GRUPPO 5 - Propylene Glycol

Nome chimico Propane-1,2-diol
CAS 57-55-6
Function and uses CARRIER,SOLVENT, HUMECTANT
CARATTERISTICHE CHIMICO FISICHE
PESO MOLECOLARE 76,1
PUREZZA:
SOLUBILITA': solubile in acqua
Stato fisico: liquido
Log pow = - 1,4

PUBBLICAZIONI

OECD SIDS/ SUMMARY CONCLUSIONS OF THE SIAR

Human Health

Propylene glycol (PG) **is not acutely toxic**. The lowest oral LD50 values range between 18 and 23.9 grams (5 different species) and the reported dermal LD50 is 20.8 grams. **PG is essentially nonirritating** to the skin **and mildly irritating to the eyes**. Numerous studies support that PG **is not a skin sensitizer.** Repeated exposures of rats to propylene glycol in drinking water or feed did not result in adverse effects at levels up to 10% in water (estimated at about 10 g/kg bw/day) or 5% in feed (dosage reported as 2.5 g/kg bw/day) for periods up to 2 years. **In cats, two studies of at least 90 days duration** show that a species-specific effect of increased Heinz bodies was observed (**NOAEL = 80 mg/kg bw/day;** LOAEL = 443 mg/kg bw/day), with other haematological effects (decrease in number of erythrocytes and erythrocyte survival) reported at higher doses (6-12% in diet, or3.7-10.1 g/cat/day). Propylene glycol did not cause fetal or developmental toxicity in rats, mice, rabbits, or hamsters (**NOAELs range from 1.2 to 1.6 g/kg bw/day in four species). No reproductive effects were found** when propylene glycol was administered at up to 5% in the drinking water (reported as 10.1 g/kg bw/day) of mice. **Propylene glycol was not a genetic toxicant as demonstrated by a battery of in vivo** (micronucleus, dominant lethal, chromosome aberration) and in vitro (bacterial and mammalian cells and cultures) studies. No increase in tumors was found in all tissues examined when propylene glycol was administered in the diet of rats (2.5 g/kg bw/day for 2 years), or applied to the skin of female rats (100% PG; total dose not reported; 14 months) or mice (mouse dose estimated at about 2 g/kg bw/week; lifetime). These data support a lack of carcinogenicity for PG.

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Environment

Propylene glycol **is not volatile**, but is miscible with water. Air monitoring data are not available, but concentrations of propylene glycol in the atmosphere are expected to be extremely low because of its low vapor pressure and high water solubility. It is readily biodegraded in water or soil. Four studies reported >60% biodegradation in water in 10 days. **PG is not expected to bioaccumulate**, with a calculated BCF <1. Measured freshwater aquatic toxicity data for fish, daphnia and algae report LC/EC50 values of >18,000 mg/l. Therefore, PG is not acutely toxic to aquatic organisms except at very high concentrations. Using an assessment factor of 100 and the Ceriodaphnia data (48-hour EC50 = 18,340 mg/l), the PNEC is 183 mg/l.

Exposure

PG production capacity in the US was 1312 million pounds (596 kilotonnes) in 1998. Domestic demand was 1050 million pounds (477 kilotonnes). PG is used as an ingredient in cosmetics at concof PG, with percent of demand, are: unsaturated polyester resins, 26 percent; antifreeze and de- icing fluids, 22 percent; food, drug and cosmetics uses, 18 percent; liquid detergents, 11 percent; functional fluids (inks, specialty anti-freeze, de-icing lubricants), 4 percent; pet foods, 3 percent; paints and coatings, 5 percent; tobacco, 3 percent; miscellaneous, including plasticizer use, 8 percent.entrations of <0.1% to >50%. Approximately 4000 cosmetic products contained PG in 1994. Uses

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- Iuclid data sheet 18/02/2000

Irritazione
Coniglio : non iritante
Uomo : non irritante
Irritazione oculare: leggera

Corrosione

Sensibilizzazione: non sensibilizzante (draize test)

Repeated dose toxicity
NOAEL ratto (orale 90 giorni): 50 mg/kg
NOAEL (orale_ gatto a 90 gg) :80 mg/kg
NOAEL (orale_ gatto 2 anni) :2000 mg/kg

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CIR Safety Review:

In an earlier review, the **CIR Expert Panel established a concentration limit of 50% for Propylene Glycol** and the Polypropylene Glycol polymers based on the results of human irritation and sensitization tests. New data provided to the CIR Expert Panel suggested that when carefully formulated to avoid skin irritation, Propylene Glycol and Polypropylene Glycol polymers can be safely used in cosmetic products at higher concentrations. Therefore, the CIR Expert Panel revised their previous limitation and concluded that Propylene Glycol and Polypropylene Glycol are safe for use in cosmetic products when formulated to be non-irritating.

Additional data reviewed by the CIR Expert Panel indicated that these compounds are **not genotoxic or carcinogenic, nor are they reproductive or developmental toxicants.**

The **National Toxicology Program's** (NTP) Center for the Evaluation of Risk to Human Reproduction (CERHR) Expert Panel in 2003 reviewed the reproductive and developmental effect of Propylene Glycol and Ethylene Glycol. For both compounds, the CERHR Expert Panel **concluded that there is "negligible concern for reproductive or developmental toxicity to humans."**

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- **TOX NET**
- Toxicol In Vitro. 2011 Dec;25(8):1664-70. doi: 10.1016/j.tiv.2011.07.003. Epub 2011 Jul 18.
- **Dermal penetration of propylene glycols: measured absorption across human abdominal skin in vitro and comparison with a QSAR model.**
- Fasano WJ, ten Berge WF, Banton MI, Heneweer M, Moore NP.
- **Source**
- E.I. Du Pont de Nemours and Company, DuPont Haskell Global Centers for Health & Environmental Sciences, Newark, DE, USA.

- **Abstract**
- The dermal penetration of undiluted monopropylene glycol (MPG) and dipropylene glycol (DPG) has been measured **in vitro using human abdominal skin under conditions of infinite dose application**, and the results compared with predictions from the SKINPERM QSAR model (ten Berge, 2009). The measured steady-state penetration rates (Jss) for MPG and DPG were 97.6 and 39.3 µg/cm2/h, respectively, and the permeability coefficients (Kp) were 9.48×10(-5) cm/h for MPG and 3.85×10(-5) cm/h for DPG. In comparison, the SKINPERM model slightly over-predicted Jss and Kp for MPG and DPG by between 2.6- and 5.1-fold, respectively. The model predictions of 254 µg/cm2/h and 24.6×10(-5) cm/h for MPG, and 202 µg/cm2/h and 19.8×10(-5) cm/h for DPG were in fairly good agreement with the measured values. Further, the model predicted a Jss of 101 µg/cm2/h and a Kp of 9.9×10(-5) cm/h for the homologue tripropylene glycol. Assuming that the measured Jss was the same under conditions of finite dose application (taken to be 10 µL/ cm2) and was maintained over a 24-h period (both conservative assumptions), **the relative dermal absorption of the applied dose was estimated to be 23%** (0.96%/h) for MPG and 9% (0.39%/h) for DPG. However, the extrapolation for MPG may be further overestimated **due to possible residence in the stratum corneum under infinite conditions of exposure that would not be applicable to a finite loading dose.**
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Calcolo del MOS

USO del glicole propilenico in un prodotto leave-on

Tipo di prodotto emulsione corpo

Concentrazione 20%

Popolazione adulta

Calculated relative daily exposure (mg/kg bw/day) SCCS/1501/12

123,2

NOAEL = 80 (1200)

SED =5,6

Con assorbimento dermico 23%

MOS = 14,1 (212)