GLYCEROL

MODULE 1

SUBSTANCE INFORMATION SHEET

GLYCEROL

CAS number	56-81-5
Natural Origin	Occurs in cherries
Chemical Formula	$C_3H_8O_3$
Synonymes	1,2,3-Propanetriol; glycerine; glycerin; glycyl alcohol; trihydroxypropane, 1,2,3-trihydroxypropane; Citifluor AF 2; Glycerin mist; Glyceritol
E number	E422
FEMA GRAS number	2525

General Information

Council of Europe (CoE)

Number	Comment
4117	N/A

US Food & Drug Administration (FDA)

Number	Comment
21 CFR 175.105, 21 CFR 175.300, 21 CFR 176.210, 21 CFR 177.2420, 21 CFR 177.2800, 21 CFR 178.3400,21 CFR 182.90, 21 CFR 182.1320, 21 CFR 172.866	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
909	NOT SPECIFIED	Evaluation not finalized, pending definition of "flavouring agent"

European Food Safety Authority (EFSA)

Number	Comment
N/A	N/A

Flavors & Extracts Manufacturers Association (FEMA)

Number	Comment
2525	Glycerol is recognized as generally safe for use in food. GRAS3

Uses and Exposure

Glycerol is found in consumer products such as pharmaceuticals, cosmetics, tobacco, food and drinks and is present in numerous other products such as paints, resins and paper.

Estimated Intake from Food and Drink

Daily Intake
For the general population, glycerol is consumed primarily from fat naturally present in vegetables, fish, milk, meat, etc. and foods in which glycerol and glycerol-related ingredients were added. When combined, the average person is estimated to consume as much as 216.0 mg/kg/day of glycerol[1,2,3].

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

Smoke Chemistry

Internal Studies	Level Tested ppm	Comment
Carmines for Philip Morris	61, 126, 28,031, 42,048	The effect of the addition of glycerol as part of a mixture at concentrations up to 42,048 ppm on the composition of the cigarette smoke was investigated.
Philip Morris	50,000; 100,000; 150,000	The effect of addition of glycerol at concentration up to 150,000 ppm on inherent toxicity of cigarette smoke was investigated.

Neutral Red Uptake Assay (NRU)

Internal Studies	Level Tested ppm	Comment
Carmines for Philip Morris	61, 126, 28,031, 42,048	The effect of addition of glycerol as part of a mixture at concentration up to 42,048 ppm on the cytotoxicity, as measured by the Neutral Red Assay was investigated.
Philip Morris	50,000; 100,000; 150,000	The effect of addition of glycerol at concentration up to 150,000 ppm on the cytotoxicity, as measured by the Neutral Red Assay was investigated.

AMES Assay

Internal Studies	Level Tested ppm	Comment
Carmines for Philip Morris	61, 126, 28,031, 42,048	The effect of addition of glycerol as part of a mixture at concentration up to 42,048 ppm on the mutagenic response, as measured by Salmonella reverse mutation assay, was investigated.

AMES Assay (Cont.)

Internal Studies	Level Tested ppm	Comment
Philip Morris	50,000; 100,000; 150,000	The effect of addition of glycerol at concentration up to 150,000 ppm on the mutagenic response, as measured by Salmonella reverse mutation assay, was investigated.

Mouse Lymphoma Assay (MLA)

Internal Studies	Level Tested ppm	Comment
Philip Morris	50,000; 100,000; 150,000	The effect of the addition of glycerol at concentrations up to 150,000 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
Carmines for Philip Morris	61, 126, 28,031, 42,048	The effect of addition of glycerol as part of a mixture at concentration up to 42,048 ppm on the toxicity of cigarette smoke, as suggested in a 90-day inhalation study, was investigated.
Philip Morris	50,000; 100,000; 150,000	The effect of addition of glycerol at concentration up to 150,000 ppm on the toxicity of cigarette smoke, as suggested in a 90-day inhalation study, was investigated.

References

1. Lucas, C.D., Putnam, J.M. and Hallagan, J.B. (1999) 1995 Poundage and Technical Effects Update Survey. Flavor and Extract Manufacturers' Association of the United States. Washington, D. C.
2. Stofberg, J. and Grundschober, F. (1987) Consumption ratio and food predominance of flavoring materials. Perfumer and Flavorist 12:27-56.
3. Hall, R.L. and Oser, B.L. (1965) Recent progress in the consideration of flavoring ingredients under the food additives amendment III. GRAS substances. Food Technology151-197.