PROPYLENE GLYCOL

MODULE 1

SUBSTANCE INFORMATION SHEET

PROPYLENE GLYCOL

CAS number	57-55-6
Natural Origin	Occurs in sesame seeds, mushrooms
Chemical Formula	C3H8O2
Synonyms	1,2–Propanediol, 1,2-Dihydroxypropane
E number	E1520
FEMA GRAS number	2940

General Information

Council of Europe (CoE)

Number	Comment
2065	N/A

US Food & Drug Administration (FDA)

Number	Comment
21 CFR 184.1666, 21 CFR 175.105, 21 CFR 175.300, 21 CFR 175.320, 21 CFR 176.210, 21 CFR 177.1680, 21 CFR 177.2420, 21 CFR 177.2600, 21 CFR 177.2800, 21 CFR 178.3300	Approved by U.S. FDA as Direct Food Additives, Food Additives Generally Recognized as Safe (GRAS) and Indirect Food Additives

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

Number	ADI	Comment
925	0-25 mg/kg/bw	Evaluation not finalized, pending definition of "flavouring agent"

Flavors & Extracts Manufacturers Association (FEMA)

Number	Comment
2940	Propylene glycol is recognized as generally safe for use in food. GRAS3

Uses and Exposure

Propylene glycol is used as an ingredient in cosmetics at concentrations of <0.1% to >50%. Approximately 4000 cosmetic products contained propylene glycol in 1994.
Uses of propylene glycol , with percent of demand, are (SIDS 2001):

- 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

Estimated Intake from Food and Drink

Daily Intake

Based on the NAS data, the average person is estimated to consume as much as 14.0113 mg/kg body weight/day or 840 mg/day of propylene glycol for an individual weighing 60 kg. Based on FEMA reported disappearance data of propylene glycol, consumption was 39.95 mg/kg/day[1,2,3,4].

Summary of the Toxicological Investigations on the Use of the Substance in Tobacco Products

Smoke Chemistry

Internal Studies	Level Tested ppm	Comment
Philip Morris	40,000; 70,000; 100,000	The effect of the addition of propylene glycol at concentrations up to 100,000 ppm on the composition of the cigarette smoke was investigated.
Philip Morris	5,000; 10,000; 20,000; 40,000	The effect of the addition of propylene glycol at concentrations up to 40,000 ppm on the composition of the cigarette smoke was investigated.
Carmines for Philip Morris	7,472; 22,710; 28,529; 47,225	The effect of the addition of propylene glycol as part of a mixture at concentrations up to 47,225 ppm on the composition of the cigarette smoke was investigated.

Neutral Red Uptake Assay (NRU)

Internal Studies	Level Tested ppm	Comment
Philip Morris	40,000; 70,000; 100,000	The effect of the addition of propylene glycol at concentrations up to 100,000 ppm on the cytotoxicity, as measured by the Neutral Red Uptake assay, was investigated.
Philip Morris	5,000; 10,000; 20,000; 40,000	The effect of the addition of propylene glycol at concentrations up to 40,000 ppm on the cytotoxicity, as measured by the Neutral Red Uptake assay, was investigated.

Neutral Red Uptake Assay (NRU) (Cont.)		
Internal Studies	Level Tested ppm	Comment
Carmines for Philip Morris	7,472; 22,710; 28,529; 47,225	The effect of the addition of propylene glycol as part of a mixture at concentrations up to 47,225 ppm on the cytotoxicity, as measured by the Neutral Red Uptake assay, was investigated.

AMES Assay

Internal Studies	Level Tested ppm	Comment
Philip Morris	40,000; 70,000; 100,000	The effect of the addition of propylene glycol at concentrations up to 100,000 ppm on the mutagenic response, as measured by the Salmonella reverse mutation assay, was investigated.
Philip Morris	5,000; 10,000; 20,000; 40,000	The effect of the addition of propylene glycol at concentrations up to 40,000 ppm on the mutagenic response, as measured by the Salmonella reverse mutation assay, was investigated..
Carmines for Philip Morris	7,472; 22,710; 28,529; 47,225	The effect of the addition of propylene glycol as part of a mixture at concentrations up to 47,225 ppm on the mutagenic response, as measured by the Salmonella reverse mutation assay, was investigated.

Mouse Lymphoma Assay (MLA)

Internal Studies	Level Tested ppm	Comment
Philip Morris	40,000; 70,000; 100,000	The effect of the addition of propylene glycol at concentrations up to 100,000 ppm on the mutagenic response, as measured by the Mouse Lymphoma Assay, was investigated.
Philip Morris	5,000; 10,000; 20,000; 40,000	The effect of the addition of propylene glycol at concentrations up to 40,000 ppm on the mutagenic response, as measured by the Mouse Lymphoma Assay, was investigated.

In vivo Micronucleus

Internal Studies	Level Tested ppm	Comment
N/A	N/A	N/A

Inhalation studies

Internal Studies	Level Tested ppm	Comment
Philip Morris	40,000; 70,000; 100,000	The effect of the addition of propylene glycol at concentrations up to 100,000 ppm on the toxicity of cigarette smoke, as suggested in a 90-day inhalation study, was investigated.
Carmines for Philip Morris	7,472; 22,710; 28,529; 47,225	The effect of the addition of propylene glycol as part of a mixture at concentrations up to 47,225 ppm on the toxicity of cigarette smoke, as suggested in a 90-day inhalation study, was investigated.

References

1. Burdock, G.A. (2001a) *Fenaroli's Handbook of Flavor Ingredients*. CRC Press, Boca Raton, FL. Pp. 1540-1541.

2. Clydesdale, F. M. (1997) *Food Additives. Toxicology, Regulation and Properties.* CRC Press, Boca Raton, FL. CD ROM.

3. HSDB (Haxardous Substances Data Base) (1995) Propylene glycol. National Library of Medicine Toxnet website visited on August 17, 2001.

4. Lucas, C.D., Putnam, J.M. and Hallagan, J.B. (1999) Flavor and Extract Manufacturers' Association of the United States. *1995 Poundage and Technical Effects Update Survey.* Flavor and Extract Manufacturers' Association, Washingon, D.C.