PROPYLENE GLYCOL

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I. IDENTIFICATION

Chemical Name: Propane-1,2-diol
Synonyms: Propylene Glycol; PG; Monopropylene Glycol; MPG; 1,2-Propanediol; 2,3-Propanediol; 1,2-Dihydroxypropane; Methylene Glycol; Trimethyl Glycol; 1,2-Propylene Glyol; Alpha-Propylene Glycol; Dowfrost; GR12; Sirlane; Propanediol; Solar Winer Ban; 2-Hydroxypropanol; Methylethyl Glycol; Methyl Glycol.
CAS Number: 57–55–6
Chemical formula: CH_3-CHOH-CH_2OH

II. CHEMICAL AND PHYSICAL PROPERTIES

Physical State: Liquid (clear, colorless, viscous)
Odor Description: Practically odorless
Molecular Weight: 76.09
Conversion Factor: 1 mg/m^3 = 0.322 ppm
1 ppm = 3.11 mg/m^3
Vapor Pressure: 0.0825 mmHG @ 20°C(68°F)
Boiling Pt: 189°C(372°F)
Melting Pt: < -60°C(140°F)
pH: Neutral
Saturated Atmosphere: 330–414 mg/m^3 (106–133 ppm) @ 25°C (77°F)
Solubility in Water: Completely miscible
Flash Pt: 109°C (228°F) covered
Flammability Limit: 2.4–17.4 vol % in air
Stability and Reactivity: Stable at normal temperatures and pressures
pK_a: not applicable
Log Octanol/Water Partition
Coefficient (K_{ow}): -1.41 to -0.3 (-0.78 preferred value)

III. USES AND VOLUME

Propylene glycol is used in the production of unsaturated polyester resins (27%); antifreeze, de-icing, and heat transfer fluids (20%); foods, drugs, and cosmetics (20%); liquid detergents (17%); paints and coatings (5%); and miscellaneous, including plasticizer use (11%). In 2001, production capacity in the US was 1280 million pounds (580,000 tons).[1]

IV. ANIMAL TOXICITY DATA

A. Acute Toxicity

1. *Oral Toxicity*

The acute oral toxicity of propylene glycol has been studied for more than 65 years in a variety of mammalian species (summarized by References 2 and 3). Representative data are presented in the table below. Signs of toxicity included loss of equilibrium, CNS depression and analgesia. The onset of clinical signs was rapid following administration of large doses, leading to coma and death after a prolonged moribund state. Less severe, reversible changes occurred after administration of smaller doses with complete recovery of the animals.

Table 1. Acute Oral Toxicity

Species	Oral LD_{50} (mg/kg bw)
Mouse	25,000
Rat	22,000–31,000
Guinea pig	20,000
Rabbit	19,000–20,000
Dog	21,000

2. *Eye Toxicity*

Undiluted propylene glycol is minimally irritating to the rabbit eye, causing no more than slight transient conjunctivitis which resolves by 24–48 hr after contact.[4, 5]

3. *Skin Toxicity*

a. Irritation

Propylene glycol produced minimal signs of dermal irritation in 4-hr studies in rabbits.[6-8] It is not classified as a skin irritant.

b. Absorption

A dermal LD_{50} of 21,000 mg/kg has been reported for undiluted propylene glycol in rabbits (no further details available).[9]

c. Sensitization

Undiluted propylene glycol was non-sensitizing in the mouse ear sensitization test[10] or in the mouse local lymph node assay.[11]

4. Inhalation

No acute data were located.

B. Genotoxicity and Mutagenicity

Propylene glycol was negative in two bacterial mutagenicity assays using *Salmonella typhimurium* indicator strains TA92, TA94, TA98, TA100, TA1535, and TA1537, conducted in the absence or presence of metabolic activation at levels of up to 1000 µg/plate.[12, 13]

There was no increase in chromosomal aberrations in human lymphocytes exposed *in vitro* to 6.25, 25 or 50 mM propylene glycol with or without metabolic activation.[14]

In contrast, an increase in chromosomal aberrations was reported in Chinese hamster fibroblasts exposed to 32 mg/mL (420 mM) propylene glycol in the absence of metabolic activation.[13] [Note: This concentration is expected to produce significant cytotoxicity and is 42-fold higher than recommended maximum of 10 nM.]

No increase in chromosomal aberrations in bone marrow nor any induction of heritable mutations in germ cells were found in male rats given 30, 2500, or 5000 mg/kg propylene glycol by gavage either once or on five consecutive days.[15]

Similarly there was no increase in micronucleated polychromatic erythrocytes in mice 18 hr after a single ip injection of propylene glycol at 2500, 5000, 10,000 or 15,000 mg/kg bw.[16]

C. Metabolism

Intestinal absorption of propylene glycol and its subsequent excretion from the body follows first order kinetics.[17] Metabolism of propylene glycol is inhibited by pyrazole, indicating a role for alcohol dehydrogenase.[17] Lactic and pyruvic acids are metabolites which are further metabolized to carbon dioxide and water.[18]

D Developmental and Reproductive Toxicity

In pregnant rats, mice, hamsters, and rabbits given oral doses, no adverse effects were seen in dams or fetuses.[19] Details of these studies are summarized in Table 2 below. There was no evidence of teratogenicity at any dose level.

In an in vitro system, pups from Swiss mice were given 10,000 mg/kg bw/day on GD 8–12.[20] There were no effects on the pups.

In a continuous breeding study, 0, 1800, 4800, or 10,100 mg/kg bw in drinking water for 98 days was without effect on the reproductive performance of male and female mice.[21-23] There was no treatment-related effect on growth or viability in the F1 or F2 generations, or on reproductive performance in the F0 or F1 generations.

In rats exposed to 55–112 ppm continuously for 18 months, no effects were observed on reproductive performance or on the animals' ability to produce live young or on the survival of the offspring.[24]

E. Subchronic Toxicity

No adverse toxicological changes were noted in rats given 10% propylene glycol in drinking water for 140 days[25], whereas, an increase in Heinz bodies was noted in cats following dietary administration of propylene glycol for 2-3 months.[26] These studies are summarized in Table 3 on the following page.

In female cats given 0, 1200, 1600, 2400, or 3600 mg/kg bw via gavage for 2, 5, or 17 weeks, Heinz bodies were noted at 2400 mg/kg bw or higher at 17 weeks.[27] In a related study, 60,000 ppm (6% in diet) for 13 weeks produced Heinz bodies in adult female cats[28] and 2750 mg/kg bw (6% in diet) for 13 weeks produced Heinz bodies in female kittens.[29]

In rats given 0 or 2942 mg/kg bw/day for 10, 20, or 30 days, a 41% reduction in body weight was noted at Day 10, but the animals recovered by Day 30.[18]

Table 2. Developmental Toxicity Data

Species	Treatment mg/kg bw/d	Treatment period	Maternal		Fetal	
			LOAEL	NOAEL	LOAEL	NOAEL
Rat	16.0, 74.3, 345, 1600	GD 6–15	>1600	1600	>1600	1600
Rabbit	12.3, 57.1, 267, 1230	GD 6–18	>1230	1230	>1230	1230
Mouse	16.0, 74.3, 345, 1600	GD 6-15	>1600	1600	>1600	1600
Hamster	15.5, 72.0, 334.5, 1550	GD 6-10	>1550	1550	>1550	1550

Groups of male and female SD rats (18–19/sex/group) were exposed (nose only) to 0, 160, 1000, or 2200 mg/m^3 propylene glycol aerosol (MMAD 1.96–2.22 μm) 6 hr/d, 5 d/wk for 13 wk.[30] There were no significant differences in respiratory rates, tidal volume or minute volume between the groups. The authors reported "nasal hemorrhaging" was seen in >90% of animals from the mid- and high exposure groups (both sexes), and 65% of males from the low exposure group at study termination. The discharge disappeared on non-exposure days each weekend. Microscopic examination of the nasal cavity showed a thickening of the respiratory epithelium (increased number of goblet cells or increase in mucin content of goblet cells) in the mid- and high dose groups only. Low dose animals of both sexes showed only sporadic changes. An increase in the incidence of ocular discharge was also reported, affecting 5–8% of controls, and 14–16%, 28–40%, and 35–40% of the low, mid and high exposure groups, respectively. No statistical analysis was reported. No other treatment-related effects were reported, and a systemic NOAEL of 1000 mg/m^3 (based on decreased food consumption and lower body weight in high dose animals) was derived from the study.

F. Chronic Toxicity

Minimal toxicological changes were seen in rats given up to 5% w/w propylene glycol in the diet for two years.[31] No Heinz bodies were noted over the 2-year oral study at 2500 mg/kg bw/day or less.

In dogs given 20% w/w in diet for 2 years, mild hematological changes (slightly decreased hemoglobin, hematocrit and total erythrocyte counts, slightly increased reticulocyte count) were apparent in animals fed 20% w/w propylene glycol.[32] Further details are shown in Table 4 below.

Table 3. Subchronic Toxicity Data

Species	Received dose (mg/kg bw/day)	Observations	Findings	Ref.
Rat	1600, 3680, 7700, or 13,200 via drinking water for 140 days	Clinical signs, body weights, food and water intake, limited urinalysis, necropsy examination, limited histopathology (heart, spleen, liver)	No albuminuria, cells or casts from urine analysis; no treatment-related macroscopic or microscopic findings. **NOAEL = 13,200 mg/kg/d**	25
Cat	80, 443, 675, 1763, or 4239 via diet for 2–3 months	Clinical signs, clinical chemistry, full hematology, urinalysis, full necropsy plus histopathological examination of major organs.	Slightly increased hemosiderin accumulation in liver and spleen from cats receiving 1763 or 4239 mg/kg/d; majority of hematology, clinical chemistry and tissue parameters normal with exception of early, dose-related increase in Heinz bodies in mid- and high dose animals. **NOAEL = 80 mg/kg/d** **LOAEL = 443 mg/kg bw/d**	26

Table 4. Chronic Toxicity Data

Species	Received dose (mg/kg bw/day)	Observations	Findings	Ref.
Rat	200, 400, 900, or 1700 in males, and 300, 500, 1000, and 2100 in females, via feed for 104 wk	Clinical signs, full hematology screen, full renal function and urine analysis, detailed necropsy plus organ weights, major organs examined by light microscopy	Hematological, renal and urinary parameters comparable to control; no effect on organ weights; no treatment-related histopathological lesions in females at 2100 mg/kg/day. **$NOAEL_{males}$ =1700 mg/kg/d** **$NOAEL_{females}$ = 2500 mg/kg/d**	31
Dog	2000 or 5000 via diet for 104 wk	Clinical signs, full hematology, clinical chemistry screen, full renal function and urine analysis, liver lipid content and energy metabolism, full necropsy plus major organs examined by light microscopy.	Total red cell count, hemoglobin concentration and hematocrit decreased, and reticulocytes increased, in high dose group, other hematological parameters unaffected; no treatment-related effects on renal function or clinical chemistry; no adverse histopathological findings in major organs. **LOAEL = 5000 mg/kg/d** **NOAEL = 2000 mg/kg/d**	32

No adverse effects were reported in rats continuously exposed to super-saturated propylene glycol vapor (i.e., in excess of 330–414 mg/m^3) for up to 18 months.[24] Observations included external appearance, body weight gain, and macroscopic and microscopic examination of lung, kidney, liver, and spleen. No adverse treatment-related effects were seen in Rhesus monkeys exposed continuously to either a supersaturated atmosphere of propylene glycol, or to approx. 100–220 mg/m^3, over 12–18 months.[24] No nasal or ocular discharge was reported in either species in this investigation.

There was no increase in dermal tumors in female mice following lifetime treatment with 2, 10, or 21 mg PG/day.[33]

No tumors were apparent by visual or microscopic examination when propylene glycol was used as a vehicle in a non-standard ear painting study in female rats lasting 10–14 months.[34]

V. HUMAN USE AND EXPERIENCE

A few cases of toxicity have been reported in the literature primarily following use of propylene glycol in medicinal preparations, but pre-existing disease, compromised metabolism, or overly rapid parenteral infusion are believed to have contributed to toxicity in these reports.[35] Propylene glycol was recertified as "Generally Regarded as Safe" when used in food as an emulsifying agent and general purpose food additive as well as in paper and paperboard products used in food packaging. It was first used in foods in the United States in 1920.

There are no known reports of eye irritation in humans after exposure to liquid propylene glycol.

In healthy subjects, the incidence of apparently 'irritant' dermal responses of skin to undiluted propylene glycol is highly variable, and may be as low as 0% (0/203 volunteers) or as high as 40% (14/35).[36]

In 42 healthy volunteers, neat propylene glycol caused faint, patchy erythema with edema in 40% of the subjects.[37]

In 1,226 patients, 5% propylene glycol in vaseline or 10, 20, or 50% in water produced dermal irritation in 195 subjects and sensitization in 13 subjects.[38]

In 866 "normal" subjects, positive reactions (erythema and edema) were noted on the skin of 138.[39]

In a repeat insult patch test, no abnormal irritant responses were seen after semi-occlusive or occlusive application of propylene glycol to the skin of more than 100 volunteers, although one subject responded with an irritant hypersensitive reaction.[40, 41]

No adverse effects were reported in 3 normal subjects or 4 patients with cystic fibrosis exposed to an aerosol containing a radio-tracer (99^m Tc) and 10% propylene glycol in water.[42] The aerosol concentration was approximately 40 mg/l, equivalent to about 4000 mg/m^3 propylene glycol, with a 1-hour exposure period.

When propylene glycol was used as a theatrical obscurant (*i.e.*, mists, smokes, fogs), no increase in the incidence of eye and respiratory tract irritation among exposed performers was reported, even among asthmatics.[43]

An increase in the incidence of eye or nasal irritation and cough and a decrease in the FEV_1/FVC (Forced Expiratory Volume; Forced Vital Capacity) ratio was noted in 27 healthy volunteers exposed for one minute to aerosolized propylene glycol up to 850 mg/m^3.[44]

The clearance half-life for blood in humans is approx. 2 hr.[45]

Workplace exposure to propylene glycol has been studied in water-based paints.[46] Personal exposures were collected over 1 hr from 20 painters working indoors. The arithmetic mean exposure was 2.6 mg/m^3, with a geometric mean and SD of 0.35 ± 0.02 mg/m^3. The maximum exposure measured in this study was 12.7 mg/m^3.

No evidence of an allergic response was seen in 204 volunteers following induction and challenge with 12% propylene glycol using a Draize procedure[47], or in 103 subjects following semi-occlusive or occlusive epicutaneous application of 50% propylene glycol.[40,41] In contrast, populations of atopic or hypersensitive individuals may respond to propylene glycol in a manner consistent with sensitization.[36]

Exposures of up to 851 mg/m^3 have been reported when propylene glycol is used as an obscurant in airline emergency escape training programs.[44]

VI. RATIONALE

Results from experimental studies demonstrate that liquid propylene glycol is minimally irritating to rabbit eye and minimally irritating to rabbit skin. Human data indicate that it has a potential to produce minimal irritation in a small fraction of human subjects.

It is not a dermal sensitizer in the mouse ear sensitization assay or local lymph node assay. No evidence of sensitizing potential was seen in human volunteers when tested using the Draize or repeat insult patch test methodologies under semi-occlusive or occlusive application conditions. In contrast, a small fraction of hypersensitive individuals with pre-existing dermal hypersensitivity responded with skin reactions upon challenge with propylene glycol.

It has a low potential to cause systemic effects following acute or repeated ingestion or inhalation. The available evidence demonstrates that it does not adversely

affect fertility or fetal development, and that it is not carcinogenic. This lack of toxicity is consistent with its rapid and complete metabolism by the body to carbon dioxide and water. Findings of hematological changes (Heinz body formation) in cats following repeat oral exposure are not replicated in other species, and appear indicative of a species-specific response.

Based on the weight of evidence, together with knowledge of its chemical structure and metabolic fate, it appears that propylene glycol is not genotoxic.

Aerosols in the range 175–850 mg/m^3 were linked to increased eye and respiratory tract irritation after 60-second exposures.

The weight of evidence from experimental studies in animals and human subjects demonstrates that propylene glycol is not a dermal sensitizer. The likelihood of allergic skin conditions following dermal contact with propylene glycol in an occupational setting appears to be of low concern.[36, 48]

Given the overall benign toxicity profile for propylene glycol, the primary endpoint in deriving an OEL value for propylene glycol is to minimize any risk of possible nose and eye irritation following exposure to the aerosol or vapor. Suitable human data are not available for setting an OEL value. The study by Suber *et al*.[30] appears to be the critical study for setting the OEL level. The results indicate that 160 mg/m^3 is a probable threshold for slight eye irritation and a NOAEL for nasal irritation in the rat (6 hr exposure period). The term 'threshold' for eye irritation is used in preference to NOAEL or LOAEL since these effects were either inconsistently expressed between the sexes (*i.e.*, present in males but not in females), or occurred at an incidence that was essentially identical to that of the controls. Robertson *et al*.[24] reported no ocular or nasal discharge in rats or Rhesus monkeys exposed continuously to super-saturated propylene glycol vapour (*i.e.*, in excess of 330–414 mg/m^3) for 12–18 months, again suggesting that propylene glycol has little potential to cause mucosal irritation. However this study predates current design guidelines and is therefore used for corroborative purposes only.

Although the toxicity data might allow a higher OEL value, it is recommended that aerosol exposures should not exceed 10 mg/m^3 TWA to maintain good industrial hygiene procedures for nuisance liquid and particulate aerosols.

VII. RECOMMENDED OEL

10 mg/m^3 (8 hr TWA) for the aerosol.

VIII. REFERENCES

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