SAFETY DATA SHEET
(According to GHS rev. 4)
Dipropylene Glycol FG (DPG FG)

1. IDENTIFICATION

Company: **Everchem Specialty Chemicals** **Address:** **1400 N. Providence Road** **Media, PA 19063** **Tel# (484) 234-5030** **Fax# (484) 234-5037**	**Substance Name:** Oxydipropanol **Trade Name:** Dipropylene Glycol FG (DPG FG) **EC No:** 246-770-3 **REACH Registration No:** 01-2119456811-38-0020 **CAS No:** 25265-71-8
	Relevant identified uses of the substance or mixture and uses advised against: Please check the identified uses in ***Appendix (separately attached)** of this safety data sheet.
	Emergency Telephone: **CHEMTREC: (800) 424-9300**

2. HAZARD IDENTIFICATION

2.1 LABEL ELEMENTS

Warning word	**No Signal Word**		
Hazard statement	Not a dangerous substance according to GHS and the other global regulation.	Not a dangerous substance according to GHS and the other global regulation.	Not a dangerous substance according to GHS and the other global regulation.
Classification criteria	**In accordance with Regulation (EC) No 1272/2008:** Substance is not classified in accordance with Regulation (EC) No 1272/2008	**In accordance with Directive 67/548/EEC:** Substance is not classified in accordance with Directive 67/548/EEC.	**Not a dangerous substance according to GHS and the other global regulation.**
Label elements:	**No label** according to Regulation (EC) no 1272/2008	**No Signal and Symbol according to GHS and the other global regulation.**	**No Signal and Symbol according to GHS and the other global regulation.**

OTHER HAZARDS

This is not considered to be a PVT or VPVB Substance.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substances:

Product identifier type in accordance with Article 18(2) of Regulation (EC) No 1272/2008	**Identifier Number**	**Identification name**	**Weight % content (or range)**	**EC Number**
CAS Number	25265-71-8	[1]oxydipropanol	100%	246-770-3

[1]Substance is not classified in terms of Regulation (EC) No. 1272/2008 Annex VI.

4. FIRST-AID MEASURES

Description of first aid measurers:
Inhalation: If effects of exposure appear, move the patient to a non-polluted area. If chemical is inhaled, consult with medical personnel immediately..
Skin contact: Wash clothing or shoes contaminated with a chemical substance before reuse. Take off and remove clothing or shoes contaminated with a chemical substance. Immediately take off and wash with soapy water for over 15 minutes to remove chemical substances
Eye contact: Irrigate eyes with a heavy stream of water for over 15 minutes.
Ingestion: If chemicals are ingested, consult with medical personnel.
Most important systoms and effects, both acute and delayed: No data available.
Indication of any immediate medical attention and special treatment needed: No data available.

5. FIRE-FIGHTING MEASURES

Extinguishing media:

Suitable extinguishing media: CO_2, powder fire extinguishing agent, water, ordinary foam.

Unsuitable extinguishing media: No data available.

For Big Fires: Use an ordinary fire- fighting agent and a fine water spray.

Special hazards arising from the substance or mixture:

Pyrolysis Products: Acids, aldehydes, carbon monoxide.

Fire and Explosion risk: Slight risk of fire.

Advice for fire fighters: Move the case from near the fire if work can be done without risk. Spray high-pressure water on the leaked substance to prevent scattering. Construct a bank for further processing. Use a fire extinguisher that has been used and found effective for nearby fire. Avoid inhalation of substances or their fumes. Stand facing the wind and avoid low areas.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Workers should only stop a chemical spill if it is not dangerous to do so.	**Methods and material for containment and cleaning up:** **Small spills:** For further disposal, move the leaked substance to a suitable case and dispose. Absorb using nonflammable substances. Quarantine the exposed area and restrict access to the area except for the related personnel. **Large spills:** No data available.
Environmental precautions: No data available.	**Reference to other sections:** See Section 7 for information on safe handling.

7. HANDLING AND STORAGE

Precautions for safe handling: Store in an enclosed case. Ventilate using an overall or local air exhauster. Wash the body and clothing after using chemicals.

Conditions for safe storage, including any incompatibilities: Store in an enclosed case.
Store in a cool and dry place. Avoid contact with moisture. Avoid contact with halogens and intermediate halogens. Store and use in accordance with the laws and regulations of the relevant government department and local self-governing bodies. Store in well-vented areas.

Specific end use(s): No data available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control paramaters: Community workplace exposure limits were not established.

DNELs:

Exposure pattern	DNEL	
	Workers	General Population
Long-term – inhalation, systemic	238 mg/m³	70 mg/m³
Long-term – dermal, systemic	84 mg/kg bw/day	51 mg/kg bw/day
Long-term – oral, systemic	-	24 mg/kg bw/day

PNECs:

Freshwater	1000
PNECmarine-water	313
PNECintermittent	
PNECsediment	
PNECsoil	
PNECSTP microbes	
PNECoral	

Exposure controls: The usual precautionary measures are to be adhered to when handling chemicals.

Appropriate engineering controls: Check whether the work process complies with the allowable standards and exposure standards of the Ministry of Labor. Install a ventilation device, such as a local exhauster, to ensure a suitable control wind speed.

Individual protection measures, such as personal protective equipment:

Eye/face protection: Install an emergency shower and basins for easy use by workers. Wear protective glasses to protect the eyes from scattering substances.

Skin protection:

Hand protection: Wear chemical resistant gloves to avoid the direct contact of water and chemicals.

Other: Wear chemical resistant protective wear to protect the skin.

Respiratory protection: Make sure to wear protection devices certified by KOSHA.

Thermal hazards: No data available.

Environmental exposure controls: Do not allow to enter sewers/surface or ground water.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties:	
Appearance:	Liquid(colorless, very hygroscopic)
Odour:	odourless
Odour threshold:	-
pH:	-
Melting point/freezing point:	< -20 ˚C
Initial boiling point and boiling range:	227˚C at 98.36 kPa
Flash point:	130 ± 2˚C at 98.88 kPa
Evaporation rate:	-
Flammability (solid, gas):	The substance is not flammable.
Upper/lower flammability or explosive limits:	-
Vapour pressure:	1.3 Pa at 25 ˚C
Vapour density:	4.63 (air=1).
Relative density:	1.02 at 20 ˚C
Solubility(ies):	Miscible with water at 20 ˚C
Partition coefficient: n-octanol/water:	-0.462 at 21.7 ˚C and pH = 6
Auto-ignition temperature:	332 ± 5˚C at 98.96-100.18 kPa
Decomposition temperature:	-
Dynamic viscosity:	118 mm^2/s at 20 ˚C, 32 mm^2/s at 40 ˚C
Explosive properties:	The substance is non explosive.
Oxidising properties:	The substance is non oxidizing.
Other information: Surface tension:	71.4 mN/m in 1.01 g/L solution at 22 °C

10. STABILITY AND REACTIVITY

Reactivity: No data available.

Chemical stability: Stable at room temperature and normal pressure.

Possibility of hazardous reactions: No polymerization.

Conditions to avoid: Heat, flames, sparks and other sources of ignition. Avoid contact with substances that are prohibited for mixing.

Incompatible materials: Acids, bases, combustible substances, halogen carbon chemicals, metals, metallic salts, oxidizers, reducers.

Hazardous decomposition products: Pyrolysis products or burning products (Carbon Oxide)

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects:

Acute toxicity:

Dipropylene glycol has a low acute toxicity by oral, dermal and inhalation routes. In rats, LD50 value by oral route is > 5000mg/kg bw. In the acute dermal toxicity study with rabbits, LD50 was > 5010 mg/kg bw. The classification for acute toxicity is not warranted based on these values. In the acute inhalation toxicity study with rats, LC50 value was > 2.34 mg/l/4h. The latter value is below the cut-off value of 5 mg/l/4 h, established for classification of aerosols in accordance to Directive 67/548/EEC. However, as higher concentration levels were not attainable and based on the absence of mortality and of any clinical signs of toxicity in the study, the classification of dipropylene glycol for acute inhalation toxicity is not warranted.

Acute toxicity: oral(1)

Method: EPA OPP 81-1 (Acute Oral Toxicity)
Species: rat (Sprague-Dawley) male/female
Routes of administration: oral: gavage
Results: LD50: > 5 g/kg bw (male/female)

Acute toxicity: oral(2)

Method: equivalent or similar to OECD Guideline 401 (Acute Oral Toxicity)
Species: rat (Wistar) male/female
Routes of administration: oral: gavage
Results: LD50: 15.8 mL/kg bw (male/female)

Acute toxicity: inhalation

Method: EPA OPP 81-3 (Acute inhalation toxicity)
Species: rat (Sprague-Dawley) male/female
Routes of administration: inhalation: aerosol (whole body)
Results: LC50 (4 h): > 2.34 mg/L air (male/female)

Acute toxicity: dermal

Method: EPA OPP 81-2 (Acute Dermal Toxicity)
Species: rabbit (New Zealand White) male/female
Coverage: occlusive
Vehicle: unchanged (no vehicle)
Results: LD50: > 5010 mg/kg bw (male/female)

Skin corrosion/irritation:

The substance is not classified for skin corrosion/irritation according to Regulation (EC) No 1272/2008.

Human data(1)

Method

Study type: 24-h semioccluded patch study in human volunteers

Subjects: 30 female and 3 male subjects entered and completed the study. The test ubstance was prepared as a 25% solution in distilled water. 0.2 ml of the solution was placed on the patch pad and applied on the paraspinal region of the back. Eight test articles, in addition to a positive irritant (0.5% sodium lauryl sulfate) and two negative irritant controls (distilled water and mineral oil USP), were tested simultaneously in this study. All skin sites were scored prior to the application, 30 min after the removal of the 24 h application and again 24 h following patch removal.

Endpoint addressed: skin irritation / corrosion

Species: human

Results: Under the conditions of the study, dipropylene glycol exhibited mild irritation compared to that of the positive control. Two subjects were clear at the 30 min evaluation, however, the response increased to mild erythema at the 24h evaluation. Nine subjects exhibited mild to moderate erythema at the 30 min evaluation. Seven of these subjects responses were resolved by the 24 h evaluation. The remaining two subjects exhibited mild erythema at the 24h evaluation.

Human data(2)

Method:

Study type: Cumulative 14-day skin irritation test with dipropylene glycol (100% and 50% solution in water) in human volunteers.

Subjects: 26 male and female volunteers (18 to 70 years) with self assessed sensitive skin were used; 25 subjects completed the study. Approximately 0.2 ml of each test material was applied neat and as 50% aqueous solutions to the upper back under occlusion. The test material was applied to the appropriate treatment side Monday through Friday. Patches applied on Friday remained in place until the following Monday for a total of 14 days of skin contact. Evaluation of each test site was conducted prior to each test application. No positive controls were used in the study.

Endpoint addressed: skin irritation / corrosion

Species: human

Results: Upon application of neat dipropylene glycol, one out of 26 subjects showed mild erythema (faint but definite pink skin) during the first 4 days of exposure to neat dipropylene glycol. Further exposure did not result in any signs of irritation in this volunteer. The other 25 subjects did not show any signs of skin irritation at any time of the exposure.

Animal data

Method: EPA OPP 81-5 (Acute Dermal Irritation)

Coverage: occlusive (clipped closely)

Species: rabbit (New Zealand White)

Results: Erythema score: 0 of max. 4; mean; 24 + 48 + 72 hr; no effects at 24 hr and thereafter, Edema score: 0 of max. 4; mean; 24 + 48 + 72 hr; no effects at 24 hr and thereafter

Serious eye damage/irritation:

The substance is not classified for eye damage/irritation according to Regulation (EC) No 1272/2008.

Method: EPA OPP 81-4 (Acute Eye Irritation)

Species: rabbit (New Zealand White)

Vehicle: unchanged (no vehicle)

Results: Cornea score: 0 of max. 4; mean; 24 + 48 + 72 h; no effects at 24 h and thereafter, Iris score: 0 of max. 2; mean; 24 + 48 + 72 hr; no effects at 24 h and thereafter, Conjunctivae score: 0 of max. 3; mean; 24 + 48 + 72 hr; no effects at 24 hr and thereafter, Chemosis score: 0 of max. 4; mean; 24 + 48 + 72 hr; no effects at 24 hr and thereafter

Respiratory irritation: not available.

Skin sensitization:

The substance is not classified for skin sensitization according to Regulation (EC) No 1272/2008.

Human data

Method

Study type: study with volunteers

Type of population: general

Subjects: TYPE OF TEST(S) USED: patch test (epicutaneous test)

ADMINISTRATION

- *Type of application:* patches were applied using Scanpor test and Finn Chambers
- *Vehicle / solvent:* water
- *Concentrations:* 10%, 5%, 2% and 1% in a pilot study, 10% in the consecutive study
- *Testing/scoring schedule:* patches were applied for 2 days and reactions scored at days 2, 3 and 5-7

Species: human male/female

Results: NO. OF PERSONS WITH/OUT REACTIONS COMPARED TO STUDY POPULATION (cosmetic grade / synthesis grade):

- Number of subjects with positive reactions: 0 / 1
- Number of subjects with negative reactions: 488 / 480
- Number of subjects with equivocal reactions: 13 / 17
- Number of subjects with irritating reactions: 2 / 5

Animal data

Method: EPA OPP 81-6 (Skin Sensitization)

Coverage: Buehler test

Species: guinea pig male/female *Induction:* epicutaneous, occlusive *Challenge:* epicutaneous, occlusive *Vehicle:* unchanged (no vehicle) *Results:*

No. with positive reactions:

1st reading: 0 out of 10 (test group); 24 h after chall.; dose: 0.5 ml

1st reading: 1 out of 5 (negative control); 24 h after chall.; dose: 0.5 ml 2nd reading: 0 out of 10 (test group); 48 h after chall.; dose: 0.5 ml

2nd reading: 0 out of 5 (negative control); 48 h after chall.; dose: 0.5 ml 3rd reading: 0 out of 10 (test group); 72 h after chall.; dose: 0.5 ml

3rd reading: 0 out of 5 (negative control); 72 h after chall.; dose: 0.5 ml

Respiratory sensitization:

No information available on respiratory sensitization.

Germ cell mutagenicity:

The substance is not classified for germ cell mutagenicity according to Regulation (EC) No 1272/2008.

Bacterial reverse mutation assay (e.g. Ames test) (gene mutation)(1)

Method: The genetic toxicity of dipropylene glycol was assessed by testing the ability of the chemical to induce mutations in various strains of Salmonella typhimurium.

Species/strain: S. typhimurium, other: TA97, TA98, TA100, TA1535, TA1537 (met. act.: with and without)

Doses: 0, 100, 333, 1000, 3333 and 10000 µg/plate

Results: negative for S. typhimurium, other: TA97, TA98, TA100, TA1535, TA1537 (all strains/cell types tested); met. act.: with and without; cytotoxicity: no

Bacterial reverse mutation assay (e.g. Ames test) (gene mutation)(2)

Method: OECD Guideline 471 (Bacterial Reverse Mutation Assay)

Species/strain: S. typhimurium, other: TA98, TA100, TA1535, TA1537, TA1538 (met. act.: with and without)

Doses: 0.100, 0.316, 1.00, 3.16, 10.0, 31.6 and 100 µl/plate

Results: negative for S. typhimurium, other: TA98, TA100, TA1535, TA1537, TA1538 (all strains/cell types tested); met. act.: with and without; cytotoxicity: no

Mammalian cell gene mutation assay (gene mutation)

Method: equivalent or similar to OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation Test)

Species/strain: mouse lymphoma L5178Y cells (met. act.: with and without)

Doses:

In the range-finding test: 0.1, 0.5, 1.0, 5.0, 10, 50, 100, 500, 1000 and 5000 µg/ml

In the main test: 50, 100, 300, 500, 700, 1000, 2500 and 5000 µg/ml

Results: negative for mouse lymphoma L5178Y cells(all strains/cell types tested); met. act.: with and without; cytotoxicity: no, but tested up to limit concentrations

In vivo data(micronucleus assay (chromosome aberration))

Method: OECD Guideline 474 (Mammalian Erythrocyte Micronucleus Test), EPA OPPTS 870.5395 (In Vivo Mammalian Cytogenics Tests: Erythrocyte Micronucleus Assay)

Species/strain: mouse (CD-1) male

Routes of administration: oral: gavage

Doses: 0, 500, 1000 and 2000 mg/kg bw (nominal conc.) Results: Genotoxicity: negative (male); toxicity: no effects

Carcinogenicity(1):

The substance is not classified for carcinogenicity according to Regulation (EC) No 1272/2008.

Method: Drinking water exposure of the male and female rats (50/sex/dose) to 0, 2500, 10000 and 40000 ppm dipropylene glycol for 105 weeks.

Species/strain: rat (Fischer 344) male/female

Routes of administration: drinking water

Doses:

0, 0.25, 1 and 4 mg/ml (target in vehicle).

115, 470 and 3040 mg/kg bw/day (males), 140, 530 and 2330 mg/kg bw/day (females) (actual ingested)
Exposure: 105 weeks (Daily)
Results:
NOAEL (carcinogenicity): 3040 mg/kg bw/day (actual dose received) (male) (No neoplastic lesions at the highest dose tested.)
NOAEL (carcinogenicity): 2330 mg/kg bw/day (actual dose received) (female) (No neoplastic lesions at the highest dose tested.)
Neoplastic effects observed in any test group: no effects

Carcinogenicity(2):

The substance is not classified for carcinogenicity according to Regulation (EC) No 1272/2008.
Method: Drinking water exposure of the male and female mice (50/sex/dose) to 0, 10000, 20000 and 40000 ppm dipropylene glycol for 104 or 105 weeks.
Species/strain: mouse (B6C3F1) male/female *Routes of administration:* drinking water *Doses:*
0, 0.25, 1 and 4 mg/ml (target in vehicle)
735, 1220 and 2390 mg/kg bw/day (males); 575, 1040 and 1950 mg/kg bw/day (females) (actual ingested)
Vehicle: water
Exposure: 104 or 105 weeks (Daily)
Results:
NOAEL (carcinogenicity): 2390 mg/kg bw/day (actual dose received) (male) (No neoplastic lesions at the highest dose tested.)
NOAEL (carcinogenicity): 1950 mg/kg bw/day (actual dose received) (female) (No neoplastic lesions at the highest dose tested.)
Neoplastic effects observed in any test group: no effects

Reproductive toxicity:

The substance is not classified for reproductive toxicity according to Regulation (EC) No 1272/2008.
Efects on fertility(continuous breeding reproduction study)
Method: NTP Reproductive Assessment by Continuous Breeding (RACB)
Species: mouse (CD-1) male/female
Routes of administration: oral: drinking water
Doses:
0, 1.82, 4.80 and 10.10 g/kg bw/day (main study) (actual ingested) 5% in water (post-cohabitation)(nominal in water)
Exposure: 14 days in the dose rangefinding study; 7 days pre-mating period, 98 days (14 weeks) cohabitation, 21 days post-cohabitation. Any litters delivered during these 21 days were kept for at least 21 days (weaning); dosing at 74 ± 10 days of age until mating (mother was dosed throughout). (Daily)
Results:
NOAEL (P): 10100 mg/kg bw/day (actual dose received) (male/female) (No effects reported at the highest dose tested.)
NOAEL (F1): 10100 mg/kg bw/day (actual dose received) (male/female) (No effects on fertility of F1 generation were observed at the highest dose.)
NOAEL (F2): 10100 mg/kg bw/day (male/female) (No effects on litter size, sex and pup weight in F2 pups were observed at the highest dose.)

Developmental toxicity(1)

Method: equivalent or similar to OECD Guideline 414 (Prenatal Developmental Toxicity Study)
Species: rat (Sprague-Dawley)
Routes of administration: oral: gavage
Doses: 0, 800, 2000 and 5000 mg/kg bw/day (nominal conc.)
Exposure: Gestation days 6-15 (Once daily)
Results:
NOAEL (developmental toxicity): 5000 mg/kg bw/day (No developmental effects observed at the highest dose tested)
NOAEL (maternal toxicity): 800 mg/kg bw/day (Clinical signs of toxicity at 2000 and 5000 mg/kg bw/day (ataxia, weight loss, lethargy, unstable gait, piloerection, morbidity and/or mortality); significant increase in the relative liver weight.)

Developmental toxicity(2)

Method: equivalent or similar to OECD Guideline 414 (Prenatal Developmental Toxicity Study)
Species: rabbit (New Zealand White)
Routes of administration: oral: gavage
Doses: 0, 200, 400, 800 and 1200 mg/kg bw/day (nominal conc.)
Exposure: Gestation days 6-19 (Once daily)
Results:
NOAEL (developmental toxicity): >= 1200 mg/kg bw/day (No developmental effects observed at the highest dose tested)
NOAEL (maternal toxicity): >= 1200 mg/kg bw/day (No signs of toxicity observed at the highest dose tested.)

STOT-single exposure:

Substance is not classified for specific target organ toxicity after single exposure according to Regulation (EC) No. 1272/2008.

STOT-repeated exposure:

The substance is not classified for repeated dose toxicity according to Regulation (EC) No 1272/2008.

Repeated dose toxicity: oral(1)

Method: Drinking water exposure of the male and female rats (50/sex/dose) to 0, 2500, 10000 and 40000 ppm dipropylene glycol for 105 weeks.
Species: rat (Fischer 344) male/female
Routes of administration: combined repeated dose and carcinogenicity (oral: drinking water)
Doses:
0, 2500, 10000 and 40000 ppm (target in vehicle)
115, 470 and 3040 mg/kg bw/day (males), 140, 530 and 2330 mg/kg bw/day (females) (actual ingested)
Exposure: 105 weeks (Daily)
Results:
NOAEL: 470 mg/kg bw/day (actual dose received) (male) (Effects in liver (increased incidence of bile duct hyperplasia) and nose (increased incidence of olfactory epithelial atrophy and degeneration)
NOAEL: 530 mg/kg bw/day (actual dose received) (female) (Effects in liver (increased incidence of bile duct hyperplasia) and nose (increased incidence of olfactory epithelial degeneration))

Repeated dose toxicity: oral(2)

Method: Drinking water exposure of the male and female rats to 0, 5000, 10000, 20000, 40000 or 80000 ppm dipropylene glycol for 14 weeks. Two groups were used: core study and clinical pathology study (10 rats/sex/dose in each group).

Species: rat (Fischer 344) male/female

Routes of administration: subchronic (oral: drinking water)

Doses:

0, 5000, 10000, 20000, 40000 or 80000 ppm (target in vehicle)

425, 890, 1840, 3890 and 12800 mg/kg bw/day (males), 460, 920, 1690, 3340 and 8950 mg/kg bw/day (females) (actual ingested)

Exposure: 14 weeks (Daily)

Results:

NOAEL: 425 mg/kg bw/day (actual dose received) (male) (Statistically significant increases in absolute and relative liver weights at 10000 ppm)

NOAEL: 460 mg/kg bw/day (actual dose received) (female) (Statistically significant increases in absolute and relative liver weights at 10000 ppm)

Repeated dose toxicity: oral(3)

Method: Expert review on renal histopathologic changes in rat toxicology studies with dipropylene glycol

Species: rat (Fischer 344) male/female

Results: Dipropylene glycol caused a marked exacerbation of chronic progressive nephropathy (CPN), a spontaneous age-related disease of laboratory rats, in males exposed chronically to a 4.0% concentration in drinking water. In advanced cases of CPN, implying those cases where functional renal mass had been reduced by CPN to a critical point, an additional, secondary nephropathic change associated with chronic exposure to the test compound was superimposed on the CPN, leading to an end-stage kidney. As rodent CPN has no strict counterpart in humans according to authors, these changes should be regarded as having no significance for human risk assessment.

Repeated dose toxicity: oral(4)

Method: Expert report on hepatic histopathological changes in 2-year rat oral studies with dipropylene glycol.

Species: rat (Fischer 344) male/female

Results: The results of this review are in essential accord with the findings reported in the NTP Technical Report Draft (National Toxicology Program, 2004). Bilary hyperplasia was increased in the female 4% treatment group and in the male 1 and 4% treatment groups. These increases were associated with the dipropylene glycol treatment and could be attributable to dipropylene glycol treatment and the presence of dipropylene glycol or metabolites of dipropylene glycol in bile. Alternatively, the authors suggest that these changes could be secondary to the activated macrophages in the liver via release of cytokines during the process of forming the histiocytic and granulomatous inflammatory lesions. Increased incidence of focal histiocytic inflammation in male rats dosed with0.25, 1.0 and 4.0% dipropylene glycol and increased incidence of focal granulomatous inflammation in the 1 and 4% male rat treatment groups were recognized to be spontaneous lesions in aging rats (Eustis, 1990). The authors conclude that dipropylene glycol treatment is likely to have intensified the rate and degree of their development; however, the biologic siginificance of these lesions is concluded to be relative insignificant by the authors.

Repeated dose toxicity: oral(5)

Method: Expert evaluation of histopathological changes in nasal tissues of rats in 2 year chronic drinking water study.

Species: rat (Fischer 344) male/female

Results: In general, the expert review concurs with the findings of the NTP pathology report. Administration of the high dose of dipropylene glycol in the drinking water induced sitespecific atrophy of olfactory epithelium in the nasal airways of ca. 80% male rats and sitespecific vacuolar degeneration of the olfactory epithelium in approximately 20% of the treated male and female rats. The underlying cellular and biochemical mechanisms responsible for these lesions are not known. The authors postulated that the restricted regional location (olfactory mucosa) and the lack of chronic inflammation associated with the treatment-induced atrophy and vacuolar degeneration of the olfactory epithelium suggests that these epithelial lesions may be due to local metabolism of the compound with generation of toxic metabolites resulting in epithelial injury, degeneration and cellular loss. Why male and not female rats developed olfactory cell atrophy is not known.

Repeated dose toxicity: oral(6)

Method: Tabulation of incidences of nonneoplastic lesions in the kidney, liver, nasal cavity and salivary gland of F-344 rats used as controls in National Toxicology Program 2-year studies reported during the 5-year period (1999-2004) was prepared using the Technical Reports for each applicable study. The number of animals examined per sex and the incidence of each nonneoplastic finding that occurred in kidney, liver, nasal cavity, or salivary gland was extracted and tabulated. For each study the percent incidence for each finding was also calculated and tabulated for each sex. When the incidence of each finding had been entered for all studies, both the total number of animals that had the tissue (organ) evaluated and the total number of occurrences across all studies were calculated and tabulated for each sex. Thereafter, the summary incidence across all studies was calculated and tabulated for each sex.

Species: rat (Fischer 344) male/female

Results: A review of the NTP historical controls database disclosed 35 studies in F-344 rats that had been reported during the 5-year period 1999 through 2004. The studies that were applicable to the tabulated data were reported during July 1999 through December 2004. The results are presented in the attachment of the IUCLID database.

Repeated dose toxicity: oral (7)

Method: Drinking water exposure of the male and female mice (50/sex/dose) o 0, 10000, 20000 and 40000 ppm dipropylene glycol for 104 or 105 weeks.

*Species:*mouse (B6C3F1) male/female

*Routes of administration:*combined repeated dose and carcinogenicity (oral: drinking water)

Doses:

0,2500,10000 and 40000 ppm (target in vehicle)

735, 1220 and 2390 mg/kg bw/day (males); 575, 1040 and 1950 mg/kg bw/day (females) (actual ingested)

Exposure: 104 or 105 weeks (Daily)

Results:

NOAEL: 1220 mg/kg bw/day (actual dose received) (male) (Decreased body weights)

NOAEL: 1040 mg/kg bw/day (actual does received) (female) (Decreased body weights.

Repeated dose toxicity: oral(8)

Method: Drinking water exposure of the male and female mice (10/sex/dose) to 0, 5000, 1000, 20000, 40000 or 80000 ppm dipropylene glycol for 13 weeks.
Species: mouse (B6C3F1) male/female
Routes of administration: subchronic (oral: drinking water)
Doses:
0, 5000, 1000, 20000, 40000 and 80000 ppm (target in vehicle)
715, 1350, 2620, 4790 and 11000 mg/kg bw/day (males); 1230, 2140, 4020, 7430 and 14700 mg/kg bw/day (females) (actual ingested)
Exposure: 13 weeks (Daily)
Results:
NOAEL: 2620 mg/kg bw/day (actual dose received) (male) (Statistically significant increases in relative liver weights at 40000 ppm;)
NOAEL: 7430 mg/kg bw/day (actual dose received) (female) (Increased relative liver weights in 80000 ppm females.)

Aspiration hazard:

The substance is not classified for aspiration hazard according to Regulation (EC) No 1272/2008.

12. ECOLOGICAL INFORMATION

Toxicity: The substance is not classified as hazradous to the aquatic environment according to Regulation (EC) No 1272/2008.

Short-term toxicity to fish

LC50 (96h) for freshwater fish (*Pimephales promelas*), static: 46500 mg/L test mat. (nominal)

LC50 (96h) for freshwater fish (*Oryzias latipes*), semi-static: > 1000 mg/L test mat. (nominal)

LC50 (24h) for freshwater fish (*Oryzias latipes*), semi-static: > 1000 mg/L test mat. (nominal)

LC50 (96h) for freshwater fish : 15167 mg/L

Long-term toxicity to fish

ChV(30d) for freshwater fish: : 1340 mg/L

Short-term toxicity to aquatic invertebrates

EC_{50} (48h) for freshwater invertebrates (*Daphnia magna*), static: > 100mg test mat. (meas. (not specified)) based on: mobility

EC50 (48h) for freshwater invertebrates (*Daphnia magna*), flow-through: > 109mg test mat. (meas. (not specified)) based on: mobility

LC50 (48h) for freshwater invertebrates (*other aquatic crustacea: daphnids*): 5943mg

Long-term toxicity to aquatic invertebrates

ChV(16d) for freshwater fish: : 466 mg/L

Toxicity to algae / aquatic plants

EC50 (72h) for freshwater algae (*Desmodesmus subspicatus*): > 100 mg/L test mat. (nominal) based on: biomass

EC50 (72h) for freshwater algae (*Desmodesmus subspicatus*): > 100 mg/L test mat. (nominal) based on: growth rate

NOEC (72h) for freshwater algae (*Desmodesmus subspicatus*): > 100 mg/L test mat. (nominal) based on: growth rate

EC50 (96h) for freshwater algae (*green algae*): 968 mg/L

Toxicity to other aquatic organisms

LC50 (48h) for vertebrates (*Xenopus laevis*): 3181 mg/L test mat. (nominal) based on: mortality

Toxicity to aquatic micro-organisms

EC50 (18h), (*Pseudomonas putida*), static: > 1000 mg/L mat. (nominal) based on: growth inhibition

Persistence and degradability: A closed bottle test (OECD 301F) showed that dipropylene glycol is ready biodegradable. Therefore, dipropylene glycol can be regarded as not persistnet.

Bioaccumulative potential: Based on the result of the octanol/water partition coefficient (Log Kow of -0.46) and from results of the bioaccumulation study with carp species, it is expected that dipropylene glycol has no bioaccumulative potential.

Mobility in soil: No data available.

Results of PBT and vPvB assessment: An assessment of the PBT status of dipropylene glycol has been made using all available data. The information available suggests that dipropylene glycol does not meet the PBT screening criteria as outlined in Annex XIII of Directive **2006/121/EC.**

Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods:

Disposal Methods: Discard the contents and case according to the regulations if it is regulated in the Waste Management Act.

Caution for Disposal: Consider the caution indicated in the regulations if it is regulated in the Waste Management Act.

14. TRANSPORT INFORMATION

ADR/RID/ADN: The substance is not subject to international regulations on transport of dangerous goods.

IMDG: The substance is not subject to international regulations on transport of dangerous goods.

ICAO/IATA: The substance is not subject to international regulations on transport of dangerous goods.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture:

Authorizations: not required

Restrictions on use: none

Other EU regulations: Oxydipropanol is not a SEVESO substance

Oxydipropanol is not an ozone depleting substance and not a persistent organic pollutant

Water contaminating class: WGK 1 slightly water endangering (Germany regulation)

Chemical safety assessment: A chemical safety assessment has been carried out for this substance.

16. OTHER INFORMATION

Indication of change:

List of relevant risk phrases and hazard statements –

Training advice: Product handling instruction shall be included into the educational system about the safety work (initial training, training at the workplace, repeated training) according to specific conditions at the workplace.

Recommended restrictions on use (i.e. non-statutory recommendations by supplier): Substance should not be used for any other purpose than for which is appointed (point 1.2). Because of the fact that specific conditions of use of substance are out of supplier's control, it is the responsibility of the user to adjust the prescribed warnings to local laws and regulations. Safety information describes the product in terms of safety and it cannot be considered as technical information about product.