Botanical Source

Synonyms IRISONE (alpha-);

CYCLOCYTRYLIDENE ACETONE (alpha-);

TRIMETHYLCYCLOHEX-2-ENYL)-BUT-3-EN-2-ONE(4-(2,6,6-

IUPAC Name

CAS Reference 127-41-3

E Number

Food Legislation

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

US Food and Drug Administration				
Number	r Comment			
172.515	Approved by the US FDA. FDA 21 CFR 172.515			

Joint FAO/WHO Expert Committee on Food Additives (JECFA)					
Number ADI Comment					
388	ADI 0-01 MG/KG BW	No safety concern at current levels of intake when used as a flavouring agent.			

FEMA		
FEMA No.	Comment	
2594	Generally recognised as safe as a flavour ingredient:GRAS List Number 4	

Natural Occurrence and Use in Food

Found in raspberry, almond, banana, blackberry, grape brandy, raspberry, brandy, capers, carrots, celery, cherry, grapefruit juice, mango, ginger, peach, peas, plum; used in chewing gum, ice cream, baked goods.

Estimated Intake from Food and Drink				
Daily Intake mg/kg/day FEMA Possible Average Daily Intake mg				
0.002387	0.957			

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

Smoke Chemistry				
Published Source	Level Tested %	Comment		
BAT 0.00100		At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.		
Philip Morris	0.00080	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		
ВАТ	0.00100	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	0.00080	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	
ВАТ	0.00100	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 0.00100		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	0.00080	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	0.00100	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.		
Philip Morris	0.00080	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.		

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.

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.

Vanscheeuwijck 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.

Tobacco Product Related Chemical and Biological Studies for Ingredients Tested Singly

References

Baker RR, Bishop LJ. The pyrolysis of tobacco ingredients. J. Anal. Appl. Pyrolysis 2004, 71, 223-311.

Toxicological Data on the Unburnt Ingredient

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

In vitro

Test system	Test conditions	Endpoint	Activation status	Results	Reference
Chinese hamster B241 cells	Cells treated for 24 hours with concentrations up to 25 nmol/l [4.8 ng/ml] and examined for chromosomal aberrations.	Chromosome damage	With and without S9	+ve	Kasamaki et al. 1982
Salmonella typhimurium strain TA98, TA100	Ames test at 0.01-50 µg/plate.	Mutation	With and without S9	-ve (limited test)	Kasamaki et al. 1982
Bacillus subtilis strain H17 and M45	Rec assay with "ionone" at 20 µl/disc.	DNA damage (indicative test)	Without	+ve	Yoo, 1986
Bacillus subtilis strain H17 and M45	Rec assay at 10 µg/disc.	DNA damage (indicative test)	Without	-ve	Oda et al. 1978

References

Kasamaki A et al. (1982). Genotoxicity of flavoring agents. Mutation Research 105, 387-392.

Oda Y et al. (1978). Mutagenicity of food flavours in bacteria. 1. Osaka-Furitsu Koshu Eisei Kenkyu Shokuhin Eisei Hen 9, 177.

Yoo Y S et al. (1986). Mutagenic and Antimutagenic activities of flavoring agents used in foodstuffs. J. Osaka City Med. Cent. 34, 267-287.