Botanical Source Theobroma cacao

Synonyms

IUPAC Name

CAS Reference 95009-22-6

E Number

Food Legislation

Council	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	
163.113	Approved by the US FDA. FDA 21 CFR 163.113	

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		
-	-	

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.	

Ames Activity		
Published Source	Level Tested %	Comment
ВАТ	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.

Micronucleus			
Published Source	Level Tested %	Comment	
ВАТ	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	
ВАТ	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.	

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.	

Mouse Skin Painting

Published Source	Level Tested %	Comment

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.

Baker RR, Pereira da Silva JR, Smith G. The effect of tobacco ingredients on smoke chemistry. Part II: casing ingredients. Food Chem Toxicol. 2004; 42 Suppl:S39-52.

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.

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.

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	Text is	Chromosome damage	-ve	Renner and
hamsters,	ambiguous,			Muenzner, 1982
6 treated	animals were			
and 6	either given 0.2 g			
controls	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.			
at :		GI I		
Chinese	Text is	Chromosome damage	-ve	Renner and
hamsters, 6 treated	ambiguous,			Muenzner, 1982
and 6	animals were either given 0.2 g			
controls	cocoa or 0.6 g			
Controls	roasted cocoa (by			
	gavage dispersed			
	in water). The			
	higher dose			
	would have been			
	approximately 5			
	g/kg bw. Bone			
	marrow cells			
	examined for			
	chromosome			
	l ala amati ama 21 lan	i e e e e e e e e e e e e e e e e e e e	I	
	aberrations 24 hr			
	later.			

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

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
Salmonella typhimurium 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
Salmonella typhimurium 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.