ETHYL BUTYRATE

MODULE 1

SUBSTANCE INFORMATION SHEET

Ethyl butyrate

CAS number	105-54-4
Natural Origin	Fruits; the synthetic material is obtained by a reaction between ethanol and butyric acid.
Chemical Formula	$C_6H_{12}O_2$
Synonyms	Ethyl butanoate
E number	N/A
FEMA GRAS number	2427

General Information

Council of Europe (CoE)

Number	Comment
264	May be used as food stuffs; no limits

US Food & Drug Administration (FDA)

Number	Comment
21 CFR 182	Food for human consumption. Substances Generally Recognized as Safe. Section 182.60. Synthetic flavoring substances and adjuvants.

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

Number	ADI	Comment
29	0-15 mg/kg bw	No safety concern at current levels of intake when used as a flavouring agent.

European Food Safety Authority (EFSA)

Number	Comment
N/A	N/A

Flavors & Extracts Manufacturers Association (FEMA)

Number	Comment
2427	Generally Recognized as Safe as a flavor ingredient - GRAS 3

Uses and Exposure

Used extensively in flavours and fragrances, specifically as a pineapple flavor. It is also used as a solvent in perfumery products and as a plasticizer for cellulose. Ethyl butyrate is often also added to orange juice, as most associate its odor with that of fresh orange juice

Estimated Intake from Food and Drink

Daily Intake
The calculated individual consumption by FDA for ethyl butyrate is 0.2541 mg/kg/day.

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	2, 6, 9 and 28	The effect of the addition of ethyl butyrate at concentrations up to 28 ppm on the composition of the cigarette smoke was investigated.
Philip Morris	100, 300, 900	The effect of the addition of ethyl butyrate 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	2, 6, 9 and 28	The effect of the addition of ethyl butyrate at concentrations up to 28 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 ethyl butyrate 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	2, 6, 9 and 28	The effect of the addition of ethyl butyrate at concentrations up to 28 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 ethyl butyrate 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	2, 6, 9 and 28	The effect of the addition of ethyl butyrate at concentrations up to 28 ppm on the toxicity of cigarette smoke, as suggested in a 90-day inhalation study, was investigated.

References

1. Clydesdale, F.M. (1997). Food additives: toxicology, Regulation and Properties. CRC Press, Boca Raton, FL.
2. JECFA-Evaluation of certain food additives and contaminants (Forty-sixth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series, No. 868, 1997.