PROPYLENE GLYCOL

CHEMICAL IDENTITY

INCI NAME: propylene glycol

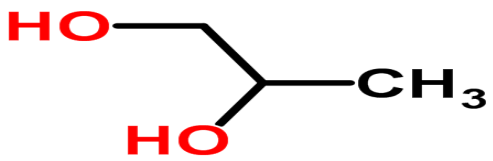
IUPAC: propane-1,2-diol

CAS: 57-55-6

EC NUMBER: 200-338-0

EMPIRICAL FORMULA: C3H8O2

STRUCTURAL FORMULA:



PHYSICAL FORM:

Colourless Transparent Liquid

MOLECULAR WEIGHT:

MW = 76,1 Da

PURITY AND COMPOSITION

PROPYLENE GLYCOL ASSAY: > = 99,5 %

IMPURITIES / CONTAMINANTS

- WATER max 0,150 %
- 1,3-PROPANDIOL max 100 ppm
- ARSENIC max 3 ppm
- HEAVY METALS max 5 ppm

SOLUBILITY

100 % in water

PARTITION COEFFICIENT (Log P_{ow})

Log Pow: - 1.07 (pH = 6.2 – 6.4; 20.5° C)

ADDITIONAL PHYSICAL AND CHEMICAL SPECIFICATIONS

Physical Property	Value	Units	Temp (deg C)
Melting Point	- 60	deg C	/
Boiling Point	187.6	deg C	/
pKa Dissociation Constant	14.9	/	/
Vapor Pressure	0.129	mm Hg	25
Density	1.035 – 1-040	g/ml	20
Refractive Index	1.431 – 1.433	/	/
Viscosity (capillary viscometer)	43.343	mPa s	25
Flash Point	104	deg C	/

STABILITY

Stable under ordinary conditions of use and storage

FUNCTION AND USES

Used as solvent and/or umectant

TOXICOLOGICAL EVALUATION

ACUTE TOXICITY		REF.
LD50 ORAL	22.000 mg/Kg b.w.	J. Ind. Hyg. Tox., 21, 173-201., 1939 (JECFA, 1974)
LD50 DERMAL	> 20.800 mg/Kg b.w.	OECD SIDS, 30-5-2001
LC50 INHALATION	317.042 g/m3 2h	Folia Morphologica, 26, 28-34
IRRITATION AND CORROSIVITY		**REF.**
SKIN IRRITATION	Not irritant (as it is)	OECD, A.K. Mallett Surrey - 1984
EYE IRRITATION	Not irritant	OECD, A.K. Mallett Surrey - 1984
SKIN SENSITISATION		**REF.**
SENSITISATION	No reactions at any concentration	OECD, A.K. Mallett Surrey - 1999

TOXICOLOGICAL EVALUATION

REPEATED DOSE TOXICITY		Ref.
REPEATED DOSE (2 years, oral, dog)	NOAEL = 2.000 mg/Kg	OECD, Weil, C.S. *et al.* (1971): *Food Cosmet. Toxicol*. 9: 479-490
(70 days, oral, cat)	NOAEL = 80 mg/Kg	OECD, Quast, J.F., Humiston, C.G., Wade, C.E., Beyer, J.E., Albee, R.R., Scheutz, D.J., and Morden, D.C. (1979). Results of a toxicology study in cats fed diets containing propylene glycol for up to three months. Unpublished report from The Dow Chemical Co., pp. 1-86.
(2 years, oral rat)	NOAEL = 1.300 mg/Kg	EFSA, JECFA (2001) (Gaunt et al., 1972).
REPRODUCTIVE TOXICITY		**Ref.**
TERATOGENICITY	Not teratogenic	OECD-(Morrissey *et al.*, 1989; Lamb *et al.*, 1997. FDA, 1973

TOXICOLOGICAL EVALUATION

REPRODUCTIVE TOXICITY		Ref.
TWO GENERATION REPRODUCTIVE TOXICITY	Not toxic	Guerrant NB *et al.*, (1947): *Bull. Natl. Formulary Comm*.15: 205-229, cited in Federal Register, Vol. 42. pgs. 30865-30866. June 17, 1977. P B-223-822.
MUTAGENICITY / GENOTOXICITY		**Ref.**
GENOTOXICITY (in vitro)	Not genotoxic	OECD-Pfieffer and Dunkelberg, 1980; Ishidate *et al.*, 1984. OECD-Erdoelchemie, 1990.
GENOTOXICITY (in vivo)	Not genotoxic	OECD-Litton Bionetics, 1974 OECD-(Hayashi *et al.*, 1988)
CARCINOGENICITY		**Ref.**
CARCINOGENICITY	Not toxic	Gaunt, I.F. *et al* (1972): *Food Cosmet. Toxicol.* 10: 151-162

TOXICOKINETICS

- According to JECFA (JECFA, 1974), propylene glycol is rapidly absorbed after oral administration and appears in the blood-stream. After a dose of 8 ml/Kg b.w. (equivalent to 8,284 mg/Kg b.w.) had been administered to dogs, approximately 24 hours were required for complete elimination from the blood-stream.

DERMAL ABSORPTION

- ECHA data: dermal absorption is 0,1 % (GLP compliance, OECD 428, 2007)

HUMAN DATA

Skin Sensitization	Human	Other; NG	Not sensitizing (Induction: 0.2 mL of 50% solution , semi-occlusive; Challenge: 0.2 mL of 50% solution semi-occlusive)
	Human	Other, NG	Not sensitizing (Induction: 0.2 mL of 50% solution , occlusive).
	Human	Other, Draize	Not sensitizing ((Induction: 0.5 g of 12% dilution in petrolatum)

SIDS Initial Assessment Report
for
11th SIAM
(USA, January 23-26, 2001)

Chemical Name : Propylene glycol

CAS No: 57-55-6

Sponsor Country: U.S.A

National SIDS Contact Point in Sponsor Country:

Oscar Hernandez
US EPA
401 M St. S.W.
Washington, DC 20460

Safety evaluation-calculation of the MoS

Face Cream at 5 % Propylene Glycol

SED = A (mg/kg bw/day) x C (%)/100 x DAp (%)/100

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application = **24,14** (THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 8TH REVISION)

C (%) = the Concentration of the ingredient under study in the finished cosmetic product on the application site = **5 %**

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions = **0,1 %**

SED = 24,14 x 5/100 x 0,1/100 = 0,0012

1) NOAEL (oral, rat, 2-years) = 1.300 mg/kg bw/day

2) NOAEL (oral, cat, 70 days)= 80 mg/kg bw/day

1) MoS = NOAEL/SED = 1.300/0,0012 = 1,08 x 10^6

2) MoS = NOAEL/SED = 80/0,0012 = 6,7 x 10^4

Safety evaluation-calculation of the MoS

Hair Glossy Fluid at 35 % Propylene Glycol (hair styling product)

SED = A (mg/kg bw/day) x C (%)/100 x DAp (%)/100

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application = **5,74** (THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 8^{TH} REVISION)

C (%) = the Concentration of the ingredient under study in the finished cosmetic product on the application site = 3**5 %**

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions = **0,1 %**

SED = 5,74 x 35/100 x 0,1/100 = 0,002009

1) NOAEL (oral, rat, 2-years) = 1.300 mg/kg bw/day

2) NOAEL (oral, cat, 70 days)= 80 mg/kg bw/day

1) MoS = NOAEL/SED = 1.300/0,002009 = 6,5 x 10^6

2) MoS = NOAEL/SED = 80/0,002009 = 4 x 10^5

PROPYLENE GLYCOL IMPURITIES

Impurity	Cramer Clasf.	TTC	Amount in PG	Amount in Face Cream (5 % PG)
1,2-propanediol	1	30 μg/Kg b.w.	100 mg/Kg	1,5 μg
As	3	1.5 μg/Kg b.w.	3 mg/Kg	0,045 μg
Pb	3	1.5 μg/Kg b.w.	5 mg/Kg	0,075 μg

CONCLUSION

Propylene glycol is safe for use in cosmetic products as umectant or solvent up to concentrations of 35 %.

According to C.I.R. statement, *“propylene glycol is safe as used in cosmetics up to concentrations of 50 %”.* (CIR EXPERT PANEL MEETING JUNE 28-29, 2010)

Safety evaluation-calculation of the MoS

Sunscreen Cream: Propylene Glycol 5 %; Cetyl Alcohol 5 %; Polysilicone-15 10 %

SED = A (mg/kg bw/day) x C (%)/100 x DAp (%)/100

A (mg/kg bw/day) = Estimated daily exposure to a cosmetic product per kg body weight, based upon the amount applied and the frequency of application = **300** (THE SCCS'S NOTES OF GUIDANCE FOR THE TESTING OF COSMETIC INGREDIENTS AND THEIR SAFETY EVALUATION 8TH REVISION)

C (%) = the Concentration of the ingredient under study in the finished cosmetic product on the application site = 3**5 %**

DAp (%) = Dermal Absorption expressed as a percentage of the test dose assumed to be applied in real-life conditions = **0,1 %**

SED (PG) = 300 x 5/100 x 0,1/100 = **0,015**; SED (CA) = 300 x 5/100 x 100/100 = 15;

SED (P-15) = 300 x 10/100 x 2/100 = **0,6**

1) NOAEL (oral, rat, 2-years) = 1.300 mg/kg bw/day

2) NOAEL (oral, cat, 70 days)= 80 mg/kg bw/day

1) MoS (PG) = NOAEL/SED = 1.300/0,015 = 86.700; 2) MoS (PG) = NOAEL/SED = 80/0,015 = 5.330

MoS (CA) = NOAEL/SED = 333,33/15 = ?; MoS (P-15) = NOAEL/SED = 1000/0,6 = 1.666