SIDS INITIAL ASSESSMENT PROFILE

CAS No.	57-55-6
Chemical Name	Propylene glycol (1,2-dihydroxypropane)
Structural Formula	СН₃-СНОН-СН₂ОН

RECOMMENDATIONS

The chemical is currently of low priority for further work.

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 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.

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 concentrations of <0.1% to >50%. Approximately 4000 cosmetic products contained PG in 1994. Uses of 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.

NATURE OF FURTHER WORK RECOMMENDED

No further work is recommended.