

COCOA AND COCOA PRODUCTS

MODULE 1

SUBSTANCE INFORMATION SHEET

COCOA AND COCOA PRODUCTS

CAS numbers	8002-31-1 84649-99-0 95009-22-6
Natural Origin	Cocoa, cocoa butter, cocoa liquor, cocoa shell powder and cocoa shell extract are all products of the same fruit from the cacao tree (<i>Theobroma cacao</i> L.).
Chemical Formula	N/A
Synonymes	Cacao bean oil; Cocoa; Cocoa absolute; Cocoa bean extract; Cocoa Beans Absolute; Cocoa extract; <i>Theobroma cacao</i> Extract
E number	N/A
FEMA GRAS number	N/A

General Information

Council of Europe (CoE)

Number	Comment
452	N/A

US Food & Drug Administration (FDA)

Number	Comment
21 CFR 182.20	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
N/A	N/A	N/A

European Food Safety Authority (EFSA)

Number	Comment
N/A	N/A

Flavors & Extracts Manufacturers Association (FEMA)

Number	Comment
N/A	N/A

Uses and Exposure

Broadly used in food industries as direct food or as flavouring agent. It also find many application in cosmetics.

Estimated Intake from Food and Drink

Daily Intake

Cocoa, cocoa extract and their products have a long history of safe use in a number of foods. The estimated daily intake of 113.3 mg/kg/day of cocoa may vary considerably between individuals, the near absence of cocoa even at multiples of this value.

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	3, 8, 9, 23,257, 644, 772, 1,932	The effect of the addition of cocoa and cocoa products as part of a mixture at concentrations up to 1,932 ppm on the composition of the cigarette smoke was investigated.
Philip Morris	10,000; 20,000; 40,000	The effect of addition of cocoa and cocoa products at concentration up to 40,000 ppm on inherent toxicity of cigarette smoke was investigated.

Neutral Red Uptake Assay (NRU)

Internal Studies	Level Tested ppm	Comment
Carmines for Philip Morris	3, 8, 9, 23,257, 644, 772, 1,932	The effect of addition of cocoa and cocoa products as part of a mixture at concentration up to 1932 ppm on the cytotoxicity, as measured by the Neutral Red Assay was investigated.
Philip Morris	10,000; 20,000; 40,000	The effect of addition of cocoa and cocoa products at concentration up to 40,000 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	3, 8, 9, 23,257, 644, 772, 1,932	The effect of addition of cocoa and cocoa products as part of a mixture at concentration up to 1,932 ppm on the mutagenic response, as measured by Salmonella reverse mutation

		assay, was investigated.
Philip Morris	10,000; 20,000; 40,000	The effect of addition of cocoa and cocoa products at concentration up to 40,000 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	10,000; 20,000; 40,000	The effect of the addition of cocoa and cocoa products at concentrations up to 40,000 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	3, 8, 9, 23,257, 644, 772, 1,932	The effect of addition of cocoa and cocoa products as part of a mixture at concentration up to 1,932 ppm on the toxicity of cigarette smoke, as suggested in a 90-day inhalation study, was investigated.
Philip Morris	10,000; 20,000; 40,000	The effect of addition of cocoa and cocoa products at concentration up to 40,000 ppm on the toxicity of cigarette smoke, as suggested in a 90-day inhalation study, was investigated.



Toxicological Data Summary

COCOA AND COCOA PRODUCTS

October 2012