LINALOOL

MODULE 1

SUBSTANCE INFORMATION SHEET

LINALOOL

CAS number	78-70-6
Natural Origin	Occurs in bananas, blackberries, beans, blueberries, apples, apricots, artichokes.
Chemical Formula	C10-H18-O
Synonymes	2,6-Dimethyl-octadien-2,7-ol-6; 2,6-Dimethyl-2,7-octadien-6-ol; Linalol; Licareol; Coriandrol; 3,7-Dimethylocta-1,6-dien-3-ol
E number	N/A
FEMA GRAS number	2635

General Information

Council of Europe (CoE)

Number	Comment
61	N/A

US Food & Drug Administration (FDA)

Number	Comment
21 CFR 182.60	Approved by U.S. FDA as Food Additives Generally Recognized as Safe (GRAS)

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

Number	ADI	Comment
356	0-0.5 mg/kg bw	No safety concern at current levels of intake when used as a flavouring agent

European Food Safety Authority (EFSA)

Number	Comment
02.013	Aliphatic, alicyclic, and aromatic saturated and unsaturated tertiary alcohols and esters with esters containing tertiary alcohols. Esters may contain any acid component.

Flavors & Extracts Manufacturers Association (FEMA)

Number	Comment
2635	Generally Recognized as Safe as a flavor ingredient - GRAS 3

Uses and Exposure

In the food industry, linalool is used as a flavoring agent and adjuvant. It is also used in many cosmetic and perfumery products, as well as in the manufacture of other flavor and aromatic substances. It is used in the manufacture of Vitamins A and E.

Estimated Intake from Food and Drink

Daily Intake
The total higher-intake consumption value for linalool was estimated by summing the FEMA disappearance per capita consumption with the eaters-only DINFO consumption, and is equal to 1.22 mg/kg/day[1,2,3,4,5,6,7].

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	1, 3	The effect of the addition of Linalool as part of a mixture at concentrations up to 3 ppm on the composition of the cigarette smoke was investigated.
Philip Morris	100, 300, 900	The effect of the addition of linalool as part of a mixture at concentrations up to 900 ppm on the composition of the cigarette smoke was investigated.

Neutral Red Uptake Assay (NRU)

Internal Studies	Level Tested ppm	Comment
Carmines for Philip Morris	1, 3	The effect of the addition of linalool as part of a mixture at concentrations up to 3 ppm on the cytotoxicity, as measured by the Neutral Red Uptake assay, was investigated.
Philip Morris	100, 300, 900	The effect of the addition of linalool as part of a mixture at concentrations up to 900 ppm on the cytotoxicity, as measured by the Neutral Red Uptake assay, was investigated.

AMES Assay

Internal Studies	Level Tested ppm	Comment
Carmines for Philip Morris	1, 3	The effect of the addition of linalool as part of a mixture at concentrations up to 3 ppm on the mutagenic response, as measured by the

		Salmonella reverse mutation assay, was investigated.
Philip Morris	100, 300, 900	The effect of the addition of linalool as part of a mixture at concentrations up to 900 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
N/A	N/A	N/A

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	1, 3	The effect of the addition of linalool as part of a mixture at concentrations up to 3 ppm on the toxicity of cigarette smoke, as suggested in a 90-day inhalation study, was investigated.

References

1. Clydesdale, F. M. (1997) Linalool. Food additives: Toxicology, Regulation and Properties. CRC Press, Boca Raton, FL. CD-ROM.

2. CSFII 1994-96 (2000) Continuing Survey of Food Intakes by Individuals (CSFII) 1994-96, 98. Agricultural Research Service, US Department of Agriculture, Washington, DC. CD-ROM.

3. JECFA (created/updated 2003c) Summary of evaluations performed by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Joint FAO/WHO Expert Committee on Food Additives. <http://jecfa.ilsi.org/evaluation.cfm?chemical=LINALOOL&keyword=LINALOOL>.

4. Lucas, C. D.; Putnam, J. M. and Hallagan, J. B. (1999) Linalool. In 1995 Poundage and Technical Effects Update Survey. Flavor and Extract Manufacturers' Association of the United States, Washington, DC. p. 166.

5. MRCA (1965) Market Research Corporation of America (MRCA), in conjunction with the "Food intake and nutritive value of the diets of men, women and children in United States, Spring 1965". United States Department of Agriculture, Washington, DC.

6. NAS (1989) Linalool. In 1987 Poundage and Technical Effects Update of Substances Added to Food. National Research Council, National Academy of Sciences, Washington, DC. p. 330.

7. Stofberg, J. and Grundschober, F. (1987) Consumption ratio and food predominance of flavoring materials. Perfumer and Flavorist 12:27-56.