

Cocoa extract

Botanical Source Theobroma cacao

Synonyms

IUPAC Name

CAS Reference 84649-99-0

E Number

Food Legislation

Council of Europe (CoE)	
Number	Comment
452	Listed by the Council of Europe as acceptable for use in food.

US Food and Drug Administration	
Number	Comment
182.20	Approved by the US FDA. FDA 21 CFR 182.20

Joint FAO/WHO Expert Committee on Food Additives (JECFA)		
Number	ADI	Comment
-	-	-

FEMA	
FEMA No.	Comment
	Generally recognised as safe as a flavour ingredient:GRAS List Number 3

Natural Occurrence and Use in Food
Found in cocoa, cocoa shells; used in baked goods.

Estimated Intake from Food and Drink	
Daily Intake mg/kg/day	FEMA Possible Average Daily Intake mg
-	-

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Tobacco Product Related Chemical and Biological Studies for Ingredients Added in a Mixture

Smoke Chemistry		
Published Source	Level Tested %	Comment
BAT	2.00000	At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.
Philip Morris	0.07720	An overall assessment of the data suggests that this ingredient did not add to the toxicity of smoke.

Ames Activity		
Published Source	Level Tested %	Comment
BAT	2.00000	Within the sensitivity and specificity of the system the Ames activity of the cigarette smoke condensate was not increased by the addition of the ingredient.
Philip Morris	0.07720	Within the sensitivity and specificity of the system the Ames activity of the cigarette smoke was not increased by the addition of the ingredient.

Micronucleus		
Published Source	Level Tested %	Comment
BAT	2.00000	Within the sensitivity of the in vitro micronucleus assay the activity of the cigarette smoke condensate was not increased by the addition of the ingredient.

Neutral Red		
Published Source	Level Tested %	Comment
BAT	2.00000	Within the sensitivity of the test system the in vitro cytotoxicity of the cigarette smoke condensate was not increased by the addition of the ingredient.
Philip Morris	0.0772	Within the sensitivity of the test system the in vitro cytotoxicity of the cigarette smoke was not increased by the addition of the ingredient.

Inhalation		
Published Source	Level Tested %	Comment
BAT	2.00000	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Lorillard	0.00020	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Philip Morris	0.07720	The data indicate that the addition of the ingredient, when added with one of three groups, did not increase the inhalation toxicity of the smoke.

Mouse Skin Painting		
Published Source	Level Tested %	Comment
Lorillard	4.40000	None of the changes appeared to be substantial enough to conclude that the tumour promotion capacity of the condensate was discernibly different between condensate produced from cigarettes with the ingredient in comparison with condensate from cigarettes without the ingredient.

References
Baker RR, Pereira da Silva JR, Smith G. The effect of tobacco ingredients on smoke chemistry. Part I: Flavourings and additives. Food Chem Toxicol. 2004; 42 Suppl:S3-37.
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Baker RR, Massey ED, Smith G. An overview of the effects of tobacco ingredients on smoke chemistry and toxicity. Food Chem Toxicol. 2004; 42 Suppl:S53-83.
Carmines EL. Evaluation of the potential effects of ingredients added to cigarettes. Part 1: cigarette design, testing approach, and review of results. Food Chem Toxicol. 2002; 40(1): 77-91.
Rustemeier K, Stabbert R, Haussmann HJ, Roemer E, Carmines EL. Evaluation of the potential effects of ingredients added to cigarettes. Part 2: chemical composition of mainstream smoke. Food Chem Toxicol. 2002; 40(1): 93-104.
Roemer E, Tewes FJ, Meisgen TJ, Veltel DJ, Carmines EL. Evaluation of the potential effects of ingredients added to cigarettes. Part 3: in vitro genotoxicity and cytotoxicity. Food Chem Toxicol. 2002; 40(1): 105-111.
Vanschaeuwijck PM, Teredesai A, Terpstra PM, Verbeeck J, Kuhl P, Gerstenberg B, Gebel S, Carmines EL. Evaluation of the potential effects of ingredients added to cigarettes. Part 4: subchronic inhalation toxicity. Food Chem Toxicol. 2002; 40(1): 113-131.

Gaworski CL, Dozier MM, Heck JD, Gerhart JM, Rajendran N, David RM, Brennecke LH, Morrissey R. Toxicologic evaluation of flavor ingredients added to cigarette tobacco: 13 week inhalation exposures in rats. *Inhal. Toxicol.* 1998; 10:357-381

Gaworski CL, Heck JD, Bennett MB, Wenk ML. Toxicologic evaluation of flavor ingredients added to cigarette tobacco: skin painting bioassay of cigarette smoke condensate in SENCAR mice. *Toxicology.* 1999; 139(1-2):1-17.

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Tobacco Product Related Chemical and Biological Studies for Ingredients Tested Singly

References
Baker RR, Bishop LJ. The pyrolysis of non-volatile tobacco ingredients using a system that simulates cigarette combustion conditions. J. Anal. Appl. Pyrolysis 2005, 74, 145-170.

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Toxicological Data on the Unburnt Ingredient

[+ve, positive; -ve, negative; ?, equivocal; with, with metabolic activation; without, without metabolic activation]

In vivo

Species	Test conditions	Endpoint	Results	Reference
Chinese hamsters, 6 treated and 6 controls	Text is ambiguous, animals were either given 0.2 g cocoa or 0.6 g roasted cocoa (by gavage dispersed in water). The higher dose would have been approximately 5 g/kg bw. Bone marrow cells were examined for micronuclei 27, 28.5 or 30 hr later.	Chromosome damage	-ve	Renner and Muenzner, 1982
Chinese hamsters, 6 treated and 6 controls	Text is ambiguous, animals were either given 0.2 g cocoa or 0.6 g roasted cocoa (by gavage dispersed in water). The higher dose would have been approximately 5 g/kg bw. Bone marrow cells examined for chromosome aberrations 24 hr later.	Chromosome damage	-ve	Renner and Muenzner, 1982

Chinese hamsters, 4 per group	Unroasted and roasted cocoa powder were given (by gavage in water) at 0.1 or 0.2 g (as a single dose), at 0.4 g (as two doses 1.5 hr apart) or at 0.6 g (as three doses 1.5 hr apart). The highest dose was equal to about 5 g/kg bw. Bone marrow cells were assessed for sister chromatid exchanges (SCEs), about 26 hr after the last dose. Cocoa powder was also given at 20% in the diet [possibly for 3 days, though this is not clear] and bone marrow cells screened for SCEs.	Chromosome effects	+ve a weak increase (less than 2-fold) was seen at the highest two dose levels following gavage -ve (SCE values were slightly elevated after dietary dosing but the increase did not reach the 1.5-fold criterion)	Renner and Muenzner, 1982
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In vitro

Test system	Test conditions	Endpoint	Activation status	Results	Reference
Chinese hamster ovary cells	Cocoa powder incubated at up to 1 mg/ml for 12 hr, cells examined for chromosome aberrations.	Chromosome damage	With and without S9	-ve	Brusick et al. 1986
Chinese hamster	Cocoa powder	Chromosome	With and	-ve	Brusick et

ovary cells	incubated at up to 1.25 mg/ml for 27 hr, cells examined for SCEs	effects	without S9		al. 1986
Human lymphocytes	Cocoa powder incubated at up to 1.25 mg/ml for 45 hr, cells examined for SCEs.	Chromosome effects	Not stated	-ve	Brusick et al. 1986
Mouse lymphoma cells	Cocoa powder incubated at up to 6 mg/ml for 4 hr.	Mutation	With and without S9	-ve	Brusick et al. 1986
<i>Salmonella typhimurium</i> strains TA98, TA100, TA1535, TA1537 and TA1538	Ames test, cocoa powder tested at up to 5 mg/plate.	Mutation	With and without S9	-ve	Brusick et al. 1986
<i>Salmonella typhimurium</i> strains TA98, TA100, TA1537 and TA1538	Ames test on fat-free cocoa powder, tested at up to 5 mg/plate.	Mutation	With and without S9	-ve	Renner and Muenzner, 1982
Mouse Balb/C-3T3 cells	Cocoa powder tested at up to 0.25 mg/ml.	Cell transformation	Apparently without	-ve	Brusick et al. 1986

References

Brusick D et al. (1986). Genotoxicity of cocoa in a series of short-term assays. *Mutation Research* 169, 115-121.

Renner H W and Muenzner R (1982). Genotoxicity of cocoa examined by microbial and mammalian systems. *Mutation Research* 103, 275-282.

