1.1- 1.4
(2) valid with restrictions
Data came from a peer reviewed reference. Purity of material is unknown.
(96)

Value : > 200 degrees C
Method : other : DIN 51 794
Test substance : as prescribed by 1.1- 1.4
Remark : Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002 (28)(29)

Value : 535 degrees C
Method : other : DIN 51 794
Remark :
Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : The study was not reviewed. A reliability rating of 2 (valid with restrictions) was assigned in the original IUCLID document published by the European Chemicals Bureau. Purity of material is unknown.
13.03.2002 (7) (31)

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

Test substance : as prescribed by 1.1 - 1.4
Result : Explosive limits in air: 1.4-9.0 Vol.%
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of material is unknown.
13.03.2002 (7) (28) (29)

Remark : nicht explosionsgefaehrlich (aufgrund der chem. Struktur) [Not hazardous to explosion (based on chemical structure)]
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of material is unknown.
(30)

2.11 OXIDIZING PROPERTIES

Result : nicht brandfördernd (aufgrund der chem. Struktur) [Does not promote combustion by oxidization (based on chemical structure)]
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of material is unknown.
(30)

2.13 VISCOSITY

Value : =30 mPa.s at 23 degrees C

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of material is unknown.
(28)

Value : 30.05 cP at 20 degrees C
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of material is unknown.
(41)

Value : ca. 30 mPa.s at 20 degrees C
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable for this submission. The study was not reviewed. Data

came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of material is unknown.

(29)

Result : Viscosity: 30.5 cP at 20 degrees C
2.3 cP at 80 degrees C

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable for this submission. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of material is unknown.

(116)

Method : OECD-Guideline 115, Ringmethode (Mehrfachbestimmung)

Remark : Literature value from the Industrial Solvents Handbook, Third Edition, Noyes Data Corporation bei 25 Grad C:
Oberflächenspannung [Surface tension](sigma) = 0.042 N/m

Guideline-Study

The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

Result : Oberflächenspannung [Surface tension] at 20 degrees C: 0.0423 - 0.0426 N/m

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable for this submission. A reliability rating of 1 (valid without restriction) was assigned in the original IUCLID document published by the European Chemicals Bureau. However, purity was not noted.

(12)

2.14 ADDITIONAL REMARKS

Result : critical temperature : 297 Grad C
critical pressure : 37.3 bar
critical Density : 0.338 g/cm3
Oberflächenspannung [Surface tension] at 25 degrees C: 42 mN/m
Spezifische Wärme [specific heat] at15 degrees C : 2.03 kJ/kg.K
Verbrennungswärme [Heat of combustion] : -29706 kJ/kg
Verdampfungswäre beim Siedepunkt [Heat of vaporization at boiling point (berechnet) (calculated)]: 411.5 kJ/kg
Bildungswärme [Heat of formation] at 25 degrees C: -2260 kJ/kg

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable for this submission. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

(31)

Remark : Angaben über IR-, UV-. Raman-, NMR- und Massenspektrum beispielsweise in Literaturstelle Angaben über IR-, UV-. Raman-, NMR- und Massenspektrum
[Data for IR-, UV-, Raman- and mass spectrum examples are found in the literature]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable for this submission. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

(73)

3.1.1 PHOTODEGRADATION

Type	:	air
Light source	:	sun light
Light spect.	:	nm
Rel. intensity	:	based on Intensity of Sunlight
Direct photolysis		
Halflife t1/2	:	=
Degradation	:	% after
Quantum yield	:	
Indirect photolysis		
Sensitizer	:	OH
Conc. of sens.	:	
Rate constant	:	= .000000000032 cm3/(molecule*sec)
Degradation	:	= 50 % after 3.9 hour(s)
Deg. Product	:	
Method	:	other: calculated using the EPIWIN AOP (v1.90) program
Year	:	2001
GLP	:	no
Test substance	:	as prescribed by 1.1 – 1.4
Reliability	:	(2) valid with restrictions. Data were obtained by modeling.
Flag	:	Critical study for SIDS endpoint

13.03.2002

3.1.2 STABILITY IN WATER

Type	:	abiotic
t1/2 pH4	:	at degree C
t1/2 pH7	:	at degree C
t1/2 pH9	:	at degree C
Deg. Product	:	
Method	:	other: calculated using EPIWIN HYDROWIN program (v1.67).
Year	:	2001
GLP	:	no
Test substance	:	as prescribed by 1.1 – 1.4
Remark	:	The EPIWIN HYDROWIN Program cannot be used to estimate the hydrolysis rate of ethers in a neutral aqueous environment. In general, ethers are stable to hydrolysis in water under neutral conditions.
Reliability	:	(4) not assignable

3.1.3 STABILITY IN SOIL

3.2 MONITORING DATA

Remark	:	Ethylene glycol phenyl ether has been detected in effluents from sewage treatments and chemical manufacturing facilities (138)
Type of measurement	:	other: GC-MS
Medium	:	other: Abwasser/Grundwasser/Oberflaechenwasser [Waste water/ground water/surface water]
Method	:	

Concentration :
Remark : GC-Analyse: Ni-Elektroneneinfang – bzw. Flammenionisations detektor (FID), siliziumgepackte GC-Saeulen mit DB-5 bzw. DB-1, Wasserstoff als Traegergas, Temperatur 70 bis 300 Grad Celcius. [GC-Analysis: Ni-electron capture or flame ionization detector (FID) silicon packed GC column with DB-5 or DB-1, hydrogen carrier gas, temperature 70 to 300 degrees C]

Result : Ergebnisse sind nur halbquantitativ, gravierende Fehlerquelle sind die hohen Hintergrundinterferenzen.
Untersuchungsort: Llobregat river in Barcelona (Spanien)
Sammelperiode: 7.02.1984 bis 9.04.1984
Phenylglykolkonzentrationen an verschiedenen Sammelpunkten:
Abwasser Fabrik A+B: kleiner 5 ppm
Abwasser Fabrik A : kleiner 20 ppb
Grundwasser 4 : kleiner 0.5 ppm
Grundwasser 5 : kleiner 0.5 ppm
Grundwasser 6 : kleiner 20 ppb
Wald bei Fabrik: kleiner 20 ppb
[Results are only semi quantitative, serious faults are the high background interferences. Place of investigation: Llobregat river in Barcelona, Spain. Collection period 7 Feb 1984 to 9 Apr 1984. Phenylglycol concentrations at various collection points:
Waste watereffluent Factory A+B;< 5ppm
Waste water effluent Factory A :<20 ppb
Ground water 4 :<0.5 ppm
Ground water 5: <0.5 ppm
Ground water 6: <20 ppb
Woods by the factory: <20 ppb]
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.

(129)

Type of measurement : other: GC-MS
Medium : drinking water
Method :
Concentration :
Remark : Sekundaerzitat [secondary citation]

Result : 2-Phenoxyethanol was qualitatively detected in drinking water concentrates collected in Cincinnati, OH on Oct 17, 1978.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

(103)

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type : Fugacity model level III
Media : water - air
Air (level III) : 0.68 %
Water (level III) : 46.2 %

Soil (level I)	:	
Biota (level II / III)	:	
Soil (level II / III)	:	53%
Method	:	other: EPIWIN Fugacity Model Level III
Year	:	2001
Test condition	:	The assumed emission rates for the program were the defaults of 1000 kg/hr each to air, water and soil. Measured inputs to the EPIWIN program were a melting point of 14°C, a boiling point of 245.2°C, a water solubility of 28,900 mg/l, and a vapor pressure of 0.013 hPa (0.00975 mmHg), and a log Kow of 1.16.
Result	:	A mass amount of 0.0866% for sediment was estimated.The predicted half-lives in hours are: Air = 7.858, water = 360, soil = 360, and sediment = 1440, based on a Biowin ultimate estimate of 3.018 weeks. The EPIWIN HENRY (v3.10) model estimates a Henry's Law Constant of 1.55x10-8 atm-m3/mole (Bond Estimate) at 25 degrees C. The EPIWIN PCKOC (v1.66) program estimates a Koc (soil-sediment partition constant) of 12.12.
Reliability	:	(2) valid with restrictions. The data were estimated using a model.
Flag	:	Critical study for SIDS endpoint

13.03.2002

Type	:	Mackay, Level I
Media	:	
Method	:	Calculation
Year	:	1995
Remark	:	Bevorzugtes Zielkompartiment: Wasser (99%) Zugrundeliegende Daten fuer die Berechnung: Wasserloeslichkeit 24000 mg/l Dampfdruck 4 Pa log Pow 1.13 [Preferred compartment: water (99%) Data used as a basis for the estimation: Water solubility 24000 mg/l Vapor pressure 4 Pa Log Pow 1.13]
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.

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3.3.2 DISTRIBUTION

Media	:	water – air
Method	:	
Year	:	
Remark	:	Based upon a vapor pressure of 0.03 mm Hg at 25 deg C 2-phenoxyethanol is expected to exist almost entirely in the vapor phase in the ambient atmosphere.
Source	:	BASF AG Ludwigshafen

EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

(56)

Type : adsorption
Media :
Method : other: calculated (PCKOC, Howard/Meylan, 1993)
Year :
Remark : Adsorption in soil: Koc = 12.12

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

(27)

Type : volatility
Media : water – air
Method :
Year :
Remark : Based upon a water solubility of 26940 mg/l and a vapor pressure of 0.03 mm Hg at 25 deg C, the Henry's Law constant for 2-phenoxyethanol can be estimated to be 2.0 * 10 E-7 atm*m3/mole. This value of Henry's Law constant indicates that 2-phenoxyethanol is essentially non-volatile from environmental waters.

Sekundaerzitat [Secondary reference]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

(50)(104)(190)

Type : volatility
Media : water – air
Method :
Year :
Result : Sekundaerzitat [Secondary reference]

The evaporation rate of 2-phenoxyethanol from solid surface is classified as smaller than 0.01 relative to butyl acetate =1. The actual evaporation loss of 2-phenoxyethanol from surface at an air temperature of 77 deg F and 15% relative humidity is 0.4 wt% in 60 min.

.

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

(50) (104)

Type :

Media :
Method : other
Year :
Remark : 2-Phenoxyethanol may leach readily in soil based upon estimated Koc values of 16 and 102.

Sekundaerzitat [Secondary reference]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

(105)

3.4 MODE OF DEGRADATION IN ACTUAL USE

Remark : In Filtraten von Naehrsalzloesungskulturen des Braunfaeule-pilzes Coniophora cerebella und der Weissfaeulepilze Pleurotus ostreatus sowie Polystictus versicolor mit 0.15 % Phenoxyethanol wurde duennschicht- und gaschromatographisch sowie UV-spektrographisch Phenol nachgewiesen.
[Phenol was detected In the filtrates of nutrient solution cultures of brownrot fungus Coniophora cerebella and the white rot fungus Pleurotus ostreatus as well as Polystictus versicolor with 0.15% phenoxyethanol using thin layer and gaschromatography as well as uv spectrography]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.

(130)

3.5 BIODEGRADATION

Type : aerobic
Inoculum : activated sludge
Concentration : 30mg/l related to
related to
Contact time : 28 day
Degradation : = 90 % after 28 day
Result : readily biodegradable
Kinetic of test substance : 3 day = 10 **%**

4 day = 60 **%**
%
%
%
Control substance : other:benzoate
Kinetic : 3 day = 60 **%**
28 day = 96 **%**
Deg. Product : not measured
Method : OECD Guide-line 301 F "Ready Biodegradability: Manometric Respirometry Test"

Year	:	1999
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	The study was conducted according to GLP with the exception that purity was not confirmed by the laboratory.
Result	:	The extent of biodegradation of test material after 28 days (based on oxygen consumption) was 90%. The time required to achieve 10 and 60% degradation was 2.6 and 4.4 days, respectively. Test material exhibited an average of 75% biodegradation based on mineralization to CO2. Test material removed 99% of dissolved oxygen (DO) in 28 days. Biodegradation of benzoate (positive control) based on O2 consumption, CO2 production and DO removal was 96%, 73% and 96%, respectively, after 28 days. The pH remained within the required range of 6.0 - 8.5 over the course of the study. Oxygen consumption of the blank reactions (26 mg/l) was below the maximum allowable limit of 60 mg/l. The temperature averaged 22.1 +/- 0.3 degrees C.
Test condition	:	Test material (1.98 ml of a stock solution) was added to 500 ml of mineral medium inoculated with 30 mg/l mixed liquor suspended solids. The final concentration of test material in the reaction vessels was 88.0 mg/l ThOD. The mixed liquor was collected from a municipal wastewater treatment plant a day before the study and was continuously aerated to allow minimization of residual dissolved organic carbon. A total of 9 reaction vessels were prepared (two blanks that contained inoculated medium only, two that contained medium plus 192 mg/l THOD benzoate (positive control), two with test material and inoculated medium, 2 with test material, inoculated medium and 250 mg/l mercuric chloride (killed control), and one with test material, benzoate and inoculated medium (test for inhibition). Samples of the medium in each vessel were removed to determine the pH and initial concentrations of dissolved oxygen (DO), and nitrate and nitrite nitrogen (NO3- and NO2-). After being connected to the respirometer, reaction vessels were purged with ambient air and the headspace volume was measured by the respirometer. The vessels were maintained in the dark at 22 +/- 1 degrees C and stirred at 150 rpm over the 28-day test period. Gas phase O2 and CO2 concentrations were measured every 6 hours. At the conclusion of the test, the medium was sampled for pH, DO, NO3- and NO2-.
Test substance	:	Dowanol EPH, 94% pure (as reported by supplier).
Reliability	:	(1) valid without restriction. The study was performed according to GLP.
Flag	:	Critical study for SIDS endpoint

08.03.2002 (71)

Type	:	aerobic
Inoculum	:	other:non-acclimated sewage microorganisms
Contact time	:	
Degradation	:	= 66 % after 20 day
Result	:	
Kinetic of test substance	:	5 day = 9 **%** 10 day = 61 **%** 20 day = 66 **%** **%** **%**
Deg. Product	:	not measured
Method	:	other: as described in "Standard Methods for the Examination of Water and Wastewater, 16th ed.", USPHA, Washington, D.C., 1985.
Year	:	1987
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4

Result	:	The calculated theoretical oxygen demand was 2.18 mg/mg. After 5, 10 and 20 days of incubation, the biooxidation was 9, 61 and 66% (respectively).
Test condition	:	A modified version of the biochemical oxygen demand (BOD method published in "Standard Methods for the Examination of Water and Wastewater", 16th edition, Am. Public Health Association, 1985 was used. Nonacclimated domestic sewage organisms were used as seed in the test. The test period was extended to 20 days. Reaeration (if needed) was accomplished by dividing the BOD bottle contents between 2 BOD bottles, sealing, shaking twenty times, returning contents to the original BOD bottle, recording the oxygen level, resealing, and returning the BOD bottle to the incubator. A discussion of these modifications appears in Price et al., "Brine shrimp bioassay and seawater BOD of petrochemicals", J. Water Poll. Control Fed., Jan. 1974.
Test substance	:	Test material was phenyl glycol ether.
Reliability	:	(2) valid with restrictions. Purity was not listed.
08.03.2002		(192)

Type	:	aerobic
Inoculum	:	
Contact time	:	
Degradation	:	= 75 % after 20 day
Result	:	other: BOD of THOD
Kinetic of test substance	:	5 day = 21 **%** 10 day = 66 **%** 20 day = 75 **%** **%** **%**
Deg. Product	:	
Method	:	other: BOD-Test
Year	:	
GLP	:	no
Test substance	:	
Remark	:	Sekundaerzitat [Secondary source]

Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity was not listed.
13.03.2002		(46)

Type	:	Aerobic
Inoculum	:	other bacteria: BASF-Belebtschlamm [BASF activated sludge]
Contact time	:	
Degradation	:	= 99 % after 12 day
Result	:	
Kinetic of test substance	:	9 day = 61 **%** **%** **%** **%** **%**
Deg. Product	:	
Method	:	other: Standversuch nach Zahn-Wellens [Static study following Zahn-Wellens]
Year	:	1980
GLP	:	No

Test substance : other TS: Monophenylglykol pure
Remark : Testergebnis bezogen auf TOC-Elimination
TOC-Anfangskonzentration: ca. 430 mg/l
[Test results obtained from TOC elimination. Initial TOC concentration: ca. 430 mg/l]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity was not listed.
13.03.2002 (23)

Type : Aerobic
Inoculum : other: BASF-Belebtschlamm [activated sludge]
Contact time :
Degradation : = 82 % after 17 day
Result :
Kinetic of test substance : 10 day = 0 **%**
13 day = 79 **%**
16 day = 82 **%**
%
%
Deg. Product :
Method : other: Standversuch nach Zahn-Wellens [Static study following Zahn-Wellens]
Year : 1982
GLP : No
Test substance : other TS: Monophenylglykol technical grade
Remark : Testergebnis bezogen auf TOC-Elimination
TOC-Anfangskonzentration: ca. 425 mg/l [Test results obtained from TOC elimination. Initial TOC concentration: ca. 425 mg/l]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity was not listed.
13.03.2002 (22)

3.6 BOD5, COD OR BOD5/COD RATIO

Remark : Analyses were made for total oxygen demand (TOD), chemical oxygen demand (potassium dichromate and alkaline potassium permanganate), and biochemical oxygen demand (BOD). Wastewater treatment plant secondary effluent was the seed material.

The total oxygen demand was 21.33 parts O2/part of test material (p/p), chemical oxygen demand was 2.12 p/p (potassium dichromate) and 1.55 p/p (potassium permanganate), and biological oxygen demand for 5, 10 and 20 days was 0.48, 1.54, and 1.74 p/p. The BOD/TOD for 5, 10 and 20 days was 21, 66 and 75%, respectively.
Test substance : Test substance was DOWANOL EPh. It contained 92% ethylene glycol phenyl ether and 8% diethylene glycol phenyl ether.
Reliability : (2) valid with restrictions. There are not enough details to assign a reliability rating of 1.
08.03.2002 (33)

Result	:	CSB = 2127 mg/g BSB5 < 2 mg/g BSB5/CSB kleiner 0.0009
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance	:	Monophenylglykol technical grade
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

13.03.2002 (21)

3.7 BIOACCUMULATION

Elimination	:	
Method	:	other: EPIWIN BCF (v2.14)
Year	:	2004
GLP	:	no
Test substance	:	as prescribed by 1.1 -1.4
Remark	:	Measured inputs to the EPIWIN program were a melting point of 14°C, a boiling point of 245.2°C, a water solubility of 28,900 mg/l, a vapor pressure of 0.013 hPa (0.00975 mmHg), and a log Kow of 1.16.A bioconcentration factor (BCF) of 0.3493 (log BCF = -0.457) was estimated.
Reliability	:	(2) valid with restrictions. Data were obtained by modeling.

17.10.2003

Elimination	:	
Method	:	other:
Year	:	
GLP	:	
Test substance	:	
Remark	:	Based upon a water solubility of 26940 mg/l at 25 deg C the BCF for 2-phenoxyethanol can be estimated to be 2 from a regression-derived equation. Based upon a measured log Kow of 1.16 the BCF for 2-phenoxyethanol can be estimated to be 4.5 from a regression-derived equation.
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

13.03.2002 (104) (190)

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	flow-through
Species	:	Pimephales promelas (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	yes
LC50	:	344
Method	:	other: following the U.S. EPA Committee on Methods for Toxicity Tests with Aquatic Organisms
Year	:	1980
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	The average (+/- SD) temperature, dissolved oxygen, hardness, alkalinity and pH of the water in the test chambers were 26.6 +/- 0.73 degrees C, 6.0 +/- 0.85 mg/l, 45.0 +/- 0 mg/l CaCO3, 42.0 +/- 0 mg/l CaCO3, and 7.62 +/- 0.28. It is not known whether these variables were affected by test material concentration. Average and ranges of analytical concentrations of the two chambers treated with 0, 68, 113, 188, 313 and 522 mg/l material were <2, 59.7 and 56.0 (48.0 to 65.0), 95 and 100 (86.0 to 107), 162 and 167 (154 to 175), 270 and 271 (239 to 303) and 454 and 494 (no other range) mg/l. When corrected for recovery (102.8 %), test material concentrations were 54.5 and 58.0, 93 and 97, 158 and 162, 263 and 264, and 442 and 481 mg/l. The mean length and weight (+/- SD) of the fish at study termination were 18.3+/- 1.917 mm and 0.107 +/- 0.0338 g. All fish exposed to the highest concentration were dead by 3 hours, and one fish exposed to 270 mg/l (analytical conc.) was dead at 96 hours. Fish exposed to 270 mg/l were immediately affected but began to respond to tap at 12 hr. They did not school for the remainder of the test. Affected fish stopped schooling, became hypoactive on the tank bottom, then lost equilibrium prior to death. Fish exposed to concentrations less than 270 mg/l did not exhibit signs of toxicity or die. The 96 hour LC50 and EC50 values (with confidence intervals) were the same (344 and 337-352 mg/l).
Test condition	:	Newly hatched minnows from adults reared in flow-through tanks were held at 25 degrees C in flowing water with a 16-hr photoperiod and were fed brine shrimp nauplii three times daily (twice on weekends). They were cultured in filtered Lake Superior water or dechlorinated water from the city of Superior, WI (exact source not given) The two waters were similar in all measured chemical parameters. This water was used for test material dilution and all tests. Healthy fish (32 days old) were fasted for 24 hours before treatment. They were pooled together in one tank and randomly distributed among the exposure chambers. Tests were initiated by adding 25 fish per treatment (68, 113, 188, 313 or 522 mg/l) and control to test chambers containing 6.3 liters of water. Fish loading was 0.408 g/l. The rate of exchange was 5.6 volumes of test water per day. Observations of fish behavior and toxic signs were made at 2-8, 24, 48, 72 and 96 hr and recorded on checklists specifically formatted to convert observational data for approximately 100 endpoints into a numerically coded form. Death (cessation of opercular movements and inability to respond when prodded) was recorded at 24, 48, 72 and 96 hours. Dead fish were removed. Tests were performed in duplicate. At study

termination, individual control fish were weighed (wet) and measured.

All test exposure chambers were sampled mid-depth at 0, and 96 hours and one of each duplicate chamber at 24, 48 and 72 hours. Concentrations of test material from the exposure tanks were analyzed using gas-liquid chromatography. All analyses included one spike and one duplicate sample for every 6 to 12 water samples.

Five water quality parameters were routinely measured for each test: temperature, dissolved oxygen, total hardness, total alkalinity, and pH. The desired test temperature was 25 +/- 1 degrees C. Daily measurements of oxygen concentration and pH were taken in each treatment and the control exposure chambers if fish were present. The low, mid and high test concentration chambers were sampled once for total hardness and alkalinity.

The estimated LC50 and EC50 values, with corresponding 95% confidence intervals were calculated using the corrected average of the analyzed tank concentrations and the Trimmed Spearman-Karber Method. The EC50 values were based on loss of equilibrium manifested by an inability of the fish to remain in an upright position when swimming. The mean concentrations used in the calculations were corrected for analytical recoveries of spiked water samples.

Test substance : Purity of test material was 95%.
Reliability : (1) valid without restriction. The study was comparable to a guideline study.
Flag : Critical study for SIDS endpoint
24.06.2002 (191)

Type : static
Species : Pimephales promelas (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring : no
LC50 : c = 478
Method : other:EPA/ASTM
Year : 1987
GLP : no data
Test substance : as prescribed by 1.1 – 1.4
Result : The 96-hr LD50 value (with 95% confidence limits) was 4787(411-558) mg/l.
Test condition : Ten test organisms were used per test concentration (not listed). Test conditions followed EPA/ASTM guidelines. Specific conditions were not listed.
Test substance : Test material was phenyl glycol ether. Purity was not stated.
Reliability : (4) not assignable. Not enough study conditions were listed to assign a reliability rating.
15.02.2002 (192)

Type : static
Species : Pimephales promelas (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring : no
NOEC : m = 100
LC50 : c = 366
LC100 : m = 560
LC10 : m = 180
Method : other
Year : 1976

GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Test conditions were not stated (with the exception of use of Finney's probit analysis). The calculated LC10, LC50, and LC90 values (with 95% confidence limits) were 236 (122-298) mg/l, 366 (286-473) mg/l, and 567 (446-1130) mg/l. The slope of the curve was 6.73 (2.85-10.60).
Test substance	:	Test substance was DOWANOL EPh. It contained 92% ethylene glycol phenyl ether and 8% diethylene glycol phenyl ether.
Reliability	:	(4) not assignable. Not enough study conditions were listed to assign a reliability rating.

08.03.2002 (33)

Type	:	flow through
Species	:	Lepomis macrochirus (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
LCLo	:	370
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Es wurde die Auswirkung der Testsubstanz auf die Atmung der Fische untersucht. [The effect of the test substance on the breathing of the fish was investigated]
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (39)

Type	:	flow through
Species	:	Pimephales promelas (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	yes
LC50	:	344
Method	:	other: following the American Society for Testing and Materials (ASTM) Guideline
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 – 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (37)

Type	:	other: no data
Species	:	Oncorhynchus nerka (Fish, fresh water)
Exposure period	:	8 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no data
LC50	:	ca. 333
Method	:	other: no data
Year	:	
GLP	:	no

Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Originalangabe [original information]: LD50 / 8h ca. 300 ul/l
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (137)

Type	:	semistatic
Species	:	Rasbora heteromorpha
Exposure period	:	48 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
LC50	:	135
Method	:	other: following the Ministry of Agriculture, Fisheries and Food: The Pesticides Safety Precautions Scheme, Working Document No. 6
Year	:	1966
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	The 24 and 48 hour LC50 values were 165 and 135 ppm, respectively.
Test condition	:	Groups of 10 harelquin fish (1.3 - 3 cm long) were put into 500 ml flasks containing tap water (at 20 degrees C) with a hardness of approximately 250 ppm (as $CaCO_3$). They were acclimated to the water for approximately one week. Stock solutions of test material were prepared with standard dilution water and added to the water in the test vessels. Test solutions were kept at 20 degrees C and replaced automatically at a rate of 100 ml every 10 minutes. Fish were observed during working hours, for a period of at least 4 days. Median periods of survival were estimated graphically by the method of Bliss (Ann Appl Biol 24:816-852, 1937). The logarithm of the median time of survival was plotted against the logarithm of the concentration and a line was fitted to the points. Median lethal concentrations at 24 and 48 hours were then interpolated graphically.
Reliability	:	(2) valid with restrictions Concentrations of test material were not analytically confirmed. The concentrations used and the numbers of deaths at each concentration (including controls) were not listed. Oxygen concentrations, alkalinity and pH were not monitored over the course of the study. Purity of the test material is unknown.

13.03.2002 (2)

Type	:	static
Species	:	Carassius auratus (Fish, fresh water)
Exposure period	:	
Unit	:	
Analytical monitoring	:	no
Method	:	other
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Die Testsubstanz fuehrte in einer Konzentration von 100 - 500 ul/l (111 - 555 mg/l) zur Narkose nach 2 - 4 Minuten. 3 bis 6 Minuten nach Expositionsende trat Erholung ein. [The test substance administered in a concentration of 100-500 ul/l (111 – 555 mg/l) lead to narcosis in 2-4 minutes. Recovery occurred 3-6 minutes after the end of exposure].
Source	:	BASF AG Ludwigshafen

EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (98)

Type : static
Species : Lepomis macrochirus (Fish, fresh water)
Exposure period : 24 hour(s)
Unit : mg/l
Analytical monitoring : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : Bei der einzigen untersuchten Konzentration von 5 mg/l wurden "keine Effekte" beobachtet. Keine weiteren Angaben. [No effects were observed at the single investigated concentration of 5 mg/l. No further information]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (5)

Type : static
Species : Leuciscus idus (Fish, fresh water)
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring : yes
NOEC : 100
LC50 : 220 - 460
Method : other: in Anlehnung an DIN 38412, Testverfahren mit Wasserorganismen Gruppe L, Teil L15 [Relying on DIN 38412, test procedures with water organisms]
Year : 1982
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (10)

Type : static
Species : Oncorhynchus kisutch (Fish, fresh water, marine)
Exposure period : 24 hour(s)
Unit : mg/l
Analytical monitoring : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : Bei der einzigen untersuchten Konzentrationvon 10 mg/l keineMortalitaet und keine Toxizitaetszeichen. [No mortality or toxic signs were observed at the single concentration (10 mg/l) tested].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (107)

Type : static
Species : Oncorhynchus mykiss (Fish, fresh water)
Exposure period : 24 hour(s)
Unit : mg/l
Analytical monitoring : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : Bei der einzigen untersuchten Konzentration von 5 mg/l wurden "keine Effekte" beobachtet. Keine weiteren Angaben. [At the single concentration of 5 mg/l studied no effects were observed. No further data].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (5)

Type : static
Species : Oncorhynchus tschawytscha (Fish, fresh water, marine)
Exposure period : 24 hour(s)
Unit : mg/l
Analytical monitoring : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : Bei der einzigen untersuchten Konzentration von 10 mg/l keine Mortalitaet und keine Toxizitaetszeichen. [No mortality or toxic signs were observed at the single concentration (10 mg/l) tested].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (107)

Type : static
Species : Petromyzon marinus
Exposure period : 24 hour(s)
Unit : mg/l
Analytical monitoring : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : Bei der einzigen untersuchten Konzentration von 5 mg/l wurden "keine Effekte" beobachtet. Keine weiteren Angaben. [No “effects” were observed at the single concentration (5 mg/l) tested. No further data].

Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (5)

Type	:	static
Species	:	Pimephales promelas (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no data
LC50	:	478
Method	:	other: following EPA-Guideline EPA/600/4-85/013
Year	:	1985
GLP	:	no data
Test substance	:	other TS
Remark	:	In einem Vorversuch ueber 24 Stunden wurde ein LC50-Wert im Bereich zwischen 100 und 500 mg/l angegeben. [n a preliminary study over 24 hours an LC50 value was seen in the range between 100 and 500 mg/l].
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance	:	2-Phenoxyethanol, technical grade, ca. 75% (verunreinigt mit Diethylenglykolmonophenylether) [contaminated with diethylene glycol monophenyl ether]
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.

13.03.2002 (156) (159)

Type	:	static
Species	:	Pimephales promelas (Fish, fresh water)
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no data
NOEC	:	100
LC50	:	366
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

13.03.2002 (149)

Type	:	static
Species	:	Ptychocheilus oregonensis (Fish, fresh water)
Exposure period	:	24 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
Method	:	other
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Bei der einzigen untersuchten Konzentration von 10 mg/l keine Mortalitaet und keine Toxizitaetszeichen. [No mortality and no toxic signs were

observed at the single concentration of 10 mg/l tested].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (107)

Type : static
Species : Salmo gairdneri (Fish, estuary, fresh water)
Exposure period :
Unit : mg/l
Analytical monitoring : no
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : Jeweils 6 Fische wurden einer Konzentration von 250, 500 bzw. 750 ul/l (ca. 277, 555 bzw. 832 mg/l) ausgesetzt. Ziel der Studie war die Bestimmung des jeweiligen Expositionszeitraumes, nach dem 50% der Fische starben (LT50). Diese Zeiten wurden von den Autoren mit 3.7h, 26.3min bzw. 10.7min bestimmt. [In each case fish were exposed to a concentration of 250, 500 or 750 microlitersl/l (ca. 277, 555, or 832 mg/l). The goal of the study was the determination of the esposure periods at these respective concentrations where 50% of the fish die (LT50). The times determined by the authors were 3.7 hours, 26.3 minutes or 10.7 minutes, respectively].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (6)

Type : other
Species : other:fish (nonspecified)
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring : no
LC50 : 718
Method : other: ECOSAR estimation (v0.99g)
Year : 2004
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : Inputs to the model were the CAS number, a water solubility of 25,000 mg/l, a vapor pressure of 0.004 mm Hg, a boiling point of 246 degrees C and a melting point of 13 degrees C. The class of chemicals was neutral organics.
Reliability : (2) valid with restrictions. Data were obtained by modeling.
21.04.2004 (57)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

Type : static
Species : Daphnia magna (Crustacea)

Exposure period	:	48 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
EC0	:	= 500
EC50	:	> 500
EC100	:	> 500
Method	:	other: Richtlinie 79/831/EWG, C.2
Year	:	1989
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	The data came from an English translation of a German language study. The original IUCLID record has been altered to contain more information.
Result	:	There was no effect of any concentration of test material on swimming ability at any time point. There was no effect of test material on pH or oxygen content. The initial and final pH of the flasks ranged from 7.96 (at 250 mg/l) to 8.01 (at 0, 31.25 and 500 mg/l), and 8.13 (at 500 mg/l) to 8.16 (at 31.25 and 62.5 mg/l), respectively. The initial and final oxygen content ranged from 8.95 (at 250 mg/l) to 9.46 (at 500 mg/l), and 8.33 (at 250 mg/l) to 8.47 mg/l (at 0 and 31.25 mg/l), respectively.
Test condition	:	The test was conducted according to the method procedure C2 of Appendix V of Richtlinie 79/831 EWG. Material was tested at concentrations of 0, 31.25, 62.5, 125, 250 and 500 mg/l (nominal concentration). The test water was deionized water to which the following were added: 144.9 mg/l Cl, 80.1 mg/l Ca, 12.2 mg/l Mg, 48.4 mg/l SO4, 47.1 mg/l HCO3, 19.8 mg/l Na, 3.2 mg/l K, 1.0 mg/l Si, 0.5 mg/l B, 0.2 mg/l Fe, NO3 and PO4, 0.1 mg/l Mn, 0.05 mg/l Li, Rb and Sr, 0.025 mg/l Br and Mo, 0.0125 mg/l Cu and Zn, 0.0025 mg/l Co and I, 0.002 mg/l Se, 0.0003 mg/l V and Na2EDTA x 2H20, 75 micrograms/l thiamin, 1 microgram/l B12 and 0.75 micrograms/l biotin. The hardness, pH, molar ratio of Ca:Mg, Na:K, oxygen content, conductance and temperature of the test water were 2.70 +/- 0.5 mmol/l, 8.0 +/- 0.5, 4:1, 10:1, > 2 mg/l, 600-700 microSiemens/cm, and 292.0 - 294.0 degrees K, respectively. Organisms were fed once daily with cultured green algae. They were kept under a 16 hr light: 8 hr darkness cycle under a light intensity of 5 microeinstein/m*m*s at 400 - 750 nm. The test water was infused and saturated with oxygen (using oil-free air) and then allowed to sit for at least 24 hours. Two to 24 hour-old organisms were used. The test volume was 10 ml. Five organisms were tested per vessel. Four vessels were prepared per concentration. Medium was sampled 0, 3, 6, 24 and 48 hours after the test was initiated. The effect of the test material on swimming ability after tapping the flasks was recorded. The EC0, EC50 and EC100 [the highest concentration causing a < = 10%, and the lowest concentrations causing 50% and 100% loss of swimming ability (respectively) were determined].
Test substance	:	Test material purity was 100 %.
Reliability	:	(2) valid with restrictions. Concentrations were not analytically confirmed
Flag	:	Critical study for SIDS endpoint

15.08.2002 (20)

Type	:	static
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
LC50	:	c = 488
Method	:	other:EPA/ASTM
Year	:	1987
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4

Result	:	Total hardness, alkalinity, pH and conductivity of the test and holding water were 55 mg/l as CaCO3, 36 mg/l as CaCO3, 6.7, and 250 micromhos/cm. The LD50 value and 95% confidence limits were 488(403-591) mg/l.
Test condition	:	Daphnia magna stocks were originally obtained from the EPA laboratory at Duluth, MN. They were maintained at 20-22 degrees C in a series of 600 ml beakers filled with Kanawha River water obtained from the South Side Boat Ramp (Charleston, SC). Daphnia were fed three times a week with a laboratory-prepared food consisting of trout food, yeast and alfalfa powder. Daphnia used in the test were offspring of 20-50 gravid females isolated for 24 hours. A series of from 5-10 equidistant concentrations based on results of fish toxicity studies (plus control) were tested. Tests were conducted in 250 ml beakers containing 100 ml of test solution (in Kanawha River water) and 5 Daphnia (less than 24 hours old). Tests were run in duplicate. Dissolved oxygen and pH were determined initially and at 48 hours for all test solutions (values were not listed). Total hardness, alkalinity, pH and conductivity of the test and holding water were 55 mg/l as CaCO3, 36 mg/l as CaCO3, 6.7, and 250 micromhos/cm. Mortalities were recorded at 24 and 48 hours.
Reliability	:	(2) valid with restrictions. Purity was not listed and concentrations were not analytically confirmed

15.02.2002 (192)

Type	:	static
Species	:	Daphnia magna (Crustacea)
Exposure period	:	48 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
NOEC	:	m = 100
EC50	:	c = 460
EC100	:	m = 750
EC10	:	m = 320
Method	:	other
Year	:	1976
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	The calculated LC10, LC50, and LC90 values (with 95% confidence limits) were 293 (218-349) mg/l, 460 (394-538) mg/l, and 721 (604-977) mg/l. The slope of the curve was 6.56 (4.26-8.85).
Test substance	:	Test substance was DOWANOL EPh. It contained 92% ethylene glycol phenyl ether and 8% diethylene glycol phenyl ether.
Reliability	:	(4) not assignable. Test conditions were not stated.

08.03.2002 (33)

Type	:	
Species	:	other aquatic crustacea: Chaetogammarus marinus
Exposure period	:	96 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
NOEC	:	= 56
LC50	:	= 357
Method	:	other
Year	:	1982
GLP	:	no
Test substance	:	
Remark	:	LC50 = 1606 mg/l/24h LC50 = 914 mg/l/48h LC50 = 563 mg/l/72h

Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test condition	:	10 Tiere pro Liter, pH = 8.0 [10 animals per liter, pH = 8.0] Temperatur: 15 Grad C
Test substance	:	Konzentrationen der Testsubstanz in natuerlichem Seewasser [concentrations of test substance in natural seawater]: 0, 56, 100, 180, 320, 560, 1000 mg/l
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (1)

Type	:	other
Species	:	other:Daphnid (nonspecified)
Exposure period	:	48 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no
LC50	:	723
Method	:	other: ECOSAR estimation (v0.99g)
Year	:	2004
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Inputs to the model were the CAS number, a water solubility of 25,000 mg/l, a vapor pressure of 0.004 mm Hg, a boiling point of 246 degrees C and a melting point of 13 degrees C. The class of chemicals was neutral organics.
Reliability	:	(2) valid with restrictions. Data were obtained by modeling.

21.01.2004 (57)

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

Species	:	Scenedesmus subspicatus (Algae)
Endpoint	:	biomass
Exposure period	:	72 hour(s)
Unit	:	mg/l
Analytical monitoring	:	no data
EC10	:	m > 500
EC50	:	m > 500
EC90	:	m > 500
Method	:	other : algae test relying on UBA
Year	:	1990
GLP	:	no data
Test substance	:	as prescribed by 1.1 – 1.4
Remark	:	The data came from an English translation of a German language study. The original IUCLID record has been altered to contain more information. The pH was not monitored. However, if differences in pH did occur between vessels, they did not have an adverse effect, since none of the concentrations tested were toxic.

Chlorophyll content is a measure of biomass. In a study described by Herman et al. (Aquatic Toxicol 18:87-100, 1990), 4 different ways of measuring biomass were checked for sensitivity (cell number, absorbance, chlorophyll content and dry weight). Measuring cell number was the most sensitive means of assessing algal cell growth, followed by absorbance

and chlorophyll content, which were of equal utility. Since most test methods use absorbance for calculating biomass, and results of tests measuring chlorophyll content and absorbance are similar, tests employing fluorescence to measure chlorophyll content should be as sensitive as those employing absorbance as a means of assessing algal biomass.

Result : None of the concentrations tested had a significant effect on fluorescence.

At time 0, fluorescence values ranged from 96.8% of control for cells treated with 125 mg/l to 101.2 % of control for cells treated with 31.25 mg/l. At 24 hours, values ranged from 98.85 % of control at 31.25 mg/l to 85.18 % of control at 250 mg/l. At 48 hours, values ranged from 103.1% of control at 125 mg/l to 92.39 % of control at 250 mg/l. At 72 hours, values ranged from 105.6% of control at 31.25 mg/l to 91.9 % of control at 500 mg/l. Values for the 4 replicates at each concentration varied by < 10%.

Test condition : A SAG 86.81 culture of Scenedesmus subspicatus (10,000 cells/ml) was maintained in OECD medium at 20 degrees C. Ten ml of cells in suspension were treated with 0 (control), 7.812, 15.625, 31.25, 62.5, 125, 250 or 500 mg/l test material in quadruplicate. Fluorescence of vials containing treated cells was determined 0, 24, 48 and 72 hours after treatment in a fluorimeter with a gain setting of 1. Average fluorescence of 2 blank vials containing test material (at each concentration) and medium without cells was subtracted from values obtained for test vials. The values for the four tests were averaged and a standard deviation was calculated. The average fluorescence value of each concentration was presented as a percentage of control values.

Reliability : (2) valid with restrictions. The purity of the test material was not listed. The pH was not monitored.

Flag : Critical study for SIDS endpoint

31.08.2002 (17)

Type : other
Species : other:green algae
Exposure period : 96 hour(s)
Unit : mg/l
Analytical monitoring : no
EC50 : 429
Method : other: ECOSAR estimation
Year : 2004
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : Inputs to the model were the CAS number, a water solubility of 25,000 mg/l, a vapor pressure of 0.004 mm Hg, a boiling point of 246 degrees C and a melting point of 13 degrees C. The class of chemicals was neutral organics.

Reliability : (2) valid with restrictions. Data were obtained by modeling.

21/01/2004 (57)

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

Type : aquatic
Species : other bacteria: sewer microorganisms
Exposure period : 16 hour(s)
Unit : mg/l
Analytical monitoring : no

IC50 : c = 1650
Method : other:
Year : 1987
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Test condition : Selected concentrations (not listed) were incubated for 16 hours at 23 degrees C on a shaker table in the presence of nutrients, buffer, growth substrate, and sewer microorganisms. Toxicity was indicated when the resulting turbidity was at (or less than) 50% of the control (IC50). Details of the test are published in: Alsop et al., "Bacterial Growth Inhibition Tests", J. Water Pollution Control Federation, Vol 52: No. 10, October, 1980.
Reliability : (2) valid with restrictions. Purity was not listed.
15.02.2002 (192)

Type : aquatic
Species : Photobacterium phosphoreum (Bacteria)
Exposure period : 5 minute(s)
Unit : mg/l
Analytical monitoring : no
EC50 : = 32.7
Method : other: Microtox test
Year : 1982
GLP : no
Test substance :
Remark : Die mittlere effektive Konzentration (EC50) ist die Konzentration, die eine 50%ige Hemmung der Bakterien- Lumineszenz bewirkt. [The mean effective concentration (EC50) is the concentration, for which a 50% inhibition of bacteria luminescence is caused].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (44)

Type : aquatic
Species : Pseudomonas putida (Bacteria)
Exposure period :
Unit : mg/l
Analytical monitoring : no
EC0 : = 1130
Method : other: Zellvermehrungshemmtest [cell reproduction inhibition test]
Year : 1989
GLP : no
Test substance : other TS: Phenylglykol pure
Remark : Beginnende Hemmwirkung bei 1130 mg/l [inhibition starts at 1130 mg/l]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (14)

Type : aquatic
Species : Pseudomonas putida (Bacteria)
Exposure period : 17 hour(s)
Unit : mg/l

Analytical monitoring	:	
EC10	:	= 320
EC50	:	= 880
EC90	:	= 2100
TGK	:	= 320
Method	:	other: Zellvermehrungshemmtest nach Bringmann/Kühn [cell reproduction inhibition test following the method of Bringmann/Kuehn] , DIN 38412/8 Entwurf [draft] 1986
Year	:	1989
GLP	:	no
Test substance	:	as prescribed by 1.1 – 1.4
Test substance	:	Purity was 100%
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.

13.03.2002 (26)

Type	:	aquatic
Species	:	other bacteria: BASF-Belebtschlamm [activated sludge]
Exposure period	:	30 minute(s)
Unit	:	mg/l
Analytical monitoring	:	
Method	:	other: Kurzzeitatmungstest [short-term respiration test]
Year	:	1981
GLP	:	no
Test substance	:	other TS: Monophenylglykol technical grade
Remark	:	Die Substanz wirkt atmungsfoerdernd. EC20/50/80 (ca.-Werte) = 5/28/80 mg/l [The substance affects respiration. EC20/50/80 (ca.- value) = 5/28/80 mg/l]
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (24)(25)

Type	:	other: Boden, Schlamm [soil, sediment]
Species	:	aerobic microorganisms
Exposure period	:	
Unit	:	
Analytical monitoring	:	
Remark	:	Harada and Nagashima isolated four strains of bacteria: Alcaligenes MC11 and TE8 from soil, Alcaligenes PE18 from active sludge and Cyanobacterium OEH8 from soil. No growth of any of the strains was observed with 2-Phenoxyethanol as sole source of carbon.
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

13.03.2002 (78)

Type	:	soil
Species	:	aerobic microorganisms

Exposure period	:	
Unit	:	
Analytical monitoring	:	
Remark	:	No growth of soil bacterium was observed on 2-Phenoxyethanol.
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

13.03.2002 (61)

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO OTHER NON-MAMM. TERRESTRIAL SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Species	:	rat
Strain	:	Sprague-Dawley
Sex	:	male/female
Number of animals	:	40
Vehicle	:	corn oil
Value	:	
Method	:	other
Year	:	1988
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Symptoms of toxicity were not listed. Animals do not appear to have been fasted before dosing.
Result	:	None of the animals dosed with 625 mg/kg bw died. One female dosed with 1250 mg/kg bw died on day 5, and one male dosed dwith 2500 mg/kg bw died on day 3. All males and 4/5 females dosed with 5000 mg/kg bw died by day 2. The remaining female in this group survived to day 14. The LD50 value (moving average method) was 2937 and 4013 mg/kg bw for males and females, respectively.
Test condition	:	Groups of 8-11 week old rats (5/sex/dose) were treated by gavage with 625, 1250, 2500 and 5000 mg/kg bw test material in corn oil vehicle, and survival was monitored for 14 days.
Test substance	:	Purity of the test material was 99.83%.
Reliability	:	(1) valid without restriction. GLP study.
Flag	:	Critical study for SIDS endpoint

13.03.2002 (69) (157)

Type	:	LD50
Species	:	rat
Strain	:	Sprague-Dawley
Sex	:	male/female
Number of animals	:	50
Vehicle	:	
Value	:	
Method	:	other
Year	:	1980
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Based on a density of 1.1 g/ml, the LD50 values in males and females are 1386 and 2563 mg/kg bw, respectively.
Result	:	All of the rats in the lowest dose group survived. One male rat in the 1.00 ml/kg bw group died 4.5 hrs after intubation. None of the males treated with 2.15 ml/kg bw survived beyond day 1, and 3/5 females dosed with 2.15 ml/kg bw survived. None of the males in the two high dose groups survived beyond 4.5 hours. None of the females in the 4.64 ml/kg group survived beyond 5 hr, and none of the females in the 10.0 ml/kg group survived beyond 1 hour. All of the survivors gained weight. The LD50 values in males and females were 1.26 and 2.33 ml/kg, respectively. Signs noted in treated animals included slight to severe reduction of activity, decreases reflexes and labored respiration. Rats treated with high doses appeared comatose before death or recovery (3 rats that were treated with 2.15 ml/kg). No lesions were found in survivors.
Test condition	:	Undiluted phenoxyethanol (cosmetic grade, minimum 92% phenoxyethanol, maximum 8% diethylene glycol monophenyl ether) was administered by intubation at 0.464, 1.00, 2.15, 4.64 and 10.0 ml/kg to five

groups of ten rats (5/sex/group). The rats were fasted for 18 hr prior to dosing, and were allowed food and water ad libitum following dosing. The rats were observed for toxicity at least twice daily for 14 days. The rats were weighed on the day of intubation and on days 7 and 14 (before termination). Necropsies were performed on all rats. All major organs were examined.

Reliability : (2) valid with restrictions. Exact purity of test material is unknown, but is >=92%.

Flag : Critical study for SIDS endpoint

11.03.2002 (60) (88)

Type : LD50
Species : rat
Strain : Wistar
Sex : male
Number of animals :
Vehicle :
Value : = 1260 mg/kg bw
Method : other
Year : 1941
GLP : No
Test substance : as prescribed by 1.1 - 1.4
Result : The LD50 value and 95% confidence limits were 1.26 (1.12-1.42) g/kg bw. The slope of the dose-mortality curve was 11.84.
Test condition : Test material was administered by stomach tube to groups of 10 rats (90-120 g) per dose. Test material was made up at a 2% concentration in water. The volumes of individual doses were not given. Doses that were given included those that produced no death and those that were 100% lethal. Rodent chow and water were freely available. Animals were observed over a period of 14 days for mortality.

Mortality data were analyzed using the method of probits. LD50 values, the range of 95% probability of the LD50 value, and the slope of the dose-mortality line when plotted by the probit method were calculated.

Reliability : (2) valid with restrictions. Purity of the test material is unknown.

11.03.2002 (139)

Type : LD50
Species : Rat
Strain :
Sex : male/female
Number of animals :
Vehicle :
Value : = 1345 mg/kg bw
Method : other
Year : 1981
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Result : The LD50 values (with confidence limits) for male and female rats were 1345 (958-1889) and 1902 (1354-2672) mg/kg bw, respectively. Clinical signs of toxicity were slight to severe weakness, unkempt hair coat, ataxia, vasoldilation, prostration and death.
Test condition : Test conditions were not listed.
Test substance : Test material was Dowanol(R) EPH solvent. The melting and boiling points were 14 and 245 degrees C, respectively.
Reliability : (4) not assignable. Insufficient information for assessment. Purity of the test material is unknown.

11.03.2002 (100) (147) (170) (175)

Type : LD50

Species	:	rat
Strain	:	
Sex	:	male/female
Number of animals	:	50
Vehicle	:	
Value	:	= 1.3 ml/kg bw
Method	:	other
Year	:	1970
GLP	:	
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Based on a density of 1.1 g/ml, the LD50 value is 1430 mg/kg bw.
Result	:	Lethargy, ataxia, hyperpnea and coma were noted. Death occurred within 24 hours of dosing. The LD50 value (and 95% confidence limits) were calculated to be 1.30(1.16 to 1.46) ml/kg.
Test condition	:	Groups of 10 rats (5/sex) were given 1.0, 1.2, 3.2, 5 and 10 ml/kg bw test material in an acute-range-finding study.
Test substance	:	The test material was PHENOXYTOL. Purity was not confirmed but is listed by the manufacturer to be > 99%.
Reliability	:	(2) valid with restrictions. The individual number of deaths at each dose and the purity of the test material were not given.

11.03.2002 (45) (119)

Type	:	LD50
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Value	:	5550 mg/kg bw
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Originalangabe [original result]: LD50 = 5000 ul/kg; 7 Tage Nachbeobachtung. [7 day post observation period]
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (11)

Type	:	LD50
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Value	:	2740 mg/kg bw
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	other TS
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance	:	2-Phenoxyethanol, technisch (ca. 80% 2-Phenoxyethanol, ca. 18% Monophenyldiglykol, ca. 0.5% Monophenyltriglykol)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-

2000.
13.03.2002 (8)

Type : LD50
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Value : 3400 mg/kg bw
Method : other: no data
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
13.03.2002 (74)

Type : LD50
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Value : 1400 - 1900 mg/kg bw
Method : other: no data
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : LD50 (male): 1400 mg/kg;
LD50 (female) : 1900 mg/kg.

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
13.03.2002 (81)

Type : LD50
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Value : 1400 - 2580 mg/kg bw
Method : other: IRLG Guidelines for Selected Acute Toxicity Tests
Year : 1979
GLP : no data
Test substance : other TS
Remark : LD50 (male): 1260 ul/kg;
LD50 (female) : 2330 ul/kg.

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol, "Cosmetic grade"; ca. 92%

2-Phenoxyethanol, ca. 8% Diethylenglykolmonophenylether

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. The material is listed as "other TS" in that document, but fits the definition of "as prescribed by 1.1 – 1.4" in the current document.

13.03.2002 (84) (162) (163)

Type : LD50
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Value : 1440 mg/kg bw
Method : other: no data
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : Originalangabe [original data]: LD50 = 1300 ul/kg

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

13.03.2002 (45)

Type : LD50
Species : rat
Strain : other: albino
Sex : female
Number of animals :
Vehicle : other: corn oil
Value : 3100 mg/kg bw
Method : other
Year : 1955
GLP : no
Test substance : other TS
Remark :

Two groups of 5 female rats (93 – 110 g) were fed a mixture of = 2-phenoxyethanol and phenyl carbitol in 10% corn oil at 2.00 or 3.98 g/kg by stomach tube and observed for 14 days. Four out of the 5 high dose animals died within 1 day of treatment. All others survived. The LD50 value was 3.08 (2.5 – 3.8) g/kg.

Test substance : Author's statement, a mixture of "Phenyl Cellosolve" = 2-phenoxyethanol and phenyl carbitol

Reliability : (4) not assignable. Insufficient information for assessment. Purity of the material is unknown.

13.03.2002 (173)

Type : LD50
Species : rat
Strain :
Sex : female
Number of animals :
Vehicle :
Value : 2000 - 3000 mg/kg bw
Method : other
Year :
GLP : no

Test substance : as prescribed by 1.1 - 1.4
Remark :

The only information given was the LD50 range.
Test substance : "Phenyl-Cellosolve" = 2-Phenoxyethanol
Reliability : (4) not assignable. Insufficient information for assessment. Purity of the test material is unknown.

13.03.2002 (173)

Type : LD50
Species : rat
Strain :
Sex : male
Number of animals : 40
Vehicle : other: 1% Tergitol
Value : 2580 mg/kg bw
Method : other
Year : 1949
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : All animals in the 3.98 and 3.16 g/kg groups died within a few hours of dosing. Four animals in the 2.2 g/kg group died (also on the first day of dosing). None of the animals in the 2.0 g/kg group died. The LD50 value was 2.58 (2.39 – 2.77 g/kg). Prostration and narcosis were noted before death.
Test condition : Ten rats per group (weight range 90-114 g) were dosed with 2, 2.52, 3.16 or 3.98 g/kg test material orally as a 20% dispersion in 1% Tergitol and observed for 14 days. Animals were not fasted before dosing.
Test substance : The material was production grade phenyl Cellosolve
Reliability : (2) valid with restrictions. Purity of the material is unknown.
13.03.2002 (172)

Type : LD50
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Value : 2580 mg/kg bw
Method : other: no data
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : Originalangabe: LD50 = 2330 ul/kg; maennliche Tiere. [Original information: LD50 = 2330 microliters/kg; male animals]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
13.03.2002 (161)

Type : LD50
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Value : 2000 mg/kg bw

Method : other: no data
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
13.03.2002 (112)

Type : LD50
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Value : ca. 7500 mg/kg bw
Method : other
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : maennliche Tiere [male animals]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
13.03.2002 (180)

Type : LD50
Species : rat
Strain :
Sex : female
Number of animals :
Vehicle :
Value : 2728 mg/kg bw
Method : other
Year : 1968
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark :
Fasted female rats were given undiluted test material by the oral route. The LD50 value was 2.46 (1.79 – 3.39) ml/kg. Based on a density of 1.109, the value in mg/kg is 2728.
Reliability : (4) not assignable. Insufficient information for assessment. Purity of the material is unknown.
13.03.2002 (174)

Type : other
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Method : other: no data
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4

Remark : Keine Toxizitaetsanzeichen bei 50 mg/kg. Bei 1400 mg/kg keine Mortalitaet (Ueberlebensrate 100%); 100% Letalitaet bei 3000 mg/kg.
[No signs of toxicity at 50 mg/kg. At 1400 mg/kg no mortality (survival rate 100%); 100% lethality at 3000 mg/kg].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (176) (179)

Type : other: Maximum Tolerated Dose (MTD)
Species : mouse
Strain : CD-1
Sex : male/female
Number of animals : 34
Vehicle : 1% methylcellulose
Method : other
Year : 1982
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Remark : No explanation was given as to why the material was more toxic in the first study than the second study.

Results :

The numbers of deaths in each group were as follows:

Study	Dose (mg/kg bw)	No. animals (M/F)	mortality
1	500	2/2	0/4
2	600	0/5	0/5
2	750	0/5	0/5
2	900	5/5	0/10
1	1000	2/2	1/4 (1 female)
1	1500	2/2	3/4 (1 male, 2 females)
1,2	2000	2/2, 5/0	4/4 (first study), 0/5 (second study)
1	2500	2/2	4/4
1	3000	2/2	1/4 (1 female)
2	4000	5/0	5/5

Most of the deaths occurred within 8 hours of dosing. Symptoms of toxicity in animals dosed with concentrations > = 2000 mg/kg bw in the first study were lethargy, ataxia and body tremors, which occurred within 6-8 hours of dosing. Mice in the 1000 and 15000 mg/kg bw groups were also lethargic. In the second study, the only animals that died were those that had been given 4000 mg/kg/bw. Lethargy and ataxia were noted in second study with mice given 2000 mg/kg bw. These symptoms resolved within 2.5 hours. Postmortem examinations of all dead mice revealed no abnormalities.

Test condition : Groups of 2 mice/sex (18-21 g bw) were administered a total of 500, 1000, 1500, 2000, 2500 or 3000 mg/kg bw phenoxyethanol in 1% methylcellulose by gavage, in two equal doses (at a volume of 0.1 ml/10g bw), 24 hours apart. An additional study was performed as follows: five females received a total dose of 600 mg/kg bw; another five females received a total dose of 750 mg/kg bw; 5 animals per sex received a total dose of 900 mg/kg bw, 5 males received a total dose of 2000 mg/kg bw and another group of 5 males received a total dose of 4000 mg/kg bw. M ice were fasted overnight before dosing. They were observed for any signs of toxicity or adverse reactions 24 hours after the last dose.

Conclusion : The MTD is 900 mg/kg bw. The LD50 value in the first study was > 1000 and < 1500 mg/kg bw and in the second study was > 2000 and < 4000

mg/kg bw.

Reliability : (2) valid with restrictions. Purity was not confirmed but is listed as > 99.0% by the manufacturer.

13.03.2002 (92) (128)

Type	:	LD50
Species	:	rat
Strain	:	other: CF Nelson
Sex	:	male
Number of animals	:	20
Vehicle	:	
Value	:	2563 mg/kg bw
Method	:	other
Year	:	1966
GLP	:	No
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	The LD50 value calculated above was different than that reported in the IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000 (1200-2300 mg/kg bw) for the same reference.
Result	:	The numbers of animals that died were 0/5, 1/5, 2/5 and 5/5 in the 0.625, 1.25, 2.5 and 5.0 ml/kg groups. All deaths occurred within 24 hours of treatment. The LD50 value was 2.33 (1.51 – 3.61) ml/kg. Based on a density of 1.109, the LD50 value in mg/kg is 2584. All survivors gained weight. Salivation, weakness and depression were noted within 6 hours of treatment.
Test condition	:	Twenty male abino rats were divided into 4 groups of 5, fasted for 24 hours, and treated orally with 0.625, 1.25, 2.5 or 5.0 ml/kg test material. They were monitored for 14 days. The average initial weights of animals in these groups were 106, 106, 115 and 106 g, respectively.
Reliability	:	(2) valid with restrictions. Purity of the test material was not listed.

13.03.2002 (4) (161) (51)

5.1.2 ACUTE INHALATION TOXICITY

Type	:	other: IRT
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Exposure time	:	8 hour(s)
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Keine Mortalitaet nach 8 Stunden Exposition in einer bei 20 Grad C gesaettigten bzw. angereicherten Atmosphaere. [No mortality after 8 hours exposure at 20 degrees C in a saturated or enriched atmosphere]
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (11)

Type	:	other: IRT
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Exposure time	:	8 hour(s)
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Keine Mortalitaet nach 8 Stunden Exposition in einer gesaettigten bzw. angereicherten Atmosphaere. [No mortality after 8 hours in a saturated or enriched atmosphere].
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (3) (188)

Type	:	other: IRT
Species	:	rat
Strain	:	
Sex	:	male
Number of animals	:	6
Vehicle	:	
Exposure time	:	8 hour(s)
Method	:	other
Year	:	1955
GLP	:	no
Test substance	:	other TS
Remark	:	No mortality after 8 hours exposure in a saturated or enriched atmosphere at room temperature.
Test substance	:	A mixture of 2-Phenoxyethanol and "Phenyl-Carbitol" "Phenyl-Carbitol"
Reliability	:	(4) not assignable. The test was done on a mixture containing 2-phenoxyethanol at an unlisted concentration.

13.03.2002 (173)

Type	:	other: IRT
Species	:	rat
Strain	:	Other: albino
Sex	:	male
Number of animals	:	6
Vehicle	:	
Exposure time	:	8 hour(s)
Method	:	other
Year	:	1949
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Six male albino rats (112 – 132 g) were exposed for 8 hours to substantially saturated vapor produced at room temperature with no untoward results. All animals survived the 14 day observation period and gained weight normally.
Test substance	:	"Phenyl-Cellosolve" = 2-Phenoxyethanol
Reliability	:	(2) valid with restrictions. Purity of the material was not listed.

13.03.2002 (172)

Type	:	other: IRT
Species	:	rat
Strain	:	other: albino
Sex	:	male
Number of animals	:	6
Vehicle	:	
Exposure time	:	7 hour(s)
Method	:	other
Year	:	1966
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Six male rats (avg. weight 166 g) were exposed to air near-saturated with vapor of the test material for 7.0 hours at 25 degrees C and observed for 14 days. Average terminal weight was 264 g. No deaths or signs of intoxication were observed.
Reliability	:	(2) valid with restrictions. Concentration of material in vapor was not determined and purity of the material was not listed.

13.03.2002 (4) (161)

Type	:	other: IRT
Species	:	quail
Strain	:	other: Coturnix
Sex	:	male
Number of animals	:	6
Vehicle	:	
Exposure time	:	7 hour(s)
Method	:	other
Year	:	1966
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Six male quail (avg. weight 110 g) were exposed to air near-saturated with vapor of the test material for 7.0 hours at 25 degrees C and observed for 14 days. Average terminal weight was 117 g. No deaths or signs of intoxication were observed.
Reliability	:	(2) valid with restrictions. Concentration of material in vapor was not determined and purity of the material was not listed.

13.03.2002 (4) (161)

5.1.3 ACUTE DERMAL TOXICITY

Type	:	LD50
Species	:	rat
Strain	:	other:CFY
Sex	:	male/female
Number of animals	:	
Vehicle	:	
Value	:	= 13 ml/kg bw (14.3 g/kg)
Method	:	other
Year	:	1970
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	The LD50 value is 14.3 g/kg bw, based on a density of 1.1 g/ml. Skin reactions were not described. It is not known if survivors were observed for 14 days after treatment. Doses that caused hemorrhagic lungs were not listed. It is not known if hemorrhagic lungs occurred only in animals that died or also occurred in some survivors.
Result	:	Death occurred 21-48 hours after dosing. Hemorrhagic lungs were found at necropsy. The LD50 value (and 95% confidence limits) was calculated to

be 13.0 (10.3 to 15.4) ml/kg bw.

Test condition : Five rats per dose were tested. Doses ranged from 1-22.2 ml/kg bw. The test material was applied to the dorsolumbar region under an occlusive patch, so that 10% of the body surface was covered. Test material remained in contact with the skin for 24 hours.

Test substance : The test material was PHENOXYTOL. Purity was not confirmed but is listed by the manufacturer to be > 99%.

Reliability : (2) valid with restrictions. Purity was not confirmed. Numbers of deaths at each dose were not given.

11.03.2002 (46) (119)

Type : LD50
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Value : 14422 mg/kg bw
Method : other: 24h, okklusiv
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : Originalangabe: LD50 = 13000 ul/kg [Original result LD50 = 13,000 microliters/kg]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

13.03.2002 (45) (118) (133)

Type : LD50
Species : rat
Strain :
Sex :
Number of animals :
Vehicle :
Value : 2300 - 3800 mg/kg bw
Method : other: no data
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

13.03.2002 (3) (188)

Type : LD50
Species : rabbit
Strain :
Sex :
Number of animals :
Vehicle :
Value : 5000 mg/kg bw
Method : other: no data

Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
13.03.2002 (134)

Type : LD50
Species : rabbit
Strain :
Sex :
Number of animals :
Vehicle :
Value : > 2218 mg/kg bw
Method : other: 24h, intakte und skarifizierte Haut [Intact and scarified skin]; nach IRLG Guidelines for Selected Acute Toxicity Tests
Year : 1979
GLP : no data
Test substance : other TS
Remark : Originalangabe: 2000 ul/kg. Keine Mortalitaet; 14 Tage Nachbeobachtung. [Original findings: 2000 microliters/kg. No mortality; 14 days postobservation]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol, "Cosmetical grade" (ca. 92% 2-Phenoxyethanol, ca. 8% Diethylenglykolmonophenylether)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.
13.03.2002 (84) (162) (163)

Type : LD50
Species : rabbit
Strain : New Zealand white
Sex : male
Number of animals : 16
Vehicle :
Value : 5545 mg/kg bw
Method : other
Year : 1955
GLP : no
Test substance : other TS
Remark :
LD50 = 5000 ul/kg. Based on a density of 1.109, the LD50 value in mg/kg is 5545 mg/kg.
Test substance : According to the author, a mixture of “Phenyl Cellosolve” = 2-phenoxyethanol and “phenyl-carbitol”
Reliability : (4) not assignable. The test was done on a mixture containing 2-phenoxyethanol at an unlisted concentration.
13.03.2002 (173)

Type : LD50
Species : rabbit
Strain :
Sex : male
Number of animals :

Vehicle :
Value : 3660 mg/kg bw
Method : other
Year : 1955
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : The only information given was the LD50 value (3300 microliters/kg). Based on a density of 1.109, the LD50 value in mg/kg is 3660 mg/kg.
Test substance : "Phenyl-Cellosolve" = 2-Phenoxyethanol
Reliability : (4) not assignable. Insufficient information for assessment. Purity of the material is unknown.

13.03.2002 (173)

Type : LD50
Species : rabbit
Strain : other: albino
Sex : male
Number of animals : 40
Vehicle :
Value : 3815 mg/kg bw
Method : other
Year : 1949
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : All animals exposed to 5.0 ml/kg and 6 animals exposed to 3.98 ml/kg died within 4 days. Five animals exposed to 3.16 ml/kg died within 1-2 days (with the exception of one that died within 13 days). One animal exposed to 2.52 ml/kg died within 3 days. The LD50 value was 3.44 (2.99 – 3.92) ml/kg. Skin erythema, pale livers, pale and swollen livers and bloody urine were symptoms of toxicity.
Test condition : Groups of 10 male albino rabbits (2100- 3400 g) were exposed to 2.52, 3.16, 3.98 or 5.0 ml/kg test material under a Vinylite dam and observed for 14 days.
Test substance : "Phenyl-Cellosolve" = 2-Phenoxyethanol
Reliability : (2) valid with restrictions. Purity of the test material was not noted.
13.03.2002 (172)

Type : LD50
Species : rabbit
Strain : other: albino
Sex : male
Number of animals : 15
Vehicle :
Value : 2251 mg/kg bw
Method : other
Year : 1966
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Remark : A mortality rate of 0/5 at a dose of 0.625 ml/kg was assumed when calculating the LD50 value.
Result : Four out of 5 rabbits dosed with 2.5 ml/kg and all rats dosed with 5.0 ml/kg died within 5 days. All rabbits dosed with 1.25 ml/kg survived over 14 days. Symptoms of toxicity were diarrhea, depression and eschar formation. Final average body weights of the survivors were 3.01 kg for the 1.25 ml/kg group and 3.06 kg for the 2.5 ml/kg group. The LD50 value was 2.03 (1.54 – 2.68) ml/kg. Based on a density of 1.109, the LD50 value in mg/kg is 2251.
Test condition : Three groups of 5 male rabbits were exposed to 1.25, 2.5 or 5.0 ml/kg test

material dermally. The material was held in continuous, 24-hour contact with the shaved skin. Initial weights of rabbits in each respective group were 3.09, 3.21 or 3.24 kg.

Reliability : (2) valid with restrictions. Purity of the test material was not listed.

13.03.2002 (4) (161)

Type	:	LD50
Species	:	rabbit
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Value	:	> 5000 mg/kg bw
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

13.03.2002 (112)

Type	:	LD50
Species	:	guinea pig
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Value	:	> 20 ml/kg bw
Method	:	other
Year	:	1981
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Not enough details are present in study documentation to make a reliability rating.
Test substance	:	Test material was Dowanol(R) EPH solvent. The melting and boiling points were 14 and 245 degrees C, respectively.
Reliability	:	(4) not assignable. Purity of the material is unknown.

(100)

Type	:	LD50
Species	:	guinea pig
Strain	:	
Sex	:	
Number of animals	:	5
Vehicle	:	
Value	:	> 22180 mg/kg bw
Method	:	other: no data
Year	:	1981
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Five animals were treated with 20 ml/kg test material dermally. The test site was kept open. None of the animals died. Slight erythema was noted initially in all animals. Based on a density of 1.109, the LD50 value in mg/kg is 22180.
Reliability	:	(4) not assignable. Insufficient information for assessment. Purity of the material is unknown.

13.03.2002 (147) (175)

5.1.4 ACUTE TOXICITY, OTHER ROUTES

Type	:	LD50
Species	:	mouse
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Route of admin.	:	i.p.
Exposure time	:	
Value	:	ca. 333 mg/kg bw
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Originalangabe: LD50 ca. 300 ul/kg; 7 Tage Nachbeobachtung. Es traten Spaettodesfaelle auf. [Original finding: LD50 ca. 300 microliters/kg; 7 days post-observation. Delayed mortality occurred]
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (11)

Type	:	LD50
Species	:	mouse
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Route of admin.	:	i.p.
Exposure time	:	
Value	:	872 mg/kg bw
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Originalangabe: LD50 = 6.32 mmol/kg. Die Tiere wurden 24h vor der Substanzapplikation intraperitoneal mit Olivenoel vorbehandelt. Vorbehandlung mit Tetrachlorkohlenstoff (2000 mg/kg i.p.) fuehrte zu einer Absenkung der LD50 auf 736 mg/kg (5.33 mmol/kg). [Original finding: LD50 = 6.32 mmol/kg. The animals were prepared intraperitoneally with olive oil 24 hours before the substance application. Prior preparation with carbon tetrachloride (2000 mg/kg i.p.) led to a lowering of the LD50 to 736 mg/kg (5.33 mmol/kg]
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

13.03.2002 (142)

5.2.1 SKIN IRRITATION

Species	:	human
Concentration	:	10 %
Exposure	:	
Exposure time	:	24 hour(s)
Number of animals	:	51:
PDII	:	
Result	:	not irritating
EC classification	:	
Method	:	other: repeated insult patch-test, 24hr, 3 Weeks (3 days/week)
Year	:	1984
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Two panelists had reaction scores of 1 (reaction visible but mild), one after induction 3 and another after induction 5 (reactions were noted before application of patches 4 and 6). In both cases, the reaction cleared by the application of the next patch.
Test condition	:	Phenoxyethanol (10% v/v in mineral oil) was tested for irritation and sensitization in a repeated insult patch test using a panel of 51 subjects (male and female), aged 16- >60. Test material (0.3 ml) was applied to a patch that was then applied to the skin of the upper arm of the panelist. The patches were applied every Monday, Wednesday and Friday for 23 weeks. The patches were removed 24 hr after application and the sites were scored before application of the next patch (or 72 hours after removal of the last patch).
Reliability	:	(2) valid with restrictions. Data came from a CIR Final report on the safety of phenoxyethanol published in J. Am. Coll. Toxicol. 9 (2): 259-277 (1990). Purity of the material is unknown.
11.03.2002	:	(87)

Species	:	Human
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	not irritating
EC classification	:	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Remark	:	Of 2736 patients patch-tested with 1% phenoxyethanol in petrolatum, none had signs of irritant or allergic reactions 2 and 4 days after application. Patch testing of 130 patients with 1, 5, and 10% phenoxyethanol in petrolatum resulted in no irritant or allergic reactions.
Test substance	:	1, 5, and 10% phenoxyethanol in petrolatum
Reliability	:	(2) valid with restrictions. Data came from a CIR Final report on the safety of phenoxyethanol published in J. Am. Coll. Toxicol. 9 (2): 259-277 (1990). Purity of the material is unknown.
15.02.2002		(102)

Species	:	human
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	

Result	:	not irritating
EC classification	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

15.02.2002 (123)

Species	:	human
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	not irritating
EC classification	:	
Method	:	other: 48h, closed patch test
Year	:	
GLP	:	no
Test substance	:	other TS: 2-Phenoxyethanol, 10% in Petrolatum
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

15.02.2002 (59)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	6
PDII	:	
Result	:	slightly irritating
EC classification	:	
Method	:	other
Year	:	1970
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Slight transient erythema was observed in 2 of the rabbits given 10% and 1 given 2% at the 24 hour reading.
Test condition	:	A single occlusive patch of 2 or 10% test material in acetone/water (10/90) was applied to the clipped and intact of abraded skin on the flanks of the rabbits. The patches remained in place for 24 hours, and the sites were examined upon patch removal and at 72 hours.
Reliability	:	(2) valid with restrictionsData came from a CIR Final report on the safety of phenoxyethanol published in J. Am. Coll. Toxicol. 9 (2): 259-277 (1990). Purity of the material is unknown.

15.02.2002 (93)

Species	:	rabbit
Concentration	:	
Exposure	:	

Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	not irritating
EC classification	:	
Method	:	other: intakte Haut [intact skin]
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

13.03.2002 (52)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	not irritating
EC classification	:	
Method	:	other: BASF-Test
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

15.02.2002 (11)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	not irritating
EC classification	:	not irritating
Method	:	OECD Guide-line 404 "Acute Dermal Irritation/Corrosion"
Year	:	1981
GLP	:	no
Test substance	:	other TS
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance	:	2-Phenoxyethanol, technical grade
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

15.02.2002 (9)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	

PDII	:	
Result	:	
EC classification	:	
Method	:	other
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	500 mg unverduennt und offen appliziert fuehrten laut Angabe der Autoren zu leichten Reizungen. Ebenfalls 500mg unter nicht naeher beschriebenen Applikationsbedingungen fuehrten zu maessiger Reizung. 2- bzw. 10%-ige Loesungen (keine weiteren Angaben) fuehrten zu leichten Reizerscheinungen. [500 mg undiluted and open applied led according to the authors to a slight irritation. Even so 500 mg exposure in which the application details were not described led to massive irritation. 2- or 10% solution (no further details) lead to slight signs of irritation].
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.
15.02.2002		(109) (118) (189)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	not irritating
EC classification	:	
Method	:	other: skarifizierte Haut [scarified skin], 24h
Year	:	
GLP	:	no data
Test substance	:	other TS
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance	:	2-Phenoxyethanol, "Cosmetical Grade" (ca. 92% 2-Phenoxyethanol, ca. 8% Diethylenglykolmonophenylether)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.
15.02.2002		(84)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	not irritating
EC classification	:	
Method	:	other
Year	:	1955
GLP	:	no
Test substance	:	other TS
Test substance	:	According to the author a mixture of “Phenyl Cellosolve” = 2-phenoxyethanol and “phenyl-carbitol”
Reliability	:	(4) not assignable. The test was done on a mixture containing 2-phenoxyethanol at an unlisted concentration.

15.02.2002 (173)

Species	:	rabbit
Concentration	:	undiluted
Exposure	:	
Exposure time	:	
Number of animals	:	5
PDII	:	
Result	:	slightly irritating
EC classification	:	
Method	:	other: rabbit belly vesicant test
Year	:	1949
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Marked capillary injection of moderate erythema was noted in 3/5 rabbbits which received 0.01 ml undiluted material in the rabbit belly vesicant test. A grade of 3/10 was assigned..
Test substance	:	"Phenyl-Cellosolve" = 2-Phenoxyethanol
Reliability	:	(4) not assignable. Insufficient information for assessment. Purity of the material is unknown.

15.02.2002 (172)

Species	:	rabbit
Concentration	:	undiluted
Exposure	:	occlusive
Exposure time	:	24 hours
Number of animals	:	6
PDII	:	
Result	:	not irritating
EC classification	:	
Method	:	other
Year	:	1966
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Irritation scores of 0 were observed at 24 and 72 hours at all intact and abraded sites (with the exception of a score of 1 at one abraded site at 24 hours in one animal). The primary irritation score was 0.04.
Test condition	:	Test material (0.5 ml) was held in continous 24-hour contact with the skin of 6 rabbits under an impervious patch. Skin was abraded at one site. Irritation was observed 24 and 72 hours after removal of the patch. The scoring system used was that of Draize et al (J Pharm Exper. Ther 82: 377, 1944). The primary irritation score was the sum of the mean values divided by 4.
Reliability	:	(2) valid with restrictions. Purity of the material was not listed.

15.02.2002 (4) (161)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	
EC classification	:	
Method	:	other: 24h, intakte und skarifizierte Haut, okklusiv [intact and scarified skin, occlusive]
Year	:	
GLP	:	no

Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Laut Angabe der Autoren maessige Reizung; keine naehere Informationen zum Grad der Reizung bei den verschiedenen Applikationsbedingungen. [According to author's findings massive irritation; no further information about the degree of irritation with varying application conditions]
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material was not listed.

15.02.2002 (112)

Species	:	rabbit
Concentration	:	
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	not irritating
EC classification	:	
Method	:	other
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material was not listed.

15.02.2002 (178)

Species	:	rabbit
Concentration	:	2 %
Exposure	:	
Exposure time	:	
Number of animals	:	
PDII	:	
Result	:	slightly irritating
EC classification	:	
Method	:	
Year	:	
GLP	:	
Test substance	:	
Remark	:	PHENOXETOL (2% and 10%) was slightly irritating to rabbit skin
Test substance	:	Purity of the test material is listed by the manufacturer to be > 99%.
Reliability	:	(4) not assignable. There are not enough details in the documentation to assign a reliability rating.

11.03.2002 (119)

Species	:	guinea pig
Concentration	:	
Exposure	:	occlusive
Exposure time	:	24 hour(s)
Number of animals	:	3
PDII	:	
Result	:	slightly irritating
EC classification	:	
Method	:	other

Year : 1981
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Result : Slight irritation was found in all animals.
Test condition : Material (volume not stated) was applied to the depilated abdomen of 3 guinea pigs (sex and weight were not stated) under an occlusive wrap for 24 hours. The grading scale was not listed.
Test substance : Test material was Dowanol(R) EPH solvent. The melting and boiling points were 14 and 245 degrees C, respectively.
Reliability : (4) not assignable. Not enough details are present in study documentation to make a reliability rating. Purity of the material is unknown.

15.02.2002 (100)

Species : guinea pig
Concentration :
Exposure : open
Exposure time : 10 day
Number of animals : 5
PDII :
Result : slightly irritating
EC classification :
Method : other
Year : 1981
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Result : Slight erythema occurred in all animals initially. The response was not aggravated by repeated exposure.
Test condition : Test material (volume not stated) was applied once daily for 10 days to the uncovered, clipped backs of 5 guinea pigs.
Test substance : Test material was Dowanol(R) EPH solvent. The melting and boiling points were 14 and 245 degrees C, respectively.
Reliability : (4) not assignable. Not enough details are present in study documentation to make a reliability rating. Purity of the material is unknown.

15.02.2002 (100)

Species : guinea pig
Concentration :
Exposure :
Exposure time :
Number of animals :
PDII :
Result : slightly irritating
EC classification :
Method : other: no data
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

15.02.2002 (147) (170) (175)

Species : guinea pig
Concentration :
Exposure :
Exposure time :

Number of animals	:	
PDII	:	
Result	:	not irritating
EC classification	:	
Method	:	other: intakte Haut [intact skin], 24 or 48h
Year	:	
GLP	:	no
Test substance	:	other TS: 2-Phenoxyethanol, 25 or 50% solution in Propylenglykol
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

15.02.2002 (182)

5.2.2 EYE IRRITATION

Species	:	rabbit
Concentration	:	undiluted
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	3
Result	:	highly irritating
EC classification	:	
Method	:	other
Year	:	1981
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	All animals had strong reactions evidenced by moderate to severe erythema and edema of the conjunctiva and nictitating membrane, injected irides, light corneal opacities, and florescein staining of the cornea and adnexa. Washing the eyes immediately after instillation reduced the reaction to slight (2/3) and moderate (1/3). The adnexa (but not the cornea) was stained in all three washed eyes.
Test condition	:	One drop of test material was instilled into the conjunctival sacs of six rabbits eyes. One eye per animal was irrigated immediately after treatment. Eyes were stained with florescein. The response was graded as slight, moderate, strong, or severe.
Test substance	:	Test material was Dowanol(R) EPH solvent. The melting and boiling points were 14 and 245 degrees C, respectively.
Reliability	:	(2) valid with restrictions. Purity of the test material was not listed.

15.02.2002 (100)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	irritating
EC classification	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen

EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
15.02.2002 (52)

Species : rabbit
Concentration :
Dose :
Exposure Time :
Comment :
Number of animals :
Result : irritating
EC classification :
Method : other: BASF-Test
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
15.02.2002 (11)

Species : rabbit
Concentration :
Dose :
Exposure Time :
Comment :
Number of animals :
Result : irritating
EC classification : irritating
Method : OECD Guide-line 405 "Acute Eye Irritation/Corrosion"
Year : 1981
GLP : no
Test substance : other TS
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol, technisch [technical grade]
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
15.02.2002 (9)

Species : rabbit
Concentration :
Dose :
Exposure Time :
Comment :
Number of animals :
Result : irritating
EC classification :
Method : other: no data
Year :
GLP : no
Test substance : as prescribed by 1.1 - 1.4
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID

document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

15.02.2002 (51) (75) (109) (189)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	irritating
EC classification	:	
Method	:	other: following IRLG Guidelines for Selected Acute Toxicity Tests
Year	:	1979
GLP	:	no data
Test substance	:	other TS
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance	:	2-Phenoxyethanol, "Cosmetic Grade" (ca. 92% 2-Phenoxyethanol, ca. 8% Diethylenglykolmonophenylether)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

15.02.2002 (84) (162)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	irritating
EC classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance	:	Test substance purity: 96.3%
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

15.02.2002 (81)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	not irritating
EC classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	other TS: 2-Phenoxyethanol, 2.2%ige waessrige Loesung [aqueous solution]
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
15.02.2002		(85) (86)
Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	irritating
EC classification	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
15.02.2002		(123)
Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	irritating
EC classification	:	
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.
15.02.2002		(147) (170) (175)
Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	irritating
EC classification	:	
Method	:	other
Year	:	1949
GLP	:	no
Test substance	:	other TS
Remark	:	The instillation of a 15% dilution of test material in propylene glycol caused severe corneal necrosis of the rabbit eye. Instillation of 5% material in propylene glycol caused minor damage. The grade assigned was 8/10.
Test substance	:	A 15% or 5% solution of phenyl Cellosolve in propylene glycol
Reliability	:	(4) not assignable. Insufficient data for assessment. Purity of the test

material was not listed.
15.02.2002 (72) (172)(173)

Species	:	rabbit
Concentration	:	undiluted
Dose	:	0.1 ml
Exposure Time	:	
Comment	:	
Number of animals	:	6
Result	:	irritating
EC classification	:	
Method	:	other
Year	:	1966
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Corneal scores were 0 in all rats at all time points (with the exception of two scores of 20 in two rabbits at 72 hours). Iridial scores of 5 were observed in all rabbits at all time points (with the exception of scores of 0 in two rabbits at 48 hours). Conjunctival scores of 10-14, 8-14 and 8-14 were observed at 24, 48 and 72 hours, respectively. Pannus formations developed in eyes of 4/6 rabbits. Necrosis was not observed.
Test condition	:	Test material (0.1 ml) was introduced into the conjunctival sac of 6 rabbits. Eyes were scored for irritation at 24, 48 and 72 hours after instillation according to the method of Draize et al (J Pharm Exper. Ther 82: 377, 1944). The maximum possible scores for eye irritation reactions were cornea: 90, iris:10 and conjunctivae: 20.
Reliability	:	(2) valid with restrictions. Purity of material was not listed.

15.02.2002 (4) (161)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	
EC classification	:	
Method	:	other
Year	:	
GLP	:	no
Test substance	:	other TS: 2-Phenoxyethanol, 5% solution in Propylenglykol
Remark	:	Laut Angabe der Autoren nur sehr leichte Reizerscheinungen in der applizierten Verduennung. [According to the authors, only very slight signs of irritation in the applied dilution].
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the material is unknown.

15.02.2002 (177)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	

Result	:	irritating
EC classification	:	
Method	:	other: no data
Year	:	
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

15.02.2002 (51) (75) (109) (189)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	6
Result	:	irritating
EC classification	:	
Method	:	other
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	One drop of test material instilled into the conjunctival sacs of 6 rabbit eyes (3 unwashed and 3 washed) produced strong eye irritation evidenced by moderate to servere erythema and edema of the conjunctiva and nictitiating membrane, injected irides, light corneal opacities and fluorescein staining of the cornea and adnexa in the unwashed eyes. Irrigation immediately following treatment was palliative.
Reliability	:	(2) valid with restrictions. Purity of material was not stated.

15.02.2002 (147) (170) (175)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	irritating
EC classification	:	
Method	:	other
Year	:	
GLP	:	no
Test substance	:	other TS
Test substance	:	A mixture of 2-Phenoxyethanol and phenyl Carbitol; 15% or 5% solution in Propylenglykol
Reliability	:	(4) not assignable. Study was performed on a mixture containing 2-phenoxyethanol at an unlisted concentration.

15.02.2002 (173)

Species	:	rabbit
Concentration	:	
Dose	:	
Exposure Time	:	
Comment	:	
Number of animals	:	
Result	:	irritating

EC classification	:	
Method	:	other
Year	:	
GLP	:	no
Test substance	:	other TS
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance	:	"Phenyl-Cellosolve" = 2-Phenoxyethanol, 15% or 5% solution in Propylenglykol
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the material is unknown.

15.02.2002 (72) (172)

5.3 SENSITIZATION

Type	:	Patch-Test
Species	:	human
Number of animals	:	
Vehicle	:	
Result	:	not sensitizing
Classification	:	
Method	:	other
Year	:	1984
GLP	:	no data
Test substance	:	other TS
Result	:	Two panelists had a mild reaction after the induction phase. No other reactions were recorded during the challenge phase.
Test condition	:	Phenoxyethanol (10% v/v in mineral oil) was tested for irritation and sensitization in a repeated insult patch test using a panel of 51 subjects (male and female), aged 16- >60. Test material (0.3 ml) was applied to a patch which was then applied to the skin of the upper arm of the panelist. The patches were applied every Monday, Wednesday and Friday for 23 weeks. The patches were removed 24 hr after application and the sites were scored before application of the next patch (or 72 hours after removal of the last patch). Any panelist who missed an induction patch received a final patch in the 4th week of the study. After 10 days to 2 weeks, a challenge patch was applied (beginning of the 6th week of the study). The challenge patch included both the induction site and an adjacent, previously untreated site. The challenge patch remained in place for 24 hr, and challenge sites were scored 24 and 72 hours later. A vehicle control was also tested.
Test substance	:	2-Phenoxyethanol, 10% in mineral oil
Reliability	:	(2) valid with restrictions. Data came from a CIR Final report on the safety of phenoxyethanol published in J. Am. Coll. Toxicol. 9 (2): 259-277 (1990). Purity of the test material was not listed.

15.02.2002 (87)

Type	:	Freund's complete adjuvant test
Species	:	guinea pig
Number of animals	:	
Vehicle	:	
Result	:	not sensitizing
Classification	:	
Method	:	other: nach [following] Hausen, B.M. und Hessling, C.: Contact Dermatitis 23, 90-95
Year	:	1990
GLP	:	no data

Test substance : as prescribed by 1.1 - 1.4
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material was not listed.
15.02.2002 (80)

Type : Guinea pig maximization test
Species : guinea pig
Number of animals :
Vehicle :
Result : not sensitizing
Classification : not sensitizing
Method : other: following the method of Magnusson und Kligman
Year :
GLP : no data
Test substance : other TS: see remark
Remark : Induktion: 0.5%ige Testsubstanz + Freunds Adjuvans, intradermal; 7 Tage spaeter epicutan an den Einstichstellen mit 25%iger Zubereitung (24h, okklusiv). Nach 14 Tagen Ausloesungsbehandlung mit 5%iger Zubereitung; weitere Ausloesungen 1 und 2 Wochen spaeter. [Induction: 0.5% test substance + Freunds adjuvant, intradermal; 7 days later epicutaneous at the needle point with 25% preparation (24 hours occlusive). After 14 days release treatment with 5% preparation; further release handling 1 and 2 weeks later].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material was not listed.
15.02.2002 (19) (187)

Type : Guinea pig maximization test
Species : guinea pig
Number of animals :
Vehicle :
Result : not sensitizing
Classification :
Method : other: following the method of Wahlberg, J.E. und Boman, A., In: Andersen, K.E. und Maibach, H.I. (eds.), Contact Allergy Predictive Tests in Guinea Pigs, S. Karger AG, Basel, Pages 59-106
Year : 1985
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : Induktion intradermal [induction intradermal]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material was not listed.
15.02.2002 (38)

Type : Intracutaneus test
Species : guinea pig
Number of animals :
Vehicle :

Result : not sensitizing
Classification :
Method : other
Year :
GLP : no
Test substance : other TS: 2-Phenoxyethanol, 25 or 50% solution in Propylenglykol
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

15.02.2002 (182)

Type : Patch-Test
Species : human
Number of animals : 501
Vehicle :
Result :
Classification :
Method : other
Year : 1986
GLP : no data
Test substance : other TS: 2-Phenoxyethanol, 5% in Petrolatum
Remark : Phenoxyethanol (5% in petrolatum) was patch tested according to ICDRG guidelines on 501 patients who were undergoing patch testing for suspected contact dermatitis. There was 1 positive reaction, for a 0.2% positive rate.

Test substance : Test material was 5% phenoxyethanol in petrolatum.
Reliability : (2) valid with restrictions. Data came from a CIR Final report on the safety of phenoxyethanol published in J. Am. Coll. Toxicol. 9 (2): 259-277 (1990).

15.02.2002 (48)

Type : Patch-Test
Species : human
Number of animals :
Vehicle :
Result : not sensitizing
Classification :
Method : other
Year :
GLP : no data
Test substance : other TS: 2-Phenoxyethanol, 1, 5, 10% in Petrolatum
Remark : Of 2736 patients patch-tested with 1% phenoxyethanol in petrolatum, none had signs of irritant or allergic reactions 2 and 4 days after application. Patch testing of 130 patients with 1, 5, and 10% phenoxyethanol in petrolatum resulted in no irritant or allergic reactions.

Test substance : Test material was 1% phenoxyethanol in petrolatum.
Reliability : (2) valid with restrictions. Data came from a CIR Final report on the safety of phenoxyethanol published in J. Am. Coll. Toxicol. 9 (2): 259-277 (1990).

15.02.2002 (102)

Type : Patch-Test
Species : human
Number of animals :
Vehicle :
Result : not sensitizing
Classification :

Method : other
Year :
GLP : no data
Test substance : other TS: 2-Phenoxyethanol, 0.16 or 0.4% in Petrolatum
Remark :
Von den insgesamt 3726 Probanden (2294 w, 1432 m) zeigten 9 Reizerscheinungen (0.24%). Bei einem Patienten wurde eine positive allergische Reaktion festgestellt. [Out of 3726 total samples (tests) 2294 female, 1432 male, 9 samples (0.24%) indicated signs of irritation. One patient experienced a positive allergic reaction]
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.

15.02.2002 (65)

Type : Patch-Test
Species : human
Number of animals :
Vehicle :
Result : not sensitizing
Classification :
Method : other
Year :
GLP : No
Test substance : as prescribed by 1.1 - 1.4
Remark : 25 Probanden (12m, 13w); keine positive Reaktion. 25 probes (12 males, 13 females); no positive reaction

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material was not listed.
15.02.2002 (181)

Type : Patch-Test
Species : human
Number of animals :
Vehicle :
Result : not sensitizing
Classification :
Method : other: following the method of Kligman, A.M.: J. Invest. Dermatol. 47, 375
Year : 1966
GLP : no data
Test substance : other TS: 2-Phenoxyethanol, 10% solution in Mineral oil
Remark : 51 Probanden; keine positive Reaktion. [51 samples, no positive reaction]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION – European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.
15.02.2002 (167)

Type : no data
Species : guinea pig
Number of animals :

Vehicle :
Result : not sensitizing
Classification :
Method : other
Year :
GLP : no data
Test substance : other TS
Remark : In der Induktionsphase wurden insgesamt 5 Applikationen (jeweils 100ul) im Abstand von 24 Stunden am Ohr aufgebracht(keine weiteren Angaben). Fuenf Tage nach der letzten Applikation wurden jeweils 200 ul einer 0.1, 1, bzw. 10%igenLoesung auf die Flanken appliziert.
[In the induction phase a total of 5 applications (each 100 microliters) were made to the ear for a 24 hour period (no further details). Five days after the final application 200 microliters of a 0.1, 1 and 10% solution were applied on the flank].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol, 10% solution (Induction) or 0.1, 1 und 10% solution (Ausloesung) [allotments]
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.

15.02.2002 (47)

Type : no data
Species : guinea pig
Number of animals :
Vehicle :
Result : not sensitizing
Classification :
Method : other
Year : 1981
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : No sensitization with the 10 tested animals

Reliability : (4) not assignable. Insufficient information for assessment. Purity of the test material is unknown.

15.02.2002 (147) (170) (175)

Type : other
Species : guinea pig
Number of animals : 10
Vehicle :
Result : not sensitizing
Classification :
Method : other
Year : 1981
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Remark : Material (volume not stated) was tested in 10 guinea pigs. No animals exhibited a positive reaction.

Not enough details are present in study documentation to make a reliability rating.

Test substance : Test material was Dowanol(R) EPH solvent. The melting and

boiling points were 14 and 245 degrees C, respectively.

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material is unknown.

15.02.2002 (100)

Type : other: maximation test
Species : human
Number of animals :
Vehicle :
Result : not sensitizing
Classification :
Method : other: following Kligman, A.M. und Epstein, W.: Contact Dermatitis 1, 231
Year : 1975
GLP : no
Test substance : other TS: 2-Phenoxyethanol, 10% in Petrolatum
Remark : 30 samples, no positive reaction

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000.

15.02.2002 (59)

Type :
Species : human
Number of animals : 138
Vehicle :
Result : not sensitizing
Classification :
Method : other:modified repeated insult patch test
Year : 1975
GLP :
Test substance : other TS
Remark : The primary reference was not consulted. Data came from a CIR Final report on the safety of phenoxyethanol published in J. Am. Coll. Toxicol. 9 (2): 259-277 (1990).
Test substance : 10% phenoxyethanol in petrolatum.
Reliability : (4) not assignable. Insufficient information for assessment.

15.02.2002 (83)

5.4 REPEATED DOSE TOXICITY

Species : rat
Sex : male/female
Strain : other: CD
Route of admin. : gavage
Exposure period : 13 Weeks
Frequency of treatment : daily
Post obs. period : none
Doses : 80, 400, 2000 mg/kg bw/day
Control group : yes
NOAEL : = 80 mg/kg bw
LOAEL : = 400 mg/kg bw
Method : other
Year : 1977
GLP : no data

Test substance : as prescribed by 1.1 - 1.4

Remark : The minor findings of low incidence in the testes of high dose males were considered by test personnel to be of equivocal toxicological significance (since they were not severe) The fact that the testicular lesions were not described as “unilateral or lateral” makes interpretation of the data difficult.

Result : A lack of grooming was evident for the first 8 weeks in rats receiving 2000 mg/kg bw/day, and for the first 6 weeks in females receiving 400 mg/kg bw/day. High dose animals (2000 mg/kg bw/day) exhibited lethargy within 10-30 minutes of dosing, followed by prostration for 2-18 hours. Females were more affected than males.

Nine rats (one control, two low dose, one mid dose, and five high dose) died or were killed in extremis. Four out of the 5 high dose animals were females. These animals exhibited prostration and marked lethargy on at least one occasion before death. There was no microscopic evidence of treatment-related pathology in these animals. Food intake and body weight of high dose males was lower than controls; females were unaffected (with the exception of reduced body weight at week 8). The efficiency of food utilization of high dose males and females was less than that of controls. The water intake of high dose animals was higher than control at Weeks 6 and 12. Lower doses had no effect on water or food intake or body weight. There was no effect of treatment on opthalmological indices.

The erythrocyte counts of high dose females were lower than control after 4 weeks of treatment (6.5 +/- 0.23 x 10E6/cubic millimeter (cmm) vs 6.92 +/- 0.33 x 10E6/cmm). This persisted until termination. Packed cell volume and hemoglobin concentrations of high dose females and males were lower than control at termination. Lower doses had no effect on these parameters. Alkaline phosphatase (AP), glutamate-pyruvate transaminase, urea and glucose concentrations of high dose males were elevated at 4 weeks. An increase in AP was also observed in mid dose males (400 mg/kg/day). Females had elevated blood glucose at 4 weeks. At termination, high dose males exhibited an increase in AP only.

Urinary volumes and numbers of epithelial cells and polymorphonuclear leukocytes in urinary sediment of high dose males and females were elevated at Weeks 4 and 12. There was no effect of treatment on specific gravity. Lower doses had no effect on any urinary parameter.

The absolute (females) and relative (males and females) liver, thyroid and kidney weights of high dose animals were greater than control. Lower doses had no effect on organ weight (with the exception of increased absolute thyroid weight in low dose females).

There was no effect of treatment on gross pathology. Pulmonary congestion, minimal peribronchial lymphoid hyperplasia, perivascular accumulations of lymphocytes, pleural adhesions, fibrosis and groups of distended macrophages were seen in many control and treated animals. No treatment-related changes were seen in the liver. Minimal inflammatory cell infiltration was seen in the kidneys of control and treated rats, with the incidence increasing with dose (especially in males). Minimal to moderate distension of the tubules was found in 2/15 mid dose and 15/15 high dose males, and 4/15 high dose females. Basophilic staining of the epithelium (minimal to moderate) was more prevalent in high dose males and females (12/15 and 11/15, respectively) than controls (1/15 males and 0/15 females, respectively). Minimal tubular atrophy of the testes was observed in 1/15 control males and 3/15 high dose males. Moderate tubular atrophy associated with a reduction of spermatozoa in the epididymal tubules was found in one high dose male. Other changes observed were not considered to be related to treatment.

Test condition : One hundred and sixty rats (4 weeks old, 60-80 g) were acclimated for 6 days. Any rat that did not gain weight normally was not used in the study. Forty rats with the highest and lowest body weights were removed from the pool. Of these, 10 rats/sex were used to provide baseline blood and urine samples. The remaining rats were randomly divided into 4 groups (15/sex/group) and were treated daily by gavage (7 days/week) with vehicle (0.5% gum tragacanth), or 80, 400, or 2000 mg/kg bw/day test material in 0.5% gum tragacanth for 13 weeks. A constant volume of 5 ml/kg bw test material was delivered. All formulations were prepared freshly each day. Animals were allowed free access to food and water throughout the study.

Animals were inspected at least once per day for mortality and physically examined at appropriate intervals (not stated) for signs of ill-health. Moribund animals were euthanized. Each rat killed in extremis or found dead was subjected to a full necropsy (unless severely autolysed). Food consumption and body weights were measured weekly. Water intake of all control, mid, and high dose animals was measured over a 6-day period in Week 6, control and high dose animals in Week 12, and low and mid dose animals in Week 13. The eyes of animals in the control and high dose groups were examined with an opthalmoscope before and after 6 and 13 weeks of treatment. Blood samples were taken from the orbital sinus of 10 rats/sex in after 4 (all groups except low dose animals) and 12 weeks of treatment (all animals). Blood from control and high dose animals was analyzed for hemoglobin concentration, red blood cell, leukocyte (total and differential), and platelet counts, packed cell volume, mean red blood cell hemoglobin concentration and mean red blood cell volume. Prothrombin time was determined on blood collected at termination. Packed cell volume, hemoglobin concentration, red blood cell, and leukocyte (total and differential) counts were determined on rats from mid dose animals at Week 4 and packed cell volume, hemoglobin concentration, and red blood cell count was measured in blood from low and mid dose animals at Week 13. Serum taken at 4 weeks was analyzed for urea, glucose, alkaline phosphatase and glutamate pyruvate transaminase in all groups (except low dose animals). Serum taken from controls and high dose animals at 4 weeks also was analyzed for total protein and electrophoretic protein fractions at 4 weeks. All 6 measurements were taken from all groups (with the exception of urea in low and mid dose animals) at Week 13.
Urine was collected over a 16-hour period from all groups (except the low dose) at 4 weeks and all groups at 12 weeks. Water was withdrawn during urine collection. Urine was analyzed for pH, specific gravity, reducing substances, glucose, protein, ketones, bile pigments, urobilinogen, hemoglobin, and cellularity.

All surviving rats were euthanized and necropsied at Week 13. The weights of the adrenals, brain, heart, kidneys, liver, lungs, ovaries, pituitary, spleen, testes (with epidiymides), thyroid and uterus were recorded. These tissues plus the cecum, duodenum, eye and optic nerve, ileum, lymph nodes (cervical and mesenteric), mammary gland (posterior), pancreas, prostate, stomach, thymus, urinary bladder and uterus from all animals that died and survived to study termination were fixed and processed for microscopic examination. All listed tissues (except the testes and kidneys) in 7 control animals per sex and all high dose animals were examined microscopically. The kidneys and testes from all animals (including those that died) were examined. Bone marrow smears were made for each rat. Samples of the aortic arch, bone, colon, mammary gland (anterior), esophagus, salivary gland, sciatic nerve, second eye and optic nerve, skeletal muscle, skin, spinal cord, tongue and trachea were fixed but were not examined microscopically.

The significance of any inter-group differences in blood composition or growth was assessed by analysis of variance or the Student's t-test. The criterion for significance was $p < 0.05$.

Test substance : Test material was PHENOXETOL. Purity was not confirmed but is listed as > 99.0% by the manufacturer.

Reliability : (2) valid with restrictions. The study was not performed according to GLP and analyses do not appear to have been done blindly. Statistical procedures and the grading system used to evaluate histopathological changes were not described.

Flag : Critical study for SIDS endpoint

11.03.2002 (35)

Species	:	rabbit
Sex	:	female
Strain	:	New Zealand white
Route of admin.	:	gavage
Exposure period	:	10 consecutive days
Frequency of treatment	:	once per day
Post obs. period	:	
Doses	:	100, 300, 600, 1000 mg/kg bw/day
Control group	:	yes, concurrent vehicle
NOAEL	:	< 100 mg/kg
LOAEL	:	= 100 mg/kg
Method	:	other
Year	:	1991
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4

Remark : Groups of 3 rabbits were also administered water (control) or a single dose of 800 mg/kg bw/day. Blood samples were taken 1,3,6, and 24 hr after exposure for hematological evaluations and to determine concentrations of metabolites, and red blood cell methemoglobin and glutathione. Red blood cell osmotic fragility was measured on blood collected at 1 and 3 hrs. The rabbits exhibited similar clinical and pathological lesions as those given multiple doses at lower concentrations. Increases in erythrocyte fragility were found in blood collected at 1 and 3 hours. No other changes were observed until 24 hours after dosing (at which time the red blood cell count, hemoglobin concentration and packed cell volume decreased and MCH and MCHC increased). Both ethylene glycol phenyl ether (up to 25 micrograms/ml) and phenoxyacetic acid (PAA) were identified in serum samples. Peak PAA concentrations (1452 micrograms/ml) occurred 3 hr after dosing.

A study to assess the hemolytic activity of the test material against rabbit erythrocytes in vitro after a 1 hr incubation also was performed. Increased cell lysis occurred at a concentration of 5 mg test material/ml, and near complete lysis was found at 10 mg/ml. Phenoxyacetic acid (a major blood metabolite) did not produce hemolysis.

Result : All rabbits in the 1000 mg/kg bw/day group were found dead or were killed moribund on test Day 2. In the 600 mg/kg bw/day group, one rabbit was found dead and two rabbits were terminated moribund on Test Days 3 and 6, respectively. One rabbit in the 300 mg/kg bw/day group was found dead on Day 10 after dosing. Signs of toxicity were anorexia, lethargy, and excretion of dark-red urine.

On day 5, mean body weights of rabbits dosed with 100, 300 or 600 m/kg bw/day were decreased 8% with respect to their preexposure weights and 10-14% from controls. Weights of rabbits in the 100 and 300 mg/kg bw/day groups remained depressed at day 10.

In general, rabbits exposed to any concentration had decreased red blood cell counts (RBC), hemoglobin concentrations and packed cell volume, with corresponding increases in nucleated and polychromatic red blood cells. Effects on these variables were dose dependent.Many animals exhibiting severe depressions in RBC showed increases in MCH, MCHC, platelets and white blood cells. In general, mean values for these variables appeared to be greater than control at the 600 and 1000 mg/kg bw/day doses. The values for MCH and MCHC were considered to be artificially elevated due to free hemoglobin in plasma.

Urine samples from animals dosed with 600 and 1000 mg/kg bw/day had decreased pH, elevated protein, bilirubin, urobilinogen, hemoglobin casts, increased ketones (1000 mg/kg bw/day only) and increased numbers of white blood and epithelial cells (one 600 mg/kg bw/day rabbit only). Decreased urinary pH and elevated protein, bilirubin, urobilinogen, white blood cells and epithelial cells were noted in the 300 mg/kg bw/day group. Decreased pH and increased bilirubin and red blood cells were observed in at least one rabbit in the 100 mg/kg bw/day group.

Most rabbits given 600 or 1000 mg/kg bw/day had enlarged and dark kidneys and spleen, dark urine in the bladder and dark urine staining the perineal region. These lesions were not observed in rabbits treated with 100 or 300 mg/kg bw/day. Most rabbits in all groups treated with test material had slight to moderate erythroid hyperplasia in bone marrow. One animal in the 1000 mg/kg bw/day dose group had decreased erythropoiesis in bone marrow. Most animals in the 1000 and 600 mg/kg bw/day groups had red pulp congestion and erythrophagocytosis in the spleen. One rabbit in the 600 mg/kg bw/day group had hematogenous pigmentation in red pulp lesions and one in the 300 mg/kg bw/day group had thrombi in the venous sinuses resulting in generalized splenic necrosis. The latter animal also had thrombi within pulmonary blood vessels. Two animals given 100 mg/kg bw/day had splenic extramedullary hematopoiesis. Some rabbits in the two highest dose groups had hemoglobin casts in the lumen of the renal tubules and collecting ducts and degeneration and necrosis of the tubular epithelium. Necrosis of gastric glandular mucosa was observed in some animals from all groups treated with test material. Several animals from all groups except controls and those treated with 1000 mg/kg bw/day had decreased thickness of the thymic cortex.

Test condition : Adult female rabbits (3200- 4500 g) were used. All animals were acclimated for a minimum of 3 weeks before use and randomly allocated to treatment groups. They were allowed free access to food and water. Groups of 3 rabbits were given 100, 300, 600 or 1000 mg/kg bw/day test material for 10 consecutive days by gavage. An additional group of 6 rabbits (control) was treated similarly with distilled water. Body weights were recorded on days 1, 5, and 10 of treatment. Blood samples (3 ml) were taken from the auricular artery prior to necropsy on day 11 (24 hr after the last dose) or at necropsy prior to euthanization of moribund animals. The following hematological measurements were made: packed cell volume, red blood cell count, hemoglobin, white (total and differential) blood cell count, red blood cell indices, and platelet count. Urine samples taken directly from collecting pans or from the bladder at necropsy were analyzed for color, appearance, specific gravity, pH, protein, glucose, ketones, bilirubin, blood and urobilinogen and sediment. The following organs were taken from animals at necropsy and were analyzed by light microscopy: liver, gallbladder, heart, spleen, pancreas, bone marrow (left femur), kidney, stomach, lung and thymus.

Test substance : Test material was analyzed as > 99% pure.

Reliability : (4) not assignable. . Data were not analyzed statistically. The duration of the test was less than 28 days.

15.02.2002 (36) (154)

Species	:	rat
Sex	:	male/female
Strain	:	Wistar
Route of admin.	:	oral feed
Exposure period	:	13 Weeks
Frequency of treatment	:	kontinuierlich im Futter [Continually in feed]
Post obs. period	:	5 Weeks
Doses	:	50, 100, 200, 500 mg/kg
Control group	:	no data specified
NOAEL	:	200 mg/kg bw
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Es wurden 20 maennliche und 20 weibliche Tiere pro Dosisgruppe eingesetzt; 5 maennliche und 5 weibliche Tiere aus jeder Gruppe wurden nachbeobachtet. Keine signifikanten Effekte wurden in den drei niedrigen Dosierungen beobachtet.In der hoechsten Dosisgruppe zeigte sich verminderte Koerpergewichtsentwicklung bei den maennlichen Tieren bei unveraenderter Futteraufnahme in der 5-woechigen Nachbeobachtungszeit. Cholesterol, Serumprotein, Blutplaettchen und Leberlipide waren bei den maennlichen Tieren der hoechsten Dosisgruppe vermindert, Cholesterol und Blutplaettchen auch in der 5-woechigen Nachbeobachtung. Die alkalische Phosphatase im Serum der maennlichen Tiere war erhoeht. Keine weiteren Angaben. Die Ergebnisse liegen lediglich als tabellarische Aufstellung vor. [20 Male and 20 female animals per dose groups were exposed; post treatment observations were made for 5 male and 5 female animals out of every group. No significant effects were observed in the three lower doses. In the highest dose group reduced body weight gain was seen for the male animals with unchanged food uptake at the 5 week post-observation time. Cholesterol, serum protein, blood platlets and liver lipids were reduced in the highest dose groups for the males; cholesterol and blood platelets were also reduced at the 5 week postobservation period. The alkaline phosphatase in the serum of the male animals was raised. No further details. The results are given solely in tabular form].
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The primary reference was not reviewed. Data came from a IULCID document prepared by the European Commission, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

15.02.2002 (186)

Species	:	rat
Sex	:	male/female
Strain	:	
Route of admin.	:	gavage
Exposure period	:	15 days
Frequency of treatment	:	daily (except weekend), for a total of 11 doses
Post obs. period	:	
Doses	:	100, 300, 1000 mg/kg bw/day
Control group	:	yes, concurrent vehicle
NOAEL	:	= 300 mg/kg
LOAEL	:	= 1000 mg/kg
Method	:	other
Year	:	1981

GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	The incidence of enlarged Peyer's patches in controls was not stated. Because this was the only abnormality noted in the 300 mg/kg bw/day group, and it was only observed in one animal, the reviewer chose 300 mg/kg/day as the NOAEL.
Result	:	There was no effect of treatment of food consumption, organ weight, or any hematological variable measured. Body weight gain was slightly reduced in the 1000 mg/kgbw/day (high dose) animals. High dose animals exhibited nervous system depression. This was severe enough to warrant euthanasia in one animal. Depression and reduced activity was not seen after the fifth dose or at the lower dose levels. The serum glutamic oxaloacetic and pyruvic transaminase concentration of the high dose animals were significantly higher than controls; however, they were within the normal range for historical controls. None of the other clinical chemistry measurements were significantly affected by treatment. Peyer's patches were enlarged in the four surviving high dose rats and in one animal each from the 100 and 300 mg/kg bw/day groups. There were no other abnormalities in the examined tissues.
Test condition	:	Groups of 5 male rats were given distilled water (control, volume not listed) or 100, 300, or 1000 mg/kg bw/day test material for 11 days out of a total of 15. Body weigh, food consumption and clinical signs were monitored (intervals were not stated). Blood taken at necropsy was analyzed for red blood cells, hemoglobin, hematocrit, red blood cell indices, platelets, and white blood cell count (total and differential). Serum was analyzed for glutamic oxaloacetic transaminase, glutamic pyruvic transaminase, creatinine, urea nitrogen, glucose, and lactate dehydrogenase. Absolute and relative liver and kidney weights were recorded. Animals were examined for gross and histopathology (organs were not listed). Statistical methodologies were not reported.
Test substance	:	Test material was Dowanol(R) EPH solvent. The melting and boiling points were 14 and 245 degrees C, respectively.
Reliability	:	(2) valid with restrictions. The test was less than 28 days. Purity of the test material is unknown.

11.03.2002 (100) (147) (171) (175)

Species	:	rat
Sex	:	female
Strain	:	Fischer 344
Route of admin.	:	gavage
Exposure period	:	up to 14 days
Frequency of treatment	:	daily
Post obs. period	:	none
Doses	:	1250, 2500 mg/kg/d
Control group	:	yes, concurrent vehicle
Method	:	other
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Es wurden drei Tiere pro Gruppe eingesetzt. Die Studie sollte lediglich die Auswirkungen der Testsubstanz bezueglich einer Haemolyse bei Ratten belegen. Insgesamt 4 Tiere (2 aus jeder Dosisgruppe) starben waehrend der Studie.Ein Tier der hohen Dosisgruppe musste aufgrund des schlechten Zustandes vor Versuchsende getoetet werden. Die durchschnittliche Zahl der applizierten Dosen betrug 6.3 in der 1250- bzw. 1.0 in der 2500 mg/kg Gruppe. Es wurden keine Anzeichen einer

Haemolyse festgestellt. [Three animals per group were exposed. The study was to address solely the effect of the test substance in inducing hemolysis in rats. A total of 4 animals (2 out of each dose group) died during the study. An animal in the high dose group which was in very bad condition had to be killed before the end of the study. The average number of applied doses amounted to 6.3 in the 1250 and 1.0 in the 2500 mg/kg groups, respectively. No signs of hemolysis were detected].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The primary reference was not reviewed. Data came from a IULCID document prepared by the European Commission, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

11.03.2002 (154) (165)

Species : mouse
Sex : male/female
Strain : CD-1
Route of admin. : oral feed
Exposure period : 14 Tage
Frequency of treatment : kontinuierlich [continually]
Post obs. period : Keine [none]
Doses : 1, 2.5, 5, 7.5, 10% im Futter [in feed] (ca. 1600, 4000, 8000, 12000, 16000 mg/kg/d)
Control group : yes, concurrent no treatment
Method : other: following Lamb, J.C.: J. Am. Coll. Toxicol. 4, 163-171
Year : 1985
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Remark : Es wurden 8 maennliche und 8 weibliche Tiere pro Gruppe eingesetzt. Es handelt sich um eine "range-finding" Studie fuer eine Reproduktionsstudie ("continuous breeding"). [Eight male and 8 female animals per group were exposed. This was a range finding study for a reproduction study ("continuous breeding")]

Result : Es wurden Todesfaelle und vermindertes Koerpergewicht in der7.5 und der 10% Gruppe beobachtet. In der 5% Gruppe war die Koerpergewichtsentwicklung im Vergleich zur Kontrolle und zur 1 bzw. 2.5% Gruppe deutlich vermindert. [Mortality and reduced body weight were observed in the 7.5 and10% groups. In the 5% groups the body weight gain was hindered relative to the gain in the 1 or 2.5% dose groups].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The primary reference was not reviewed. Data came from a IULCID document prepared by the European Commission, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

11.03.2002 (82) (120)

Species : mouse
Sex : male
Strain : ICL-ICR
Route of admin. : gavage
Exposure period : 5 weeks
Frequency of treatment : daily, 5 days per week
Post obs. period : none
Doses : 500, 1000, 2000 mg/kg
Control group : yes, concurrent vehicle
Method : other
Year :
GLP : no data

Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Additional information about this study is listed in Section 5.8.
Result	:	Die Studie diente zur Feststellung toxischer Effekte an den Hoden; pro Gruppe wurden fuenf Tiere eingesetzt. Lediglich bei 1000 mg/kg fanden sich bei einem von fuenf Tieren atrophierte Tubuli seminiferi. Die Signifikanz des Befundes ist aufgrund der geringen Inzidenz und des Auftretens gleichartiger Befunde bei Kontrolltieren fraglich. Die Untersuchung haematologischer Parameter zeigte keine toxischen Effekte. [The study served for the determination of the toxic effects on the testicle; five animals were employeed per group. Atrophied tubuli seminiferi were found in one of five animals only at 1000 mg/kg. The significance of this finding is in question because of the isolated incidence and because of the same finding in the control group. The investigation of hematologic parameters showed no toxic effects].
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. There are not enough details to assign a reliability rating.Data came from a IULCID document prepared by the European Commission, dated 11-FEB-2000, and was translated and verified. Purity of the test material is unknown.

11.03.2002 (114)

Species	:	rat
Sex	:	male/female
Strain	:	Wistar
Route of admin.	:	oral feed
Exposure period	:	4 Wochen
Frequency of treatment	:	kontinuierlich im Futter [continually in feed]
Post obs. period	:	keine Angaben [no details]
Doses	:	50, 100, 200, 500 mg/kg
Control group	:	no data specified
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Es wurden 10 maennliche und 10 weibliche Tiere pro Dosisgruppe eingesetzt. Keine signifikanten Effekte wurden in den drei niedrigen Dosierungen beobachtet. In der hoechsten Dosisgruppe wurden verminderte Koerpergewichtsentwicklung und bei den maennlichen Tieren erhoehte alkalische Phosphatase Werte im Plasma festgestellt. Keine weiteren Angaben. Die Ergebnisse liegen lediglich als tabellarische Aufstellung vor. [10 male and 10 female animals were employed per dose group. No significant effects were observed in the three lower dose groups. In the highest dose groups reduced body weight gain was seen and in the male animals elevated alkaline phosphatase values in plasma were determined. No further remarks, since the results were summarized in tabular form].
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The primary reference was not reviewed. Data came from a IULCID document prepared by the European Commission, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

11.03.2002 (185)

Species	:	rabbit
Sex	:	male/female
Strain	:	New Zealand white
Route of admin.	:	dermal
Exposure period	:	90 days

Frequency of treatment	:	6 hr/day, 5 days/week
Post obs. period	:	
Doses	:	50, 150, 500 mg/kg bw/day
Control group	:	yes
NOAEL	:	= 500 mg/kg
Method	:	other
Year	:	1991
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	No overt signs of toxicity were noted in the animals. There were no deaths. There was no significant effect of treatment on body or organ weights, clinical chemistries, hematologic variables, or pathology. The only potentially treatment-related effects was the sporadic observation of erythema (4 males) and very slight to slight scaling of the skin at the site of test material application (8 males and 9 females at week 7) in animals exposed to 500 mg/kg bw/day. Exfoliation was resolved in all but 2 females during weeks 9-13. As these observations were not associated with any gross or histological changes in the skin, they were not considered to be of toxicologic significance.
Test condition	:	Adult male and female rabbits approximately 5 months of age were used. All animals were acclimated for a minimum of 3 weeks before use and randomly allocated to treatment groups. They were allowed free access to food and water. Ten rabbits/sex/group were treated with 0, 150, or 500 mg/kg bw/day of undiluted test material for 6 hr/day, 5 days/week for 13 weeks. Dosing volume was approximately 0.05 to 0.50 ml/kg bw/day and was adjusted weekly based on body weight. Control rabbits received 0.5 ml/kg bw/day distilled water. Test material was uniformly spread over a clipped area (approximately 10 x 15 cm). The application site was reclipped as required to keep it free from hair. An occlusive wrap of absorbent gauze and nonabsorbent cotton was placed over the application area and was held in place with an elastic jacket. All wraps were removed 6 hr after each dose was applied. All rabbits were weighed prior to the first exposure and weekly thereafter. The condition of the skin was assessed prior to each dosing for the first 2 weeks and approximately weekly thereafter by a modified Draize procedure. Blood samples (approximately 7 ml) were obtained form the auricular artery approximately 1 week prior to dosing and after 4 and 13 weeks of treatment. Blood was analyzed for red blood cells, white blood cells, platelets, hemoglobin, packed cell volume, and red blood cell indices (MCV, MCH, MCHC). Differential leukocyte and reticulocyte counts and red blood cell morphologies were conducted on 13-week samples from control and high dose animals. Serum was analyzed for alanine and aspartate aminotransferases, urea nitrogen, alkaline phosphatase, glucose, total protein, albumin, globulin, and total bilirubin. Aliquots of serum samples were analyzed by HPLC and GC/MS to identify metabolites of the test material. Animals were euthanized a day after the last dermal application, weighed, and examined grossly. Brain, heart, liver, kidneys and testes were weighed and relative organ weights (to body weight) were calculated. The liver, spleen, pituitary, adrenals, small intestine, cecum, epididymides, vagina, prostate, lungs, aorta, mesenteric lymph node, parathyroid glands, tongue, eyes, mediastinal tissues, mesenteric tissues, heart, pancreas, spinal cord, kidneys, sacculus rotundus, large intestine, uterus, ovaries, trachea, thymus, skeletal muscle, skin, nasal tissues, bone (not specified), larynx, gallbladder, brain, peripheral nerve, stomach, appendix, testes, cervix, oviducts, urinary bladder, exophagus, mediastinal lymph node, thyroid gland, salivary glands, mammary gland, bone marrow and oral

tissues were collected and preserved. Tissues from controls and high dose animals were examined histologically.

Body and organ weights, and hematological and clinical chemistry data were analyzed using Bartlett's test for equality of variances. Based on the outcome, a parametric or nonparametric analysis of variance was conducted, followed by Dunnett's test or the Wilcoxon rank-sum test with Bonferroni's correction. The critical level of significance was $p < 0.05$. Statistical outliers were identified by a sequential outlier test but were not excluded from analysis.

Test substance : Test material was analyzed as > 99% pure.
Reliability : (1) valid without restriction. The study was performed according to GLP.
Flag : Critical study for SIDS endpoint
11.03.2002 (36) (125) (155) (166)

Species : rabbit
Sex : female
Strain : New Zealand white
Route of admin. : dermal
Exposure period : 14 days
Frequency of treatment : daily
Post obs. period : none
Doses : 1000 mg/kg
Control group : yes, concurrent vehicle
Method : other
Year :
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Result : Die Studie diente lediglich zur Untersuchung der Reproduzierbarkeit des haematolytischen Effektes der Testsubstanz. 7 von 10 eingesetzten Tieren starben oder mussten aufgrund ihres schlechten Zustandes nach 5 - 8 Applikationen getoetet werden. Die vorwiegenden toxischen Schaedigungen bestanden in intravasaler Haemolyse und den daraus resultierenden pathologischen Organveraenderungen. Die ueberlebenden Tiere zeigten keine haematolytischen Veraenderungen. [The study served solely to investigate the reproducibility of the hematolytic effects of the test substance. After 8-10 applications 7 out of 10 exposed animals died or had to be killed on the basis of their poor condition. The primary toxic damage consisted of intravascular hemolysis and the resulting pathological changes in the organs. The surviving animals showed no hematolytic changes].
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The primary reference was not reviewed. Data came from a IULCID document prepared by the European Commission, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.
11.03.2002 (58) (150) (152) (153)

Species : rabbit
Sex : female
Strain : New Zealand white
Route of admin. : dermal
Exposure period : 6. - 18. dag der Traechtigekit [6-18th day of pregnancy]
Frequency of treatment : daily
Post obs. period : none
Doses : 300, 600, 1000 mg/kg/d
Control group : yes, concurrent vehicle
NOAEL : 600 mg/kg bw

Method	:	other
Year	:	
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Es wurden 10 traechtige Tiere pro Gruppe eingesetzt. Es wurden minimale Toxizitaetszeichen in der hoechsten Dosisgruppe mit Gewichtsverlust vom 15.-18. Tag der Traechtigkeit beobachtet. In den beiden niedrigen Dosisgruppen wurden keine Anzeichen maternaler Toxizitaet festgestellt. Die Studie diente als Vorversuch zur Dosisfindung fuer eine Teratogenitaetsstudie. Aufgrund der Ergebnisse wurden die gewaehlten Dosierungen fuer den Hauptversuch uebernommen. Im Hauptversuch zeigte sich dann eine hohe maternale Toxizitaet und Letalitaet bei 600 und 1000 mg/kg. Die Autoren koennen fuer diese Diskrepanz keine Gruende angeben. [Ten pregnant animals were employed per group. Minimal signs of toxicity were observed in the highest dose group with weight loss from the 15^{th} -18^{th} day. In both lower dose groups no signs of maternal toxicity were determined. The study served as a preliminary dose finding study for a teratogenicity study. Based on the preliminary study results the chosen doses were adopted for the main study. In the main study a high maternal toxicity and lethality was observed at 600 and 1000 mg/kg. The authors can give no explanation for this discrepancy].
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The primary reference was not reviewed. Data came from a IULCID document prepared by the European Commission, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

11.03.2002 (136) (148) (151) (152) (164)

Species	:	rabbit
Sex	:	female
Strain	:	New Zealand white
Route of admin.	:	dermal
Exposure period	:	14 days
Frequency of treatment	:	daily
Post obs. period	:	none
Doses	:	1000 mg/kg/d
Control group	:	yes, concurrent vehicle
Method	:	other
Year	:	
GLP	:	yes
Test substance	:	other TS
Result	:	Es wurden 10 Tiere eingesetzt. Waehrend der Studie wurde beijeweils 9/10 Tieren Erythembildung und Abschilferung an der Applikationsstelle beobachtet. Zwei Tiere starben nach der 9. bzw. der 10. Applikation; ein Tier musste nach der 6. Applikation aufgrund des schlechten Zustandes getoetet werden. Diese drei Tiere zeigten deutliche Hinweise (Haematologie, Urinuntersuchung, pathologische Untersuchung)auf eine abgelaufene regenerative intravaskulaere haemolytische Anaemie. Die Untersuchungen der ueberlebenden Tiere zeigten keine signifikanten Unterschiede im Vergleich zur Kontrolle, insbesondere keine Anzeichen einer Haemolyse. [Ten animals were employed. During the study erythrocyte formation and scaling of the application spot was observed. Two animals died after the 9^{th} or 10^{th} application; an animal had to be killed after the 6^{th} application because of moribund condition. These three animals showed clear signs (hematology, urinalysis, pathological examination) of a progressive regenerative intravascular hemolytic anemia. The examination of the surviving animals showed no significant difference in comparison to the controls; especially no signs of hemolysis].
Source	:	BASF AG Ludwigshafen

EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Test substance : 94.4% 2-Phenoxyethanol, 4.8% Diethylenglykolphenylether, 0.2% Phenol, 0.06% Propylenglykolphenylether

Reliability : (4) not assignable. The primary reference was not reviewed. Data came from a IULCID document prepared by the European Commission, dated 11-FEB-2000, and was translated.

11.03.2002 (169)

Species : rabbit
Sex : male/female
Strain : New Zealand white
Route of admin. : dermal
Exposure period : 6 hours
Frequency of treatment : daily for 14 continuous days
Post obs. period : no
Doses : 2000 mg/kg bw
Control group : yes
NOAEL : 2000 mg/kg bw
Method : other
Year :
GLP : yes
Test substance : other TS
Remark : The test material was applied dermally to 8 rabbits of each sex. The toxicity was assessed on the basis of overt clinical signs (performed daily), dermal irritation (observed daily), animal suvival (performed twice daily), weekly body weight change, hematology (pretraetment and terminal evaluation), organ weights, and gross/microscopic pathological changes.
Result : No significant clinical observations, changes in body weight gain, gross findings at necropsy, organ weight differences or adverse microscopic findings were reported for treated animals. Slight skin irritation at the site of application was reported for about one half of the traeted animals on some days of the study. Histopathologic examination revealed that test article administration did not cause any microscopic lesions of the organs/tissues evaluated. In addition, there were no biologicallly significant changes noted in organ weight or body weight that could be attributed to dermal treatment of the test article.
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-phenoxyethanol, 4% aqueous
Reliability : (4) not assignable. The primary reference was not reviewed. Data came from a IULCID document prepared by the European Commission, dated 11-FEB-2000.

11.03.2002 (183)

5.5 GENETIC TOXICITY 'IN VITRO'

Type : Ames test
System of testing : Salmonella typhimurium TA98, TA100, TA1535, TA1537, TA1538
Concentration : 50 - 5000 micrograms/plate
Cytotoxic conc. : > 5000 micrograms/plate
Metabolic activation : with and without
Result : negative
Method : other
Year : 1982
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Result : Test material was not toxic at up to 5000 micrograms/plate. No substantial increases in the number of revertant colonies were observed following

treatment with the test material, either in the absence or presence of S-9 (in either test). In the absence of metabolic activation, the number of colonies in controls were 15, 12, 10, 29 and 93 for strains TA1535, TA1537, TA1538, TA98, and TA100. The number of colonies in the same strains (respectively) incubated with test material ranged from 11-15, 11-17, 8-14, 27-44 and 63-88. In the presence of S-9, the number of colonies in controls were 16, 19, 23, 33 and 99 for strains TA1535, TA1537, TA1538, TA98, and TA100. The number of colonies in the same strains (respectively) incubated with test material plus S-9 ranged from 12-16, 18-24, 11-16, 32-40 and 68-86. The tests were valid, as the positive controls induced at least a 3-fold increase in the number of mutants.

Test condition : The method used is described in an internal company protocol (NPA 18, Appendix 1). The solvent was ethanol. Strains tested were TA98, TA100, TA1535, TA1537 and TA1538. Concentrations of 5, 50, 500 and 5000 micrograms/plate were tested in a range finding study, and 50, 150, 500, and 5000 micrograms/ml were tested in the absence and presence of S-9 (from Aroclor 1254-induced rat liver) in the definitive study. The positive controls were 2 nitrofluorene at 10 micrograms/plate for strains TA1538 and TA98, 9-aminoacridine at 20 micrograms/ plate for strain TA 1537, sodium azide at 5 micrograms/plate for strains TA 1535 and TA 100, and 2-aminoanthracene at 2 micrograms/plate for all strains in the presence of S-9. Three plates were prepared per treatment. Plates were incubated for 72 hours at 37 degrees C, after which colonies were counted with an automatic colony counter. The test was repeated.

Test substance : Test material was PHENOXETOL. Purity was not confirmed but is listed as > 99.0% by the manufacturer.

Reliability : (2) valid with restrictions. Purity was not confirmed.

Flag : Critical study for mutagenicity endpoint

11.03.2002 (127)

Type : Ames test
System of testing : Salmonella typhimurium TA98, TA100, TA1535, TA1537, TA1538
Concentration : 50, 150, 500, 1500, 5000 ug/Platte
Cytotoxic conc. :
Metabolic activation : with and without
Result : negative
Method : other: no data
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material is unknown.

13.03.2002 (92)

Type : Ames test
System of testing : Salmonella typhimurium (keine weiteren Angaben) [No further data]
Concentration : no data
Cytotoxic conc. :
Metabolic activation : no data
Result : negative
Method : other: no data
Year :
GLP : no data
Test substance : as prescribed by 1.1 - 1.4
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID

document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material is unknown.

13.03.2002 (122)

Type	:	Cytogenetic assay
System of testing	:	CHO-cells
Concentration	:	no data
Cytotoxic conc.	:	
Metabolic activation	:	no data
Result	:	negative
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Keine weiteren Angaben zum Testsystem; die Studie liegt lediglich als Abstract vor. [No further data about the test system; the study was only in abstract]
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

13.03.2002 (118)

Type	:	Cytogenetic assay
System of testing	:	CHO cells1
Concentration	:	125-1000 ug/ml (ohne metabol. Aktivierung)[without metabolic activation]; 500-3000 ug/ml (mit metabol. Aktivierung [with metabolic activation]
Cycotoxic conc.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Es wurden chromosomale Aberrationen untersucht. Laut Angabe der Autoren bei 1000 ug/ml ohne metabolische Aktivierung leichte Hemmung der Mitose. [Chromosomal abberation was investigated. According to the authors, slight inhibition of mitosis was observed at 1000 micorgrams/l without metabolic activation].
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

13.03.2002 (184)

Type	:	HGPRT assay
System of testing	:	CHO-cells (CHO-K1-BH4)
Concentration	:	2000 – 3500 ug/ml
Cycotoxic conc.	:	
Metabolic activation	:	with and without
Result	:	negative
Method	:	other: following Hsie, A.W. et al., Mutation Research 86, 193-214
Year	:	1981
GLP	:	yes

Test substance : as prescribed by 1.1 - 1.4

Result : Cell survival: The preliminary toxicity tests showed that 3500 micrograms/ml gave relative cell survival rates of 6.2% and 3.4% in the non-activation and activation assays (respectively) and that 2500 micrograms/ml was non-toxic to the cells. In the mutation assay conducted in the absence of S-9 mix, 3500 micrograms/ml gave a relative cell survival (rcs) of 25.6%. In the mutation assay conducted with S-9 mix, 3500 micrograms/ml gave a rcs value of 3.8%, which was interpreted to be too severe. The rcs at 3250 micrograms/ml in the presence of S-9 mix was 14.2%.

Mutagenicity: The frequencies of mutants in the absence (ranged from 1.2 – 6.6 per 10E6 clonable cells) or presence of S-9 mix (ranged from 2.0 – 8.0 per 10E6 clonable cells) were not significantly different from the concurrent negative (5.1 and 5.7 per 10E6 clonable cells without and with S-9 mix, respectively) and or historical control values. There was no dose-dependent increase in the number of mutants in cultures treated with the test material.

The positive controls EMS and 20-MCA caused significant increases in the frequencies of mutants (341.7 and 279.5 per 10E6 clonable cells, respectively), indicating that the test was valid.

Test condition :

Cells: The CHO-K1-BH4 cell line originally obtained from Dr. Hsie. Oak Ridge National Laboratory, Oak Ridge TN, was used in the study. Stock cultures were stored at approximately -100 degrees C. Periodic checks for mycoplasma contamination were negative. The cells were grown as monolayer cultures in plastic dishes at 37 dgrees C in a humidified incubator (5% CO2 in air).

Media: The cells were maintained in Ham's F-12 nutrient mix supplemented with 5% (v/v) heat-inactivated, dialyzed fetal bovine serum, 25 mM HEPES and antibiotic-antimycotics (0-25 microgram/ml Fungizone, 100 U/ml penicillin G, 0.1 mg/ml streptomycin sulfate). The selection method used for the detection of mutants was Ham's F-12 nutrient mix supplemented with 10 micromolar 6-thioguanine, 5% serum and the above mentioned antifungal-antibiotics.

Test materials: The test material was tested at 2500, 3000, 3250, 3375 and 3500 micrograms/ml in the absence of S-9 mix and 2000, 2500, 3000, 3250 and 3500 micrograms/ml in the presence of S-9 mix. The negative control was culture medium. The positive controls in the absence and presence of S-9 were ethylmethanesulfonate (EMS, 621 micrograms/ml) and 20-methylcholanthrene (20-MCA, 4.03 micrograms/ml). The test material and EMS were dissolved in culture medium and the 20-MCA was first dissolved in DMSO. The final concentration of DMSO in the medium was 0.5%.

S-9 mix; The S-9 was prepared from the livers of Aroclor-1254-treated (500 mg/kg), male, Sprague-Dawley rats. Thawed S-9 was reconstituted at a final concentration of 10% (v/v) in a mix adapted from O'Neill et al., 1982 (Environ. Mutagen. 4: 7-18). Reconstituted S-9 mix was added to the culture medium to obtain the final concentration of 2%.

Test conduct: Cells in the logarithmic growth phase were trypsinized and placed in medium containing % serum at 200 cells/100 mm dish for the toxicity assay and 1 x 10E6 cells/100 mm dish for the mutation assay. The medium was replaced with serum-free medium containing S-9 mix (where applicable) and test material (or positive or negative control) the day following plating. The total volume of the treatment was 10 ml/100 mm

dish. The cells were treated for 4 hr at 37 degrees C. Exposure was terminated by washing the cells with phosphate-buffered saline. Cultures were trypsinized 18-24 hours after treatment and replated at a density of 1 x 10E6 cells/100 mm dish. The cells were cultured once on the 3rd day and again on the 6th day and plated at the aforementioned density. On day 8, the cells were trypsinized and plated at a density of 2 x 10E5 cells/100 mm dish (five dishes per treatment) in selection medium for the determination of mutants and at 200 cells/60 mm dish (five dishes per treatment) in Ham's F-12 medium without hypoxanthine for determination of cloning efficiency. The dishes were incubated for about 7-9 days, fixed with methanol and stained with crystal violet. The mutation frequency at each dlse level was calculated as the number of mutant colonies/cloning efficiency/total number of cells plated.

Cytotoxicity Assay: Three cultures per dose level were treated with test material or negative control in the presence or absence of S-9 mix. After treatment, the cultures were incubated for 7 days, fixed with methanol and stained with crystal violet. The number of colonies/dish was counted and the mean colonies/dosh/treatment were compared to the negative control value.

Statistical analyses: Data were evaluated using pairwise tests comparing the frequencies of mutants per 10E6 clonable cells in treated cultures vs. negative controls (alpha = 0.01, one-sided). Linear and quadratic trend analyses (alpha = 0.025, one-sided) were also conducted over the dose range.

Test substance : Purity of the test material was 99.83%
Reliability : (1) valid without restriction. Comparable to a guideline study.
13.03.2002 (158) (168)

5.6 GENETIC TOXICITY 'IN VIVO'

Type : cytogenetic assay
Species : rat
Sex : male/female
Strain : Sprague-Dawley
Route of admin. : gavage
Exposure period : up to 48 hours
Doses : 280, 933, 2800 mg/kg bw
Result : negative
Method : other
Year : 1988
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Result : The LD50 value (moving average method) was 2937 and 4013 mg/kg bw for males and females. Based on these results, 2800 mg/kg bw was chosen as the highest dose to be used in the cytogenicity study. GC analysis revealed that the concentrations of test material in the low and high dose groups were higher than the targeted concentrations. Food consumption in the high dose and positive control groups was lower than the negative control. Cytogenetic data from one animal each in the control and high dose group could not be collected at 6 hrs due to technical errors. One male in the high dose group died before the scheduled euthanization time of 6 and 24 hours, and one negative control male and 3 high dose males did not survive to the scheduled euthanization time of 48 hours. Among females treated with 2800 mg/kg bw, 1, 3, and 3 animals died before the scheduled euthanization times of 6, 24 and 48 hours, respectively. All

positive controls and animals treated with lower doses of test material survived.

There were no significant increases in the incidence of total or specific type of cytogenetic anomalies in groups treated with 933 or 2800 mg/kg bw test material at any time point compared to negative controls. The highest number of aberrations observed in treated animals was 6 (in female rats treated with 933 mg/kg bw for 6 hrs) compared to 3 in female controls at the same time point. There was no effect of treatment on the percentage of cells with gaps. Data on mitotic indices indicated that there was no excessive cell toxicity among groups treated with 933 and 2800 mg/kg bw. The positive controls induced a significant increase in the total number of aberrations (48 and 54 in males and females, respectively). Therefore, the test was valid.

Test condition : A preliminary test was conducted to determine the LD50 value. Groups of rats (5/sex/dose) were treated by gavage with 625, 1250, 2500 and 5000 mg/kg bw test material in corn oil vehicle, and survival was monitored for 14 days. The highest dose selected for the cytogenetic test was approximately 80% of the LD50 value and middle and low doses were 1/3 and 1/10 of the highest dose, respectively.

For the definitive test, test chemical was mixed with corn oil and administered to rats (8-11 weeks old) by single oral gavage at 280, 933 and 2800 mg/kg body weight. Negative control rats were treated with corn oil (10 ml/kg). Groups of animals were euthanized 6, 24 and 48 hours after treatment. Rats treated with 2000 mg/kg trimethylphosphate (positive control) were euthanized at 24 hr. Freshly prepared solutions (less than 2 hours old) were used. Concentrations of test material were verified by gas chromatography. There were 5 animals/sex/dose level/time point. Total food consumption of the rats was measured.

Rats were injected i.p. with 2 mg/kg colchicine approximately 3 hours prior to euthanization. The bone marrow was removed, and slides of fixed cells were stained with Giemsa. Slides were coded and scored blindly. Fifty metaphases were examined from each surviving animal in the negative control, positive control and the 933 and 2800 mg/kg bw groups for the presence of various cytogenetic anomalies. Only metaphases that contained 42 centromeres were scored (with the exception of severely damaged cells in which centromeres could not be accurately counted). Cells having 10 or more aberrations were classified as severely damaged. Chromatid and chromosome gaps were counted but were excluded from the total aberration frequency. Slides for the low dose groups were not scored.

The following parameters were evaluated for statistical significance: total aberrations (excluding gaps), number of cells with aberrations (excluding gaps), number of gaps, number of cells with gaps, miscellaneous aberrations (e.g. chromosomal disintegration and pulveration), and severely damaged cells. The raw data were first transformed by adding 1 to each count and then taking the natural log of the adjusted number. The transformed data and data on mitotic indices were analyzed by a three-way analysis of variance (sex, dose and time), assuming the three-way interaction to be zero. Depending on a review of two-way interactions, the data for main effects were analyzed by one, two, or three-way analysis of variance. Pairwise comparisons of treated vs. negative control data were made using a t-test (with Bonferroni correction for multiple comparisons). The criterion for significance was $p < 0.01$.

The test material was considered positive if it induced a significant and dose-related increase in total aberration frequency (chromatid-type plus

chromosome-type aberrations). Significant increases in the total aberration frequency at only a single dose level was to be verified with an additional experiment. The test chemical was considered negative if it failed to induce a significant increase in the total aberration frequency at the 2 high dose levels (provided there was not excessive cell toxicity). Significant increases in miscellaneous aberrations and severely damaged cells (if present) were evaluated critically for biological significance.

Test substance : Purity of the test material was 99.83%.
Reliability : (1) valid without restriction. The study was performed according to GLP.
Flag : Critical study for cytogenicity endpoint.
11.03.2002 (69) (157)

Type : micronucleus assay
Species : mouse
Sex : male/female
Strain : CD-1
Route of admin. : gavage
Exposure period : divided doses every 24 hours
Doses : 300, 600, 1200 mg/kg bw (total dose)
Result : negative
Method : other
Year : 1982
GLP : yes
Test substance : as prescribed by 1.1 - 1.4
Remark : The authors stated that the 2-hour delay in the harvest of control rats at the first time point had no significant effect on the results.
Result : No clinical signs or mortalities occurred in the definitive study. There was no effect of test material on the number of micronucleated cells/ 1000 polychromatic erythrocytes (PCE). The mean number of micronucleated cells/1000 PCE was 0.6 and 0.7 in controls at 26 and 48 hours, 1.0 - 1.5 and 0.5 - 0.9 in animals treated with test material for 24 or 48 hours, and 22.33 and 17.38 in positive controls at 26 or 48 hours, respectively ($p < 0.001$ vs. control).

There was no effect of treatment on the ratio of normochromatic/ polychromatic cells. The ratio of normochromatic/polychromatic cells was 2.79 and 2.15 in controls at 26 and 48 hours, 1.99 - 3.94 and 1.72 - 2.74 in animals treated with test material for 24 or 48 hours, and 51.55 and 27.19 in positive controls at 26 or 48 hours, respectively ($p < 0.001$ vs. control).
Test condition : A preliminary toxicity study was carried out to determine the maximum tolerated dose. The results indicated that 1200 mg/kg bw would cause 10-20% mortality. In the definitive study, mice (18-21 g) were administered two equal doses of test material in a 1% methylcellulose vehicle by gavage at 24 hour intervals for total doses of 300, 600 or 1200 mg/kg bw (10/sex/dose). All animals were fasted overnight prior to dosing. A negative control group (10/sex/dose) was dosed identically with the vehicle (1% methylcellulose). A positive control group (10/sex/dose) was dosed twice with mitomycin C (i.p., total dose 8 mg/kg). The mice were observed for either 24 or 48 hours, after which times 5 animals/sex from each dose group were euthanized and bone marrow cells were removed, fixed, and stained. Due to an oversight the control animals were killed 2 hours later than the test animals at the first sample time.

Coded smears were examined for the number of micronucleated cells/1000 polychromatic erythrocytes per mouse and for the ratio of normochromatic to polychromatic erythrocytes.

The Kruskal-Wallis mean ranks test was used to analyze the data due to heterogeneity of variance. Data from treated groups was compared to

control using the non-parametric equivalent of the method of least significant differences. The criterion for significance was $p < 0.05$.

Test substance : Test material was PHENOXETOL. Purity was not confirmed but is listed as > 99.0% by the manufacturer.

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

11.03.2002 (128)

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

Type	:	Two generation study
Species	:	mouse
Sex	:	male/female
Strain	:	CD-1
Route of admin.	:	oral feed
Exposure period	:	98 days
Frequency of treatment	:	continuous
Premating exposure period		
Male	:	7 days
Female	:	7 days
Duration of test	:	
Doses	:	0.25, 1.25, 2.5% (0.4, 2.0 and 4 g/kg/day)
Control group	:	yes
NOAEL Parental	:	= 400 mg/kg bw
NOAEL F1 Offspr.	:	= 400 mg/kg bw
NOAEL F2 Offspr.	:	= 400 mg/kg bw
Method	:	other:NTP continuous breeding protocol
Year	:	1990
GLP	:	yes
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	It was remarked in the methods section that organ weights were to be listed relative to body weight. While liver weights were reported in this manner, weights of seminal vesicles do not appear to have been adjusted for body weights. When reported relative to body weight, the weights of seminal vesicles in F1 mice treated with 1.25% EGPhE (.306 g/30.71g bw = 0.010) are identical to control (.357 g/34.61 g bw = 0.0103). Therefore, the reduced seminal vesicle weights in these animals appear to be due to reduced body weight. When reported relative to body weight, weights of seminal vesicles of F0 mice treated with 2.5 % EGPhE also were identical to their controls. The toxicity of ethylene glycol monobutyl ether (EGBE) also was tested. The same protocol was followed with EGBE as for ethylene glycol monophenyl ether (EGPhE), with the exception that EGBE was given to mice in the drinking water (at 0.5, 1.0 and 2.0%). EGBE was toxic to F0 females at 1.0 and 2.0%. Thirteen out of 22 high dose females and 6/20 mid-dose females died during the cohabitation period. Both mid and high dose animals treated with EGBE produced fewer litters/pair and fewer pups/litter and had pups with lower weight than controls. Parental animals in these groups exhibited decreased body weight, water consumption and increased kidney weight. Live pup weights from EGBE F0 animals (but not F1 animals) exposed to 0.5% were reduced, and F1 parental animals treated with this concentration exhibited decreased liver (males and

females) and kidney (females only) weights. The crossover breeding trial with EGBE indicated that the female was primarily affected. Testes and epidiymes weights and sperm number and motility of males in these treatment groups were normal. In the EGBE study, The NOAELs for parental and reproductive effects (decreased pup weight) were < 0.5%.

Result : Two high dose EGPhE females (2.5%) and one mid dose female (1.25%) died during the continuous breeding phase. There was no effect of treatment on food consumption (approximately 5.6 g/day/mouse). The daily dose in males was approximately 0.4, 2.0 and 4.0 g/kg bw. The daily dose in females fluctuated with the stage of gestation (data were not shown).

2.5% EGPhE: Treatment with 2.5% resulted in decreased number of F1 live pups per litter (9.0 +/- 0.8 vs. 11.0 +/- 0.4 in control), the proportion of pups born alive (0.9 +/- 0.60 vs. 0.98 +/- 0.01 in control), live pup weight (1.52 +/- 0.04 g vs. 1.65 +/- 0.02 in control), and adjusted live pup weight (1.48 +/- 0.03 vs. 1.65 +/- 0.02 in control). Further analyses revealed that 12/20 (60%) of high dose F0 pairs had a fifth litter compared to 36/40 (90%) of control F0 pairs. The results of the crossover mating study (Task 3) were inconclusive, as no mating or fertility indices or reproductive organs were altered. Only live pup weight was decreased (by 12%) in the control x high dose female mating. In this study, body weights of F0 males (but not females) were decreased, and relative liver weights of both sexes were increased. F1 weanlings exposed to 2.5% test material had lower birth, weaning and mating weights and high lethality rates (25/32 males and 21/24 females). Therefore, Task 4 was conducted with the control and 1.25% treatment group.

1.25% EGPhE: Body weights of F1 males and females were decreased and relative liver weights were increased. The adjusted pup weight of F1 (1.59 +/- 0.02 vs 1.65 +/- 0.02 in control) and F2 pups (1.45 +/- 0.02 vs 1.59 +/- 0.03 in control) was decreased in the 1.25% group. Weaning and mating weights of F1 males and females from the last litter (litter 5) also were lower than control. There was no effect of treatment on any other parameter measured in Task 4 [with the exception of decreased weight of seminal vesicles of F1 males (306 +/- 14 mg vs. 357 +/- 15 in control)]. Treatment with this concentration had no other effects on parents, reproduction or offspring.

0.25 % EGPhE: No adverse effects on parents, reproduction or offspring were noted at this concentration.

Test condition : Each dose of ethylene glycol monophenyl ether (EGPhE) was independently blended into a small amount of ground feed. This mixture was added to a preweighed portion of feed and mixed in a blender for 15 min. Dosed feed was found to lose about 5% of test material over 7 days, therefore, dosed feed was prepared fresh weekly. Concentrations were found to be within 96-105% of target levels.

Animals were 6 weeks old upon receipt and were quarantined for 2-5 weeks. During this period, 2 females and 2 males were killed and their sera was analyzed for 11 viruses. All tests were negative. Mice were allowed free access to food and water. They were randomly assigned to groups by body weight.

Task 1: An initial dose finding study was performed in which 8 animals/sex were exposed to 0, 1.0, 2.5, 5.0, 7.5 and 10% in the feed for 14 days. Clinical signs, body weight and food consumption were monitored. Animals treated with 7.5 and 10% lost 10% of their body weight, and three of each sex died. The doses chosen for use in the reproductive study were

0.25, 1.25 and 2.5%.

Task 2: For the reproductive study, eleven-week old mice were allocated into 4 treatment groups. There were 40/sex for untreated controls and 20/sex in each of the following dose groups: 0.25, 1.25, and 2.5% in feed. Separate sexes were group housed for a premating exposure period of 7 days. Females and males from the same dose group were then paired, housed one breeding pair per cage, and cohabitated for 98 days. Test material exposure was continuous. The pairs were separated and the male and female mice were housed individually and exposed continuously. Any litters born after the continuous breeding phase were reared by the dam until weaning, after which the test material was provided to the F1 animals (offspring) at the same concentration as the F0 animals (parents). The number of pairs producing a litter/number of breeding pairs, the number of litters per pair and live pups per litter, the proportion of pups born alive, sex of live pups, and pup weights within 18 hours of birth were recorded. Food consumption, parental body weights (time not specified), mortality and clinical signs of toxicity of parents also were evaluated.

Task 3: When a positive effect on fertility was detected, a one-week crossover mating trial was performed with F0 animals after the last litter was weaned to determine the affected sex. Three groups of 20 pairs each were mated in the following manner: control males x control females, control males x high-dose females, and control females x high-dose males. Pairs were mated for 7 days or until a copulatory plug was detected (whichever came first). Treatment was discontinued during the mating phase and then was reinstated until necropsy (which is assumed to have taken place 98 days after mating). Animals were evaluated for reproductive toxicity (as described in Task 2 above and the body weight and weight of the liver and kidney (with adrenals attached). Selected reproductive tissues from males (left testis with epididymis attached, right testis, right epididymis, prostate and seminal vesicles) and females (ovary with oviduct attached, and uterus) were weighed, fixed and embedded in paraffin, stained and evaluated by light microscopy. The sperm concentration, percentage of motile sperm, and percentage of abnormal sperm in the right cauda epididymis were also evaluated in males and estrous cyclicity (as monitored by vaginal lavage for the preceding 7 days) was measured in females.

Task 4: The final litters of the F0 generation were reared, weaned and exposed to the same concentration of test material as their parents. They were paired with nonsiblings from the same dose group at 74 +/- 10 days. These animals were cohabitated either for 1 week or until a copulatory plug was detected (whichever came first). The F1 parents were euthanized and necropsied. The litters produced and parents were evaluated for reproductive toxicity as previously described (Tasks 2 and 3). Organs and tissues examined upon necropsy were the same as those listed for Task 3.

The Cochran-Armitage test was used to evaluate any dose-related trends in fertility. A chi square test was used to analyze data from Task 3. Pairwise comparisons between the control and dosed groups were made with the Fisher's exact test. The number of litters and the number of live pups per litter were computed on a fertile pair basis and treatment group means were determined. Dose groups means for these variables, the sex ratio and the proportion of live pups were analyzed using a Kruskal-Wallis test. Ordered differences were tested for by Jonckheere's test. The Wilcoxon-Mann-Whitney U test was used to make intergroup pairwise comparisons.

		An analysis of covariance was performed to correct for the potential effect of the number of pups per litter on the average pup weight. The covariate used was average litter size, including live and dead pups. Least squares estimated of dose group means, adjusted for litter size, were computed and tested for overall equality using an F test and pairwise equality was tested using a t test. Average organ weights adjusted for body weight were tested for equality an analysis of covariance. Absolute organ weights were analyzed by the Kruskal-Wallis and Wilcoxon-Mann-Whitney U tests. Dose-related trends were tested for by Jonckheere's test. Analyses were performed on data for males and females separately and with both sexes combined. The criterion for significance was $p < 0.05$.
Test substance	:	The purity of the test material was 94-95%, with 6 impurities estimated at a total concentration of 5.5-6% (identities were not listed). No single impurity was present at greater than 1%.
Conclusion	:	In summary, ethylene glycol monophenyl ether produced reproductive and developmental toxicity at doses that increased liver weight in treated F_0 and F_1 mice (2000 and 4000 mg/kg bw/day). At these doses, EGPhE caused toxicity to growing animals, as evidenced by the reduced body weight in neonates in Tasks 2, 3, and 4, and the large increase in postnatal lethality as the F_1 animals grew to the age of mating. No effects were observed in animals treated with 400 mg/kg bw/day.
Reliability	:	(1) valid without restriction. The study was performed according to GLP.
Flag	:	Critical study for SIDS endpoint
19.02.2002		(82)
Type	:	other: examination of testes
Species	:	mouse
Sex	:	male
Strain	:	other:JCL-ICR
Route of admin.	:	gavage
Exposure period	:	5 weeks
Frequency of treatment	:	5 days per week
Premating exposure period		
Male	:	
Female	:	
Duration of test	:	
Doses	:	500, 1000, 2000 mg/kg bw/day
Control group	:	yes
Method	:	other
Year	:	1984
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Ethylene glycol monomethyl and ethyl ethers and acetates and ethylene glycol dimethyl ether were tested in this study and were found to produce decreased testicular weights and leukocyte counts and dose-related atrophy of the seminiferous tubule epithelium.
Result	:	There was no effect of treatment on weights of testes or combined weights of the seminal vesicles and coagulating gland. Whether the test material had any effects on the morphology of blood or the testes was not stated.
Test condition	:	Groups of 5 male mice (6 weeks old) were treated with 500, 1000, or 2000 mg/kg bw/day test material by gavage, 5 days/week for 5 weeks. Samples were diluted with water or olive oil. A group of 5 control mice was given water. Animals were euthanized and necropsied a day after the last dose was given. The testes, seminal vesicles and coagulating gland were weighed. Tissues were fixed, stained and examined microscopically. Blood was taken from the posterior vena cava for hematological examination.
Test substance	:	Purity of the test material was not listed.

Reliability : (4) not assignable. There are not enough details to assign a reliability rating. Purity of the test material is unknown.

17.02.2002 (114)

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

Species	:	rabbit
Sex	:	female
Strain	:	New Zealand white
Route of admin.	:	dermal
Exposure period	:	days 6-18 of gestation
Frequency of treatment	:	24 hr/day throughout the treatment period
Duration of test	:	to day 28 of gestation
Doses	:	300, 600, 1000 mg/kg bw/day
Control group	:	yes
NOAEL Maternalt.	:	= 300 mg/kg bw
NOAEL Teratogen	:	= 600 mg/kg bw
Method	:	other
Year	:	1987
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Four rabbits in the 600 mg/kg bw/day group and 3 in the 1000 mg/kg bw/day group had darkened areas of skin at the application site. Staining in the perineal region or dark colored urine was noted in several animals in these groups. Nine rabbits in the 1000 mg/kg bw/day and five in the 600 mg/kg bw/day groups died or were killed moribund. Most deaths occurred between gestation Days 11 and 18. Most of these animals had dark colored urine in the bladder, jaundice and dark kidneys. Gross findings were consistent with hemolysis. In moribund animals for which hematological parameters were evaluated, red blood cell and platelet counts were severely depressed, reticulocytes were elevated, and red cell fragility was increased. There were no intact red blood cells in the urine sediment. Blood from animals that survived treatment with 600 or 1000 mg/kg bw/day appeared normal. The specific cause of death for 3 animals (2 at 600 mg/kg/day and one at 1000 mg/kg bw/day) could not be determined. All remaining animals in the 1000 mg/kg bw/day group that survived to Day 18 (with the exception of 5 that had already survived to Day 28 due to staggered initiation) were killed on Day 18 for humane reasons with no further observations. Rabbits in the 600 (N = 20) and 1000 mg/kg bw/day (N = 5) groups that survived to Day 28 of gestation had no evidence of treatment-realted effects. No signs of maternal toxicity were seen at 300 mg/kg bw/day. No differences in body weight gains or absolute or relative liver weights were observed between treated rabbits or controls. Treatment with 300 or 600 mg/kg bw/day had no adverse effect on the pregnancy rate, the number of corpora lutea, implantations, resorbed implantations, or live fetuses per litter or fetal body measurements. Treatment with up to 600 mg/kg bw/day had no effect on the incidence or type of external, visceral or skeletal malformations. Fetuses from the 5 animals treated with 1000 mg/kg bw/day that survived to Day 28 also did not exhibit external, visceral or skeletal alterations.
Test condition	:	Male and female rabbits were allowed to acclimate for at least 2 weeks prior to breeding. Females (3.5 to 4.5 kg) were artificially inseminated, with the day of insemination considered as Day 0 of gestation. A section on the back of each female was clipped free of hair prior to insemination. Animals had free access to food and water.

Animals were randomized to 4 groups of 25 according to day of gestation. They were treated with 0 (control), 300, 600 or 1000 mg/kg bw/day undiluted test material on the clipped area on Days 6 through 18 of gestation. The volume of material applied was 0.91 ml/kg bw distilled water (control), or 0.27, 0.55 and 0.91 ml/kg bw test material. The highest dose chosen was one that did not cause excessive runoff or loss into the occluding bandage. The application site was occluded with a piece of gauze and nonabsorbent cotton covered by a cotton flannel bandage held in place with tape. The bandaged remained in place 24 hours a day (except during material application). Prior to each application of test material, the skin at the application site was examined for signs of irritation and hair regrowth and was reclipped as needed. The application site was washed with water on Day 19 of gestation to prevent oral ingestion for the remainder of the
study.

Animals were observed daily and maternal body weights were recorded on Days 6 through 19 and on Day 28. Blood was collected from an ear vein from approximately 10 animals per dose group (0, 300 and 600 mg/kg bw/day) on Day 19 of gestation. Two moribund animals in the 600 mg/kg bw/day group and one in the 1000 mg/kg bw/day group were killed at this time. Blood was also collected from these animals. All blood collected was analyzed for packed cell volume, hemoglobin, erythrocyte and leukocyte (total and
differential), reticulocyte, and platelet counts, and red blood cell indices (MCV, MCH, and MCHC), and osmotic red blood cell fragility. Urine was collected at the time of necropsy from the bladders of two of the moribund rabbits (one each at 600 and 1000 mg/kg bw/day) and was analyzed for color, appearance, specific gravity, pH, protein, glucose, ketones, bilirubin, blood, urobilinogen, white blood cells, red blood cells, crystals and epithelial cells. Maternal liver weights were recorded at the time of cesarean section on Day 28 of gestation.

The number of corpora lutea and the number and position of implantations, resorptions and live or dead fetuses were recorded. The uteri of apparently nonpregnant females were stained and examined for evidence of early implantation sites. All fetuses were weighed, measured (crown-rump length), sexed and examined for external alterations. The number of fetuses (and litters) externally examined from the control, 200, 600 and 1000 mg/kg bw/day groups were 128 (17), 142 (20), 136 (15) and 49 (5). One half of each litter was examined for evidence of visceral alterations. All fetuses were preserved and examined for skeletal alterations.

Maternal and fetal body weights, absolute and relative organ weights, hematologic variables and fetal length data were analyzed using a parametric or nonparametric analysis of variance followed by a Dunnett's test or the Wilcoxon rank sum test with Bonferroni's correction where appropriate. Preimplantation loss, resorptions, and fetal alterations were analyzed by a censored Wilcoxon test with Bonferroni's correction. Corpora lutea, implants and litter size were analyzed with a nonparametric analysis of variance followed by the Wilcoxon rank sum test with Bonferroni's correction. Pregnancy rates were analyzed by the Fisher's exact probability test and fetal sex ratios were analyzed by a binomial distribution test. The critical value for statistical significance was $p < 0.05$.

Test substance : Analyzed purity of the test material was > 99%.
Reliability : (1) valid without restriction. The study was comparable to a guideline study.
Flag : Critical study for SIDS endpoint
16.02.2002 (136)

Species : rat

Sex	:	female
Strain	:	Long-Evans
Route of admin.	:	gavage
Exposure period	:	6. – 15th day of pregnancy
Frequency of treatment	:	daily
Duration of test	:	no data
Doses	:	3, 30, 300 mg/kg
Control group	:	yes
NOAEL Maternalt.	:	300 mg/kg
NOAEL Teratogen	:	other: not able to be determined
Method	:	other: no data
Year	:	1987
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	The study is available only as an abstract, and the authors describe a plethora of fetal anomalies occurring. The doses at which these effects occurred are not stated. The correlation coefficient that the authors describe as being significant at the $p < 0.05$ level is 0.40, which does not appear to be significant. A summary of this study was written in German in the ICULID document published by the European Chemicals Bureau. The English translation of this summary is as follows: "No data on maternal toxicity. The study is available only as an abstract, and the authors describe a plethora of fetal anomalies occurring. No listing of the dose groups is available. The anomalies were detailed as hydronephroses and skeletal variations. There is a great lack of detail. Furthermore the authors deduce a dependence of the effects on the condition of the fetuses in the uterus relative to the sex of the adjacent fetus. The study is not decipherable because of the faulty description of experimental part as well as the results. Especially, the plethora of enlarged renal pelvises in the rats and their heavy differentiation relative to hydronephrothy leads to significant questions about the relevance of the effects". The preparer of the summary for the current submission is in agreement with the European summary with the following exceptions: 1) effects on maternal weight and food consumption were determined (but not other measures of maternal toxicity) and 2) there was no mention of enlarged renal pelvises.
Result	:	The results are listed here exactly as quoted in the abstract. "Phenoxyethanol caused a significant increase in fetal anomalies (hydronephrosis and variant ossification patterns of the skull and sternum) considered to be suggestive of retarded growth. The expression of anomalies was significantly ($p < 0.05$) correlated to the prevalence of males within a litter ($r = 0.40$). Significant birthweight depression was detected among male pups a the highest (300 mg/kg) dose; and male pups which were contiguous to two male siblings were preferentially and most severly affected (absolute and relative birth weights which were decreased to an average of 3.24g which was but 86% of control weights). Doses of up to 300 mg/kg of phenoxyethanol had no observable or significant effect on feed consumption or maternal body weights during gestation. These data support the concept that intrauterine position, particularly with reference to contiguous male siblings, affecets the expression of developmental toxicity in polytocous rodent species."
Test condition	:	Long Evans rats (numbers and ages of rats were not given) were administered 0, 3, 30 or 300 mg/kg test material by gavage from days 6-15 of gestation. No further details about test conditions were mentioned.
Reliability	:	(4) not assignable. The results are not supported with sufficient data and are difficult to interpret. Test conditions and statistical analyses are not

adequately described. The work has not been published in a peer-reviewed journal. Purity of the test material is unknown.

13.03.2002 (108)

Species	:	rat
Sex	:	female
Strain	:	Wistar
Route of admin.	:	s.c.
Exposure period	:	6. – 15th Tag der Traechtigkeit [day of pregnancy]
Frequency of treatment	:	daily
Duration of test	:	bis zum 21. Tag post partum [up to the 21st day post partum]
Doses	:	111, 222, 444 mg/kg (100, 200, 400 ul/kg)
Control group	:	yes, concurrent vehicle
Method	:	other: no data
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Es wurden 30 traechtige Tiere pro Gruppe eingesetzt; die Wuerfe von jeweils 10 Tieren wurden bis zum 21. Tag post partum nachbeobachtet. In der hoechsten Dosisgruppe zeigte sich maternale Toxizitaet: vermindert Koerpergewichtsentwicklung (6.-10., 15.-21. Tag der Traechtigkeit, 0.-21. Tag p.p.), verminderte Futteraufnahme (7.-10., 11.-15. Tag der Traechtigkeit, 0.-21. Tag p.p.), verringertes Uterusgewicht. Das korrigierte maternale Koerpergewicht am 21. Tag d.T. war unveraendert; es zeigte sich weiterhin Haemoglobinurie und bei 1/3 der Tiere Methaemoglobinurie. In der mittleren und der niedrigen Dosisgruppe zeigte jeweils ein Tier Haemoglobinurie. Die Koerpergewichtsentwicklung war in der mittleren Dosisgruppe am 11.-15. Tag der Traechtigkeit vermindert. Die Zahl der intrauterinen Todesfaelle war in der mittleren und der hohen Dosisgruppe erhoeht, statistisch signifikant jedoch nur in der hoechsten Dosierung. In der hoechsten Dosierung war die Zahl der Feten mit unossifizierten cervikalen Zentren statistisch signifikant, in der mittleren Dosierung numerisch erhoeht. Die Fetengewichte und die Koerpergewichte der Nachkommen bei der Geburt waren in der hoechsten Dosierung vermindert. Die Ergebnisse liegen lediglich als tabellarische Aufstellung bzw. als Abstract vor. [Thirty pregnant animals were employed per group; the litters of which from 10 animals were observed post partum up to Day 21. In the highest dose group maternal toxicity was observed: reduced weight gain (6-10th ,15-21st day of pregnancy, 0-21st day post partum) reduced feed uptake (7-10th, 11-15th day of pregnancy 0-21st day post partum.), reduced uterus weight. The corrected maternal body weight on the 21st day was unchanged; hemoglobin in urine was observed and with 1/3 animals methemaglobinuria was seen. In the middle and the lower dose groups in each case one animal exhibited hemoglobinuria. The body weight gain was reduced in the middle dose group on the 11-15th day of pregnancy. The number of intrauterine resorptions were raised in the middle and the high dose groups, statistically significant however only in the highest dose group. In the highest dose group the number of fetuses with unossified cervical centers was statistically significant, in the middle dose group this occurrence was numerically increased. The body weights of the offspring were reduced in the highest dose group. The results were presented solely in tabular form or in abstract].
Source	:	BASF AG Ludwigshafen EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Reliability	:	(4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

13.03.2002 (19) (187)

5.09 SPECIFIC INVESTIGATIONS

Type : other : metabolism
Test substance : as prescribed by 1.1 -1.4
Remark : Groups of 3 rabbits were administered water (control) or a single dose of 800 mg/kg bw/day. Blood samples were taken 1,3,6, and 24 hr after exposure to determine concentrations of metabolites. Both ethylene glycol phenyl ether (up to 25 micrograms/ml) and phenoxyacetic acid (PAA) were identified in serum samples. Peak PAA concentrations (1452 micrograms/ml) occurred 3 hr after dosing.

Toxicity data for this study are described in Section 5.4, This study was given a reliability rating of (4) not assignable for repeated dose toxicity.

Reliability : (2) valid with restrictions
Basic data given about metabolism to PAA.

(36)

Type : Biochemical or cellular interactions
Remark : Die Autoren beobachteten eine Veraenderung des muskulaeren Phosphatstoffwechsels bei Fischen (Cobitis biwae) unter dem Einfluss der anaesthesierenden Wirkung der Testsubstanz. Creatinin-Phosphat war erhoeht, waehrend die Konzentration von anorganischem Phosphat erniedrigt war; beide Werte normalisierten sich mit dem Abklingen der anaesthetischen Wirkung. Ebenfalls erhoeht war die Zucker-Phosphat-Konzentration ohne Tendenz zur Normalisierung. [The authors observed a change of the muscular phosphate exchange with fish (Cobitis biwae) under the influence of the anesthetic effect of the test substance. Creatinine phosphate was elevated, and the concentration of inorganic phosphate was lowered. Both values resumed normal levels with the termination of the anesthetic effect. The sugar phosphate concentration became elevated without the tendency to renormalize].
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.
16.02.2002 (42)

Type : Biochemical or cellular interactions
Remark : Es wurden die haemolytischen Auswirkungen verschiedener Glykolether, unter anderem auch der Testsubstanz, an Ratten nach 4-stuendiger Inhalation untersucht. Eine gesaettigte Testsubstanzatmosphaere fuehrte nicht wie die anderen Glykolether zu einer erhoehten Erythrozytenresistenz. [The hematolytic effect of various glycol ethers as well as the test substance on rats was studied via four hour inhalation exposure. The atmosphere saturated with the test substance did not lead as the other glycols to an elevated erythrocyte resistance].
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.
16.02.2002 (40)

Type : Biochemical or cellular interactions
Remark : Die einmalige Gabe von 800 mg/kg an drei weibliche Kaninchen(New

Zealand White) fuehrte zu significant erhoehter Erythrozytenresistenz im Vergleich zur Kontrolle; der Haemoglobin- und Glutathiongehalt der roten Blutkoerperchen war jedoch nicht veraendert. Phenoxyessigsaeure wurde als Hauptmetabolit im Blut identifiziert. [The one-time dose of 800 mg/kg to three female rabbits (New Zealand White) led to significant elevated erythrocyte resistance in comparison to the control; the hemoglobin and glutathione content of the red blood cells was, however, not altered].

In vitro (Kaninchen-Erythrozyten) zeigte die Testsubstanz hohe haemolytische Aktivitaet mit vollstaendiger Lysis ab einer Konzentration von 1.0%. [In vitro (rabbit erythrocytes) the test substance showed high hemolytic activity with complete lysis starting with a concentration of 1.0%]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Test substance : 2-Phenoxyethanol

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (154) (165)

Type : Biochemical or cellular interactions

Remark : Es wurde die Auswirkung der Testsubstanz (im Vergleich zum Anaesthetikum Tricainmethansulfonat (MS222) auf die Glucose-Produktion in isolierten Hepatozyten von Regenbogenforellen untersucht. Weiterhin wurde der Gehalt von Glykogen, Glucose, Lactat, ATP, ADP und AMP in der Leberermittelt; es wurden keine signifikanten Unterschiede zwischen beiden Behandlungen festgestellt. Die Glucose Produktion war unter Anaesthesie mit der Testsubstanz im Vergleich zu MS222 etwas vermindert (lt. Angabe der Autoren vermutlich wegen verminderter Glykogenolyse).[The effect of the test substance (in comparison to the anesthetic tricainmethanesulfonate (MS222)) on glucose production in isolated hepatocytes of rainbow trout was studied. Further, the level of glycogen, glucose, lactate, ATP, ADP and AMP in the liver was ascertained; there were no significant differences found between both treatments. Glucose production was somewhat lessened under anesthesia with the test substance in comparison to MS222].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Test substance : 2-Phenoxyethanol

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (126)

Type : Biochemical or cellular interactions

Remark : Die Testsubstanz zeigte spermizide Aktivitaet im Konzentrationsbereich zwischen 0.01 und 0.03 M (1380 – 4140 mg/l). Schaafsamen wurde in vitro mit der Testsubstanz behandelt und die Auswirkungen auf die Sauerstoffaufnahme, die Fructolyse und die Spermienmobilitaet untersucht. Die Fructolyse wurde bei 0.01 M zu 20% und bei 0.03 M vollstaendig inhibiert. Die Sauerstoffaufnahme und die Mobilitaet waren deutlich vermindert. Weiterhin beobachtetendie Autoren die Freisetzung von Cytochrom c aus den Spermatozoen in den extrazellulaeren Raum, moeglicherweise aufgrund substanzbedingter Veraenderungen der Zellmembran Permeabilitaet. Die Autoren merkten jedoch an, dass die beobachteten Effekte nur in einem sehr hohen, nichtphysiologischen Konzentrationsbereich festzustellen waren. [The test substance showed spermizide activity in a concentration range between 0.01 and 0.03 M (1380-4140 mg/l) Sheep semen was treated in vitro with the test substance and the effect upon oxygen uptake, fructolysis and the sperm

mobility were studied. Fructolysis was inhibited 20% at 0.01 M and completely at 0.03 M. Oxygen uptake and mobility were clearly reduced. Furthermore the authors observed the liberation of cytochrome C from the spermatozoa in the extracellular space, possibly on the basis of substance caused changes in the cell membrane permeability. The authors remarked, however, that the observed effects were determined only in a very high, non-physiological range of concentration].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (99)

Type : Biochemical or cellular interactions
Remark : Es wurde die Auswirkung der Testsubstanz in vitro auf die osmotische Resistenz von Ratten-, Kaninchen- und Humanerythrozyten untersucht. Hierbei zeigte die Testsubstanz keine haemolytischen Effekte bis zu Konzentrationen von 0.5% bei Ratten- und Kaninchenerythrozyten bzw. 1% bei Humanerythrozyten. [The effect of the test substance was studied in vitro on the osmotic resistance of rats, rabbits and human erythrocytes. Hereby the test substance showed no hemolytic effects at concentrations up to 0.5% with rats and rabbits and 1% with human erythrocytes.]

In einer weiteren Untersuchung (Breslin et al.) zeigte die Testsubstanz in vitro hoehere haemolytische Aktivitaet an Kaninchenerythrozyten als der Hauptmetabolit 2-Phenoxyessigsaeure. Eine Testsubstanzkonzentration von 1% fuehrte zu vollstaendiger Erythrozyten-Lysis. [In a further study (Breslin and al.) in vitro the test substance showed elevated hemolytic activity toward rabbit erythrocytes as the main metabolite 2-phenoxyacetic acid. A test substance concentration of 1% led to complete erythrocyte lysis].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (36) (117)

Type : Cytotoxicity
Remark : Die Behandlung von Escherichia coli NCTC5933 mit der Testsubstanz (0.05 - 0.4%) fuehrte zu einer konzentrationsabhaengigen Wachstumsinhibition. In analoger Weise wurde die Assimilation von 14C-markiertem Thymidin, Uracil und von Glucose inhibiert; die 14C-Phenylalanin Inkorporation wurde deutlich weniger beeinflusst. Die Testsubstanz fuehrte somit laut Angabe der Autoren zu einer deutlichen Beeinflussung der DNA- und der RNA Biosynthese. [The treatment of Escherichia coli NCTC5933 with the test substance (0.05-0.4%) led to a concentration-dependent growth inhibition. In analogous ways the assimilation of C14-marked thymidine, uracil and glucose was also inhibited; the C14 phenylalanine incorporation was clearly less influenced. The test substance led according to the authors' statement to a clear influence of the DNA and the RNA biosynthesis.]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID

document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (67)

Type : Cytotoxicity
Remark : Es wurde die Auswirkung der Testsubstanz (Wachstumshemmung, Kalium- und Rubidiumfreisetzung) an Escherichia coli PC1349 und Pseudomonas aeruginosa 799 untersucht. Wachstumshemmung wurde ab einer Testsubstanzkonzentration von 0.25% beobachtet. [The effect of the test substance (growth inhibition of potassium and rubidium liberation) on Escherichia coli PC 1349 and Pseudomonas aeruginosa 799 was investigated. Growth inhibition was observed at a test substance concentration upwards of 0.25%].
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (62)

Type : Cytotoxicity
Remark : Es wurde die zytotoxische Wirkung der Testsubstanz als 50%ige Verminderung der Neutralrot-Aufnahme an V79-, primaeren Rattencornea Zellen und an humanen epidermalen Keratinozyten untersucht. Die IC50-Werte wurden bei Konzentrationen von 1070, 1400 und 1850 ug/ml ermittelt. Laut Angabe der Autoren ergaben sich gute Korrelationen zwischen den in vitro Zytotoxizitaetsdaten von verschiedenenuntersuchten Substanzen mit in vivo Ergebnissen zur Augenreizung (Draize Tests). [The cytotoxic effect of the test substance was investigated in terms of a 50% reduction of neutral red uptake in V79 primary rat cornea cells and in human epidermal keratinocytes. The IC50 values were ascertained at concentrations of 1070, 1400 and 1850 micrograms/ml. According to the authors there was good correlation between the *in vitro* cytotoxicity data for various investigated substances with *in vivo* results on eye irritation (Draize tests)].
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (94)

Type : Cytotoxicity
Remark : Die Autoren haben in ihrer Untersuchung die zytotoxische Wirkung von verschiedenen Substanzen (u.a. auch die der Testsubstanz) in drei Zellinien (Balb 3T3, ARLJ301-3 (Rattenleber) und FRSK (Rattenkeratinocyten)) und in einer Primaerzellkultur (RC-1, Kaninchencornea) untersucht und mitin vivo Draize-Test Daten verglichen. Die Autorenbeobachteten jeweils relativ gute Korrelationen. [The authors studied the cytotoxic effects of various substances (including the test substance) in three cell types (Balb 3T3, ARLJ301-3 (rat liver) and FRSK (rat keratinocytes) and in a primary cell culture (RC-1, rabbit cornea) and compared results with the *in vivo* Draize-test data. The others observed relatively good correlation in each case].
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (135)

Type : Cytotoxicity
Remark : Es wurde die zytotoxische Wirkung verschiedener Glykolether,unter anderem auch der Testsubstanz gegenueber Neuroblastom Zellen N18TG-2 und Gliom Zellen C6 untersucht und mit in vivo Daten zur akuten Zoxizitaet (Maus, i.p.) verglichen. Fuer die Testsubstanz wurden ED50 Werte (50%ige Verminderungder Lebensfaehigkeit der Zellen) bei einer Konzentration von8.58 bzw. 4.54 mM (1184 bzw. 627 mg/l) ermittelt. Signifikante Korrelationen zwischen der ED50 und der LD50 wurden nicht beobachtet. [The cytotoxic effect of various glycol ethers, including the test substance toward neuroblastoma cells N18TG-2 and glioma cells C6 was examined, and compared with *in vivo* data for acute toxicity (mouse, i.p.). For the test substance the ED50 values (50% inhibition of the liver function of the cells) occurred at a concentration of 8.58 and 4.54 mM (1184 and 627 mg/l). Significant correlations between the ED50 and the LD50 were not observed].
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (142)

Type : Cytotoxicity
Remark : Im "bacterial inhibition test / Microtox" wurde der IC50-Wert (50%ige Wachstumsinhibition) bei einer Testsubstanzkonzentration von 1650 mg/l beobachtet. [In “bacterial inhibition test / Microtox” the IC50 value (50% growth inhibition) was observed at a test substance concentration of 1650 mg/l].
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol, technisch [technical grade[ca. 75% (verunreinigt mit [contaminated with]Diethylenglykolmonophenylether)
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.

16.02.2002 (156) (159)

Type : Cytotoxicity
Remark : Im Rahmen einer Zytotoxizitaetsuntersuchung an Salmonella typhimurium TA100 (zur Untersuchung der Eignung verschiedener Substanzen als Loesungsmittel im Ames-Test), zeigte sich die Testsubstanz als hochgradig zytotoxisch und daher als Loesungsmittel im Ames-Test ungeeignet. In allen 5untersuchten Konzentrationen (25, 50, 100, 200, 500 ul/Platte) wurden keine ueberlebenden Bakterien beobachtet. [In the framework of a cytotoxicity investigation of Salmonella typhimurium TA100 (to study the suitability of various substances as solvents in Ames test) the test substance showed itself was intensely cytotoxic, and therefore unsuited as solvent in Ames-Test. In all five investigated concentrations (25, 50, 100, 200, 500 microliters/plate) no surviving bacteria were noted].
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-

2000, and was translated. Purity of the test material is unknown.
16.02.2002 (110)

Type : Cytotoxicity
Remark : MTT test, MTT50 = 8.53 mM,
Evaluation of stringing-inducing chemicals using cultured neuronal cells: an electrophysiological approach

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.
16.02.2002 (97)

Type : Absorption
Remark : Only an abstract of the paper was reviewed. Since the material was applied in methanol, this study should not be used to predict absorption of the neat material.

2-phenoxyethanol applied in methanol was absorbed (64 +/- 4.4% at 24 hours) through unoccluded rat skin in vitro in a static diffusion cell with ethanol/water as receptor fluid. Less material (43 +/- 3.7% in 24 hours) was absorbed in a flow-through diffusion system with tissue culture medium as receptor fluid. 2-phenoxyethanol applied in methanol was absorbed (59.3% +/- 7.0 % at 6 hours) through unoccluded human skin in the flow-through diffusion system with tissue culture medium. Skin (post mitochondrial fraction) metabolized 2-phenoxyethanol to phenoxyacetic acid at 5% of the rate for liver. Metabolism was inhibited by 1 mM pyrazole, suggesting involvement of alcohol dehydrogenase. However, first-pass metabolism of phenoxyethanol to phenoxyacetic acid was not detected during percutaneous penetration through viable rat skin in the flow-through system.
Reliability : (4) not assignable. Abstract. Purity of the test material is unknown.
(131)

Type : Metabolism
Remark : Laut Angabe der Autoren liegen keine Daten zum Stoffwechsel der Testsubstanz vor. In Analogie zu n-Butoxyethanol wird 2-Phenoxyessigsaeure als Hauptmetabolit angenommen. [According to the authors no metabolism data are available on the test substance. By analogy to n-butoxyethanol, 2-phenoxyacetic acid is assumed to be the primary metabolite].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.
16.02.2002 (160)

Type : Metabolism
Remark : Die orale Aufnahme der Testsubstanz (10.6 mg in Wasser) fuehrte bei einem maennlichen Probanden zur quantitativen Ausscheidung im Urin innerhalb von 24 Stunden. Der ausgeschiedene Hauptmetabolit 2-Phenoxyessigsaeure lag im Urin 85% frei und 15% als saeurelabiles

Konjugat vor; die unveraenderte Testsubstanz konnte im Urin nicht nachgewiesenwerden. Bei 4 Probanden (1m, 3w), denen eine Hautcreme mit 1.2% der Testsubstanz dermal appliziert wurde, konnten 9 - 48 % der aufgenommenen Testsubstanz im Urin wiedergefunden werden. Bei einem Probanden wurden innerhalb von 6 Stunden 55% der aufgenommenen Testsubstanz im Urin wiedergefunden. [Test substance (10.6 mg in water) given orally to male rats was quantitatively eliminated in urine within 24 hours. Eighty five percent of the eliminated principal metabolite 2-phenoxyacetic acid was present in the urine in free form and 15% as the acid labile conjugate. The unchanged test substance could not be detected in the urine. With four animals (1 male and 3 female) to which a skin cream with 1.2% of the test substance was dermally applied, 9-48% of the absorbed test substance could be recovered in the urine. With one sample 55% of the absorbed test substance was recovered in the urine within 6 hours].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (90)

Type : Metabolism
Remark : Die orale Gabe der Testsubstanz an jeweils 4 Tiere (15.6, 27.4, 160.7 mg/kg) fuehrte zu einer Wiederfindung der applizierten Substanz zwischen 95 und 98%; hierbei wurden 91-94% im Urin, 0.8-1.3% in den Faeces gefunden, 1.3-2.2% wurden als Kohlendioxid abgeatmet. Bei der dermalen Applikation (6.2 - 24 mg/kg) betrug die Wiederfindungsrate zwischen 65 und 99%; auch hier wurde der Hauptanteil im Urin und nur geringe Mengen in den Faeces gefunden. Im Urin wurden als Hauptmetaboliten die 2-Phenoxyessigsaeure(>75%) und die unveraenderte Testsubstanz sowie zwei weitere Stoffwechselprodukte in geringen Mengen nachgewiesen. [After oral administration to four rats (15.6, 27.4, 160.7 mg/kg) between 95-98% of the test material was recovered; of which 91-94% was in the urine, 0.8-1.3% in the feces and 1.3-2.2% was exhaled as carbon dioxide. With dermal application (6.2-24 mg/kg), the recovery rate was between 65-99%; the major portion also was in the urine and only small amounts were in the feces. In urine the chief metabolite was 2-phenoxyacetic acid (>75%) and the unchanged test substance as well as two further metabolized products in small amounts].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.

16.02.2002 (90)

Type : Toxicokinetics
Remark : Es wurde die Aufnahme, Verteilung und Ausscheidung der Testsubstanz bei der Regenbogenforelle untersucht. Die Testsubstanz wurde im Gehirn, in der Leber, der Niere und der Gallenblase, vor allem aber im Kleinhirn nachgewiesen. Die Testsubstanz wurde schnell eliminiert; die biologische Halbwertszeit betrug unter den Versuchsbedingungen ca. 30 Minuten. Es

liegt lediglich das englische Abstract der japanischen Originalliteratur vor. [The uptake, distribution and elimination of the test substance was studied in rainbow trout. The test substance was detected in the brain, in the liver, the kidneys and the gall bladder, especially in the cerebellum. The test substance was eliminated rapidly; the biological half life amounted to about 30 minutes under the test conditions. The study was available only as an English abstract of a Japanese original text].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.
16.02.2002 (95)

Type : other
Remark : Es wurde die Auswirkung der Testsubstanz auf die Herzfrequenz, den Blutdruck und das EKG bei Fischen (Oncorhynchus mykiss) untersucht. Die Testsubstanz fuehrte zu einer drastischen Verminderung von Herzfrequenz und Blutdruck, sowie zu veraendertem EKG. Waehrend der Erholungsphase waren Herzfrequenz und Blutdruck kurzzeitig ueber Normalniveau erhoeht. [The effect of the test substance was studied on the heart rate, blood pressure and the EKG in fish (Oncorhynchus mykiss). The test substance led to a drastic reduction of the heart frequency and blood pressure, as well as an altered EKG. During the recovery phase the heart frequency and blood pressure was elevated above normal level for a short time.]

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated. Purity of the test material is unknown.
16.02.2002 (63)

Type : other
Remark : Flow -cytometric sceening for the modulation of receptor-mediated endocytosis in human dentritic cells. Implications for the development of an in vitro technique for predictive testing of contact sensitizers 2-phenoxyethanol was negative

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-phenoxyethanol, Fluka
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material is unknown.
16.02.2002 (34)

Type : other: (Q)SAR
Remark :
Title: "Application of the Group Contribution Method for Predicting the Toxicity of Organic Chemicals".

Titel: "A QSAR Model of Teratogenesis".

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material is unknown.
16.02.2002 (66) (70)

Type : other: Anaesthesie
Remark : Es wurde die anaesthesierende Wirkung (Herzschlag, EKG, Atmung) der Testsubstanz am Karpfen untersucht. Eine Testsubstanzkonzentration von 400 mg/l fuehrte zu starker Beruhigung, beschleunigter Herztaetigkeit, erhoehter Ventilation bzw. bei 600 mg/l zum wieder normalisierter Herztaetigkeit, veraendertem EKG und verminderter Atmung. Die anaesthetische Wirkung zeigte sich durch Frischwasser reversibel. Bei 800 mg/l wurde fortschreitende Verlangsamungdes Herzschlages, starke EKG-Veraenderungen und zeitweise aussetzende Atmung beobachtet; die Aussetzung gegenueber Frischwasser brachte keine Veraenderung. Der Tod der Fische bei 800 mg/l wurde auf Anoxie durch Laehmung des Atmungszentrums zurueckgefuehrt.

[The anesthetic effect (heart beat, EKG, inhalation) of the test substance was studied in the carp. A test substance concentration of 400 mg/l led to strong calming of the animal, accelerated heart activity, elevated ventilation and 600 mg/l normalized heart activity, altered EKG and reduced breathing. The anesthetic effect was reversible as shown by replacing the water with fresh water. At 800 ml/l progressive retardation of the heart beat was observed, and also pronounced EKG alterations and intermittent breathing. Exposure to fresh water brought no change. The death of the fish at 800 mg/l was attributed to lack of oxygen through paralysis of the breathing center].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000 and was translated. Purity of the test material is unknown.
16.02.2002 (194)

Type : other: QSAR
Remark :
Titel: "QSAR modelling of the ERL-D fathead minnow acute toxicity database".
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material is unknown.
16.02.2002 (115)

Type : other: antitumorigener Effekt [antitumorigenous effect]
Remark : Maennlichen F344 Ratten wurde die Testsubstanz im Trinkwasser (2.5, 5 bzw. 10 mg/ml Trinkwasser, entspr. ca. 230, 460, 930 mg/kg/d) verabreicht. Zusaetzlich zur Substanzbehandlung wurde eine Leukaemie-Zellinie s.c. appliziert. Die Testsubstanz zeigte keinen anti-leukaemischen Effekt (im Gegensatz zu Ethylenglykolmonomethylether). [Male F344 rats were administered the test substance in drinking water (2.5, 5 and 10 mg/l concentrations corresponding to 230, 460 and 930 mg/kg/d). At the same

time of the substance administration a leukemia cell culture was applied s.c. The test substance showed no antileukemia effect (in contrast to ethylene glycol monomethyl ether)].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000 and was translated. Purity of the test material is unknown.
(49)

Type : other: in vitro predictive testing of contact sensitizer
Remark : Predictive testing of contact sensitizers in vitro by monitoring their influence on endocytotic mechanisms

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-phenoxyethanol, Fluka
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material is unknown.
16.02.2002 (101)

Type : other: review
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material is unknown.
16.02.2002 (68)

Type : other: zusammenfassende Darstellungen [summarized presentation]
Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)
Test substance : 2-Phenoxyethanol
Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000. Purity of the test material is unknown.
16.02.2002 (54) (55) (60) (79) (121) (160)

5.10 EXPOSURE EXPERIENCE

Result : Twelve panelists had reactions of varying duration following irradiation. Five had readily visible but mild reactions (a score of 1) at 1 hour, three panelists had scores of 1 at 24 hours, and one had a score of 1 at both 1 and 24 hour. All of these reactions had subsided by the next evaluation. The final two panelists had reactions at 1, 24 and 48 hr, and at 1, 48 and 72 hr, respectively. All of these reactions were readily visible but mild. One panelist also had a mild reaction at 72 hours at the unexposed patch site. This panelists had no reactions at the irradiated site.

It was concluded that phenoxyethanol was not phototoxic under the conditions of the study.
Test condition : Phenoxyethanol (0.3 ml) was applied undiluted to patches which were then applied in duplicate to the volar surface of the forearm of each of 28 panelists (male and female, aged 18-50). One patch was removed after 24 hr. The site was rinsed and dried, and was then exposed for 10 min to 16-20 J/cm of UVA light. The second patch was removed, and the site was rinsed and dried. All sites were evaluated 1, 24, 48 and 72 hours

after irradiation.

Reliability : (2) valid with restrictions. . Data came from a CIR Final report on the safety of phenoxyethanol published in J. Am. Coll. Toxicol. 9 (2): 259-277 (1990). Purity of the material was not listed.

13.03.2002 (89)

Remark : Multi-center Studie: 3726 Patienten (2294 Frauen, 1432 Maenner) wurden von Juni 1989 bis Mai 1990 mit dem Konservierungsmittel Euxy (R) K 400 (1,2-Dibrom-2,4-dicyanbutan und Phenoxyethanol) in 15 Klinikenepikutan getestet. Die Reaktivitaet war gering: Irritative (unspezifische) Reaktionen auf Dibromdicyan (BCB) zeigten sich in zwoelf (.3 %), auf Euxyl K 400 in sechs (0.16 %) und auf Phenoxyethanol in neun Faellen (0.24 %). Kontakt-allergische Reaktionen auf Euxyl K 400 wurden festgestellt bei 36 (1.0 %), auf Dibromdicyanbutan bei 30 (0.8 %) und auf Phenoxyethanol bei einem Patienten. [Multi-center study: 3726 patients (2294 women, 1432 men) were tested from June 1989 until May 1990 with the preservative Euxy ® K 400, 1,2-dibromo-2,4-dicyanobutane, and phenoxyethanol in 15 clinics percutaneously. The reactivity was minimal: irritative (unspecific) reactions toward dibromodicyanobutane (BCB) were seen in 12 patients (.3%), toward Euxyl K 400 in 6 patients (0.16%) and toward phenoxyethanol in new cases (0.24%). Contact-allergic reactions with Euxyl K 400 were determined in 36 patients (1.0%), 30 patients (0.8%) and with dibromodicyanobutane, and one patient with phenoxyethanol].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000 and was translated. Purity of the material is unknown.

16.02.2002 (65)

Remark :

This study was originally described in an European IUCLID document as follows: Fallbericht: Es werden 3 Faelle von akuten und chronischen zentralnervoesen Stoerungen beim Umgang mit 2-Phenoxyethanol beschrieben. Nach Hautkonatkt ueber einen Zeitraum von 5 Monaten bis 2 Jahren traten unmittelbar nach Beginn der Exposition Kopfschmerzen, Schwaechegefuehl und Muedigkeit auf, und nach 1-2 Jahren kognitive Stoerungen, die auch zwei Jahre nach Expositionsende nur leichte Verbesserungen zeigten. Die Exposition ist nicht genau quantifiziert. Es liegen keine Vergleichsbefunde (Vorbefunde, Kontrollgruppe) vor. Angaben zu weiteren gehandhabten Stoffen und dem Arbeitsumfeld fehlen.

This translates to: [Case report: Three cases of acute and chronic central nervous disturbances associated with 2-phenoxyethanol were described. After skin contact over a time period of 5 months to 2 years headaches, general weakness and tiredness was experienced after the beginning of the exposure, and after 1-2 years cognitive disturbances were observed that even 2 years after the end of exposure improved only slightly. The exposure was not quantified. No basis of comparison (exposed versus control groups) is available. Data on concurrent exposure to other substances present in the workplace are lacking].

The study was reviewed. The following summary contains information obtained from this review: The three subjects were women employed in a fish hatchery in a rural Oregon community, who tagged and/or trimmed fish from 1983 to 1985. Each tagger put about 80 fingerlings into a small dishpan about half full of water, added several “squirts” of 2-

phenoxyethanol to partially anesthetize the fish, then picked up the fish bare-handed for tagging. For fish trimming, larger pans and more 2-phenoxyethanol were used. The three taggers/trimmers handled about 4000 to 8000 fish per day. Use of phenoxyethanol was discontinued in April, 1985.

Patient 1 was a 34-year old lefthanded white woman who started working at the hatchery in March, 1983. From the beginning, she had mild signs of intoxication on the job, followed by weakness and partial numbness in the left hand and left median nerve parethesia. In February of 1984, she started experiencing chronic, excessive fatigue, abnormal irritability, forgetfulness, difficulty maintaining concentration and alcohol intolerance. Beginning in early 1985, she experienced tachycardia and dyspnea while tagging or trimming. In March of 1985, she went on medical leave and was referred to a clinic. On examination, she had diminished left hand grip strength and impaired recent memory. Neurological testing in June 1985 showed low-average intellectual function, significant additional impairment of verbal learning and comprehension and impaired dexterity and strength in the left hand. Nerve conduction measurements and a CT scan were normal. Testing in September 1986 showed improved intellectual function, normal hand strength and continued impairment of sustained concentration and visual-motor assembly. Visual memory was normal, but verbal and spatial learning and memory continued to be impaired.

Patient 2 was a 35-year old white woman who started working in June, 1983. She had weakness and numbness of both hands when tagging or trimming fish. By the summer of 1984 she was aware of constant irritability and forgetfulness. She had brief blank spells that caused her to fail to complete sentences. By the winter and spring of 1985 she had slow mental function, abnormal somnolence in the late afternoons and workdays, less steady balance, and an intolerance to alcohol. She began medical leave in July. She was referred the neurological clinic and had a normal neurologic cognitive function examination in March 1986. Additional testing showed impairments of sustained concentration, spatial memory and ability to conceptualize. In March 1987, repeat testing showed some improvement in concentration, some deterioration in visual memory and continued limitation of conceptualization. An electroencephalogram and a CT scan were normal. In January of 1988 she reported vestibular dysfunction symptoms from elevator rides and riding in a car over a mountain pass. In May 1988 a neuro-otologist diagnosed bilateral labyrinthine hypofunction. No further followup was noted.

Patient 3 was a 21-year old white woman who started tagging or trimming in Dec 1984. She developed headaches after 2 weeks, and migraines after 1 month. By February of 1985 the headaches were occurring on weekends and her weight had dropped by approximately 8 kg. She experienced afternoon and evening somnolence, restless sleep, abnormal irritability, depression, abnormal forgetfulness and difficulty with concentration. She passed out twice during work. In April 1985 she developed a rash on her right hand and forearm and an enlarged liver (without evidence of viral hepatitis). She was placed on medical leave and some of her symptoms abated within 2 weeks. She returned to work in Dec 1985 (after phenoxyethanol use had been discontinued). At work she had a mild hand tremor and less dexterity than before, but did not have numbness or weakness of hands, depression or abnormal sleep. She quit work in May 1986 to have a baby. She was referred to the neurologic function clinic in Jan 1987 because of persistent headaches, forgetfulness and difficulty in concentration. She had a normal exam, except for slowed rapid alternating finger movement on the right hand. There were no sensorimotor deficits.

Neuropsychologic testing showed low-average intellectual function with significant impairment of new learning, recent memory, concentration ability, and visual motor assembly skills. No further followup was noted.

Reliability : (4) not assignable
(4) not assignable. The concentration of phenoxyethanol (or other chemicals) that the subjects were exposed to were not listed. Neurologic function prior to employment was not assessed. Therefore, it is unknown if some of the deficits were present prior to employment. Changes were present in subjective measures of neurologic function, but not in objective tests such as CT scans, nerve conduction measurements and electroencephalograms. Use of alcohol and other substances that could have influenced the results was not listed. A detailed history of work prior to employment at the hatchery was not obtained. No basis of comparison (exposed versus control groups) is available. Numbers of workers who performed the same job but did not experience symptoms were not noted. The effects were not clearly presented and the contribution of a highly repetitive, tedious task to reported signs was not considered. Existing animal data do not indicate any nervous system effects other than possible depression of the CNS.

16.02.2002 (113)

Remark : An adverse reaction occurred in a patient with a 6-month history of hand eczema and a childhood history of flexural eczema after use of an aqueous cream containing 1% phenoxyethanol in place of soap. This patient had a positive patch test to phenoxyethanol.

Reliability : (2) valid with restrictions. Data came from a CIR Final report on the safety of phenoxyethanol published in J. Am. Coll. Toxicol. 9 (2): 259-277 (1990).

16.02.2002 (102)

Remark : Phenoxyethanol (5% in petrolatum) was patch tested according to ICDRG guidelines on 501 patients who were undergoing patch testing for suspected contact dermatitis. There was 1 positive reaction, for a 0.2% positive rate.

Test substance : Test material was 5% phenoxyethanol in petrolatum.

Reliability : (2) valid with restrictions. Data came from a CIR Final report on the safety of phenoxyethanol published in J. Am. Coll. Toxicol. 9 (2): 259-277 (1990).

16.02.2002 (48)

Remark :
Uebersichtsarbeit: experimentelle Untersuchung an 51 Probanden, keine Hautreizung oder Sensibilisierung bei Testung mit Phenoxyethanol (0.3 ml). experimentelle Untersuchung an 138 Probanden, keine Sensibilisierung bei Testung mit Phenoxyethanol (10 % in Vaseline). experimentelle Studie an 28 Probanden, keine Photosensibilisierung bei Testung mit Phenoxyethanol (0.3 ml). [Survey review: experimental study of 51 probes, no skin irritation or sensitization on testing with phenoxyethanol (0.3 ml). Experimental study with 138 probes, no sensitization on testing with phenoxyethanol (10% in Vaseline). Experimental study with 28 probes, no photosensitization on testing with phenoxyethanol (0.3 ml)].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000 and was translated.

16.02.2002 (60)

Remark : Fallbericht: positive Patch-Testreaktion auf Phenoxyethanol (5 % in Vaseline) bei einem von 11 Patienten mit Kontaktekzem. [Case report: positive patch test reaction with phenoxyethanol (5% in Vaseline) with one of 11 patients with contact eczema].

The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000 and was translated.

16.02.2002 (143)

Remark : Fallbericht: negative Patch-Testreaktion auf Phenoxyethanol (1 % in Vaseline) bei 2 Patienten mit Kontaktdermatitis auf Euxyl K 400 [Case report: negative patch test reaction of phenoxyethanol (1% in Vaseline) in two patients with contact dermatitis on Euxyl K 400].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000 and was translated.

16.02.2002 (132)

Remark : Fallbericht: gute Wirksamkeit einer exterenen 2.2 % Phenoxyethanol-Lsg. bei 3 Patienten mit Hautinfektion mit Pseudomonas aeruginosa. [Case Report: Good effectiveness of an external solution of 2.2% phenoxyethanol solution with 3 patients with skin infection with Pseudomonas aeruginosa].

Source : BASF AG Ludwigshafen
EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA)

Reliability : (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000 and was translated.

16.02.2002 (111)

Remark : Erhebung subjektiver Symptome bei Studenten im Umgang mit formaldehyd-praeparierten Leichen, bei denen die verbleibenden Aldehydreste in einem 1 %-igem Phenoxyethanol-Bad ausgewaschen wurden. Von 240 Betroffenen nahmen 113 an der Befragung teil. Ueberwiegend leicht bis maessige Augenreizungen wurden von 33 % und leichte bis maessige Muedigkeit und Schwindel wurden von 35 % angegeben. Die Luftkonzentration fuer Formaldehyd in den Praepariersaealen wurde mit > 0.5 ppm angegeben. [Elevation of subjective symptoms with students in contact with formaldehyde-prepared cadavers, of which the remaining aldehyde residue was washed away with a 1% phenoxyethanol bath. 113 were examined out of 240 exposed. Preponderant light to heavy eye irritation was observed in 33%, and light to heavy tiredness and vertigo was found in 35%. The air concentration for formaldehyde in the preparation rooms was stated to be >0.5 ppm].

Source : BASF AG Ludwigshafen

Reliability : EUROPEAN COMMISSION - European Chemicals Bureau Ispra (VA) (4) not assignable. The study was not reviewed. Data came from a IUCLID document published by the European Chemicals Bureau, dated 11-FEB-2000, and was translated.

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