BETA-CYCLODEXTRIN

MODULE 1

SUBSTANCE INFORMATION SHEET

BETA-CYCLODEXTRIN

CAS number	7585-39-9
Natural Origin	N/A
Chemical Formula	C42-H70-O35
Synonymes	Beta-Cycloamylose; Cycloheptaamylose; Cycloheptaglucan; Cycloheptaglucosan; Cyclomaltoheptaose; beta-Dextrin; Dextrin, beta-cyclo;
E number	E459
FEMA GRAS number	4028

General Information

Council of Europe (CoE)

Number	Comment
N/A	N/A

US Food & Drug Administration (FDA)

Number	Comment
N/A	

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

Number	ADI	Comment
N/A	0-5 mg/kg bw	

European Food Safety Authority (EFSA)

Number	Comment
N/A	N/A

Flavors & Extracts Manufacturers Association (FEMA)

Number	Comment
4028	Generally Recognized as Safe as a flavor ingredient - GRAS 21

Uses and Exposure

β-cyclodextrin is a versatile encapsulating agent for food additives, flavorings, vitamins and drugs; it has also been used as a food processing aid, stabilizer and thickening agent.

Estimated Intake from Food and Drink

Daily Intake
Intake of β-cyclodextrin in food applications is estimated to be 0.000032 mg/kg/day and the consumption of β-cyclodextrin from medical uses is estimated to be 0.00007 mg/kg/day. Estimations by FDA indicate that daily intake is 0.066 mg/kg/day[1,2].

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

Smoke Chemistry

Internal Studies	Level Tested	Comment
Philip Morris	0, 2.5% and 5%	The effect of the addition of beta-cyclodextrin at concentrations up to 5% on the composition of the cigarette smoke was investigated.

Neutral Red Uptake Assay (NRU)

Internal Studies	Level Tested	Comment
Philip Morris	0, 2.5% and 5%	The effect of the addition of beta-cyclodextrin at concentrations up to 5% on the cytotoxicity, as measured by the Neutral Red Uptake assay, was investigated.

AMES Assay

Internal Studies	Level Tested	Comment
Philip Morris	0, 2.5% and 5%	The effect of the addition of beta-cyclodextrin at concentrations up to 5% on the mutagenic response, as measured by the Salmonella reverse mutation assay, was investigated.

Mouse Lymphoma Assay (MLA)

Internal Studies	Level Tested	Comment
Philip Morris	0, 2.5% and 5%	The effect of the addition of beta-cyclodextrin at concentrations up to 5% on the mutagenic response, as measured by the Mouse Lymphoma Assay, was investigated.

In vivo Micronucleus

Internal Studies	Level Tested	Comment
Philip Morris	0, 2.5% and 5%	The effect of the addition of beta-cyclodextrin at concentrations up to 5% on the clastogenic/aneugenic response, as measured by the in vivo Micronucleus Assay, was investigated.

Inhalation studies

Internal Studies	Level Tested	Comment
Philip Morris	0, 2.5% and 5%	The effect of the addition of beta-cyclodextrin as mix at concentrations up to 5% on the toxicity of cigarette smoke, as suggested in a 90-day inhalation study, was investigated.

References

1. U.S.Census Bureau (1998) 1997 Population Profile of the United States. (Visited on May 7) URL: http://www.census.gov/prod/3/98pubs/p23-194.pdf.

2. FDA (2001) Agency Response Letter GRAS Notice No. GRN 000074. U.S. Food and Drug Administration. (Visited on March 2) URL: http://www.cfsan.fda.gov/rdb/opa-g074.html.