Propylene glycol

Botanical Source

Synonyms PROPANEDIOL(1,2-);
1,2-DIHYDROXYPROPANE;
METHYL GLYCOL;
PROPANEDIOL

IUPAC Name

CAS Reference 57-55-6

E Number E1520

Food Legislation

Council of Europe (CoE)	
Number	Comment
-	-

US Food and Drug Administration	
Number	Comment
184.1666	Approved by the US FDA. FDA 21 CFR 184.1666

Joint FAO/WHO Expert Committee on Food Additives (JECFA)		
Number	ADI	Comment
925	N/A	ADI 0-25 mg/kg bw.
		Evaluation not finalized, pending definition of "flavouring agent"

FEMA	
FEMA No.	Comment
2940	Generally recognised as safe as a flavour ingredient:GRAS List Number 3

Natural Occurrence and Use in Food
Found in sesame seed, mushroom; used in confection, frostings, cheese, candy.

Estimated Intake from Food and Drink	
Daily Intake mg/kg/day	FEMA Possible Average Daily Intake mg
14.01129	0.347

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Tobacco Product Related Chemical and Biological Studies for Ingredients Added in a Mixture

Smoke Chemistry		
Published Source	Level Tested %	Comment
BAT	8.33000	At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.
Philip Morris	4.72250	An overall assessment of the data suggests that this ingredient did not add to the toxicity of smoke.

Ames Activity		
Published Source	Level Tested %	Comment
BAT	8.33000	Within the sensitivity and specificity of the system the Ames activity of the cigarette smoke condensate was not increased by the addition of the ingredient.
Philip Morris	4.72250	Within the sensitivity and specificity of the system the Ames activity of the cigarette smoke was not increased by the addition of the ingredient.

Micronucleus		
Published Source	Level Tested %	Comment
BAT	8.33000	Within the sensitivity of the in vitro micronucleus assay the activity of the cigarette smoke condensate was not increased by the addition of the ingredient.

Neutral Red		
Published Source	Level Tested %	Comment
BAT	8.33000	Within the sensitivity of the test system the in vitro cytotoxicity of the cigarette smoke condensate was not increased by the addition of the ingredient.
Philip Morris	4.72250	Within the sensitivity of the test system the in vitro cytotoxicity of the cigarette smoke was not increased by the addition of the ingredient.

Inhalation		
Published Source	Level Tested %	Comment
BAT	8.33000	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Lorrilard	2.20000	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Philip Morris	4.72250	The data indicate that the addition of the ingredient, when added with one of three groups, did not increase the inhalation toxicity of the smoke.

Mouse Skin Painting		
Published Source	Level Tested %	Comment
Lorillard	1.47400	None of the changes appeared to be substantial enough to conclude that the tumour promotion capacity of the condensate was discernibly different between condensate produced from cigarettes with the ingredient in comparison with condensate from cigarettes without the ingredient.

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Tobacco Product Related Chemical and Biological Studies for Ingredients Tested Singly

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Toxicological Data on the Unburnt Ingredient

[+ve, positive; -ve, negative; ?, equivocal
with, with metabolic activation; without, without metabolic activation]

In vivo

Species	Test conditions	Endpoint	Results	Reference
Groups of five mice	Mice were given propylene glycol as either a single oral dose, daily oral doses for 5 days, or as a single intraperitoneal injection. The dose levels were not disclosed in the expert review of this study. The bone marrow was examined for chromosomal aberrations.	Chromosome damage	-ve	Vargova et al. 1980
Groups of five rats	Rats were given (by stomach tube) single doses of up to 5 g/kg bw or daily doses of 5 g/kg bw for 5 days. Bone marrow examined for chromosomal aberrations.	Chromosome damage	-ve [probably an acceptable quality study]	Litton Bionetics Inc, 1974
Groups of six mice	Mice received a single intraperitoneal injection of 2.5, 5, 10 or 15 g/kg bw (the latter killing three of the six animals) or daily	Chromosome damage	-ve	Hayashi et al. 1988

	injections of up to 5 g/kg bw/day for 5 days. Bone marrow examined for micronuclei.			
Mice	Intraperitoneal administration of 0.1 ml. Spermatocytes evaluated for chromosomal aberrations.	Chromosome damage	+ve	Razvi et al. 1979 (cited in HSDB, 2004)
Groups of ten male rats	Dominant lethal assay in which propylene glycol was given by stomach tube to male rats at a single dose of up to 5 g/kg bw or daily doses of 5 g/kg bw/day for 5 days. Treated animals were then mated with untreated females. Genetic damage in sperm cells would be reflected by an increased incidence of early foetal deaths.	Mutation and/or chromosome damage	-ve [probably an acceptable quality study]	Litton Bionetics Inc, 1974
Groups of male mice	Dominant lethal assay in which propylene glycol, as the "control", was given by i.p. injection as a single dose of 10 mg/kg bw. Treated animals then mated with untreated females.	Mutation and/or chromosome damage	-ve (was used as control agent)	Kennedy et al. 1975 (cited in OECD, 2001)

	Genetic damage in sperm cells would be reflected by increased incidence of early foetal deaths.			

In vitro

Test system	Test conditions	Endpoint	Activation status	Results	Reference
Human white blood cells	Chromosome aberration assay. Tested up to 3.81 mg/l.	Chromosome damage	With and without metabolic activation	-ve	EC Erdolchemie GmbH, 1990 (cited in OECD, 2001)
Human cells	Several studies in which treated cells were examined for sister chromatid exchanges or chromosome aberrations.	Chromosome damage and other chromosome effects	The original reports do not specify whether activation fractions were included	-ve	Bibra, 1996 (citing 4 studies: Green, 1977; Kawachi et al. 1981; Litton Bionetics Inc., 1974; Sasaki et al. 1980)
Hamster cells	Treated cells examined for sister chromatid exchanges (SCE).	Chromosome effects	Without	There was a very weak, but dose-related increase in SCE	Sasaki et al. 1980
Chinese hamster lung (fibroblast) cells	Treated at 32 mg/ml for 48 hr, cells examined for chromosome aberrations.	Chromosome damage	With and without S9	+ve (but only without S9. There was no response when S9 was	Ishidate et al. 1984 & 1988

				included)	
Chinese hamster lung (V79) cells	Assay for DNA damage measured by increased elution rate of single-stranded DNA under alkaline conditions.	DNA damage	With and without S9	-ve	Svenberg et al. 1976
Hamster cells	Assay for cell transformation. [A positive result is indicated by a change in the character of cells such that they more closely resemble cancer cells.]	Cell transformation	Not stated	-ve	Pienta, 1980
Salmonella typhimurium including TA92, TA1535, TA100, TA1537, TA94, TA98	Several studies (with test amounts up to 10 mg/plate; one study with said to test at 76 mg/plate). Some studies apparently very limited, others of good quality.	Mutation	With and without S9	-ve [included good quality studies]	Bibra, 1996 (citing 3 studies: Clark et al. 1979; Ishidate et al. 1984; Kawachi et al. 1981); JECFA 2002 (citing Florin et al. 1980; Haworth et al. 1983; McCann & Ames, 1976; Stolzenberg & Hine, 1979)

Salmonella typhimurium including TA1535, TA100, TA1537, TA98	Ames assay. No data on dose(s) used.	Mutation	Without S9	-ve	Pfieffer & Dunkelberg, 1980 (cited in OECD, 2001)
Salmonella typhimurium TA1530, G46	Host-mediated assay in which bacteria were resident in the peritoneal cavity of mice treated by stomach tube with doses up to 5 g/kg bw given singly or daily for 5 days.	Mutation	Not relevant	-ve (An equivocal response was seen in strain G46 at the top dose) [a negative result in a host-mediated assay is of limited significance]	Litton Bionetics Inc, 1974
Saccharomyxes cerevisiae D3 yeast cells	Yeast cells treated directly or in a host-mediated assay in which yeast were resident in the peritoneal cavity of mice treated by stomach tube with doses up to 5 g/kg bw given singly or daily for 5 days.	Mutation	Without (in the direct treatment) Not applicable (in the host-mediated assay)	+ve (weak in both assays)	Litton Bionetics Inc, 1974
Escherichia coli	Host-mediated assay in which bacteria were present in the blood of mice that received	Mutation	Not applicable	-ve	Solt & Neale, 1980

	an intravenous injection of 2.7 g/kg bw.				
Escherichia coli	Assay for DNA damage, no details given in citing review	DNA damage	With and without S9	-ve	McCarroll et al. 1981
Bacillus subtilis	Assay for DNA damage, no details given in citing review	DNA damage	Without	-ve	Kawachi et al. 1981
Syrian hamster embryo cells	Cell transformation assay. No further details given.	Cell transformation	"Metabolic activation not stated"	-ve	Anon. 1983 (cited in OECD, 2001)

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