**Botanical Source** 

Synonyms CYCLOTENE;

MAPLE LACTONE; CORYLONE; CORILONE;

HYDROXY-3-METHYL-2-CYCLOPENTEN-1-ONE (2-); HYDROXY-3-METHYL CYCLOPENT-2-EN-1-ONE (2-);

HYDROXY-1-METHYLCYCLOPENTEN-3-ONE (2-);KETONAROME;

METHYL-1,2-CYCLOPENTANEDIONE (3-); METHYLCYCLOPENTANE-1,2-DIONE (3-)

**IUPAC Name** 

CAS Reference 765-70-8

80-71-7

**E Number** 

### **Food Legislation**

Council	Council of Europe (CoE)		
Number	Comment		
758	Listed by the Council of Europe as acceptable for use in food at up to 50 ppm.		

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

Joint FAO/WHO Expert Committee on Food Additives (JECFA)					
Number	ımber ADI Comment				
418	890	No safety concern at current levels of intake when used as a flavouring agent.			

FEMA		
FEMA No.	Comment	
2700	Generally recognised as safe as a flavour ingredient:GRAS List Number 9	

### **Natural Occurrence and Use in Food**

Found in carambola (starfruit), cheese, tomato; used in breakfast cereals, baked goods, candy.

Estimated Intake from Food and Drink				
Daily Intake mg/kg/day FEMA Possible Average Daily Intake mg				
0.01156	3.197			

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

Smoke Chemistry				
Published Source Level Tested % Comment				
BAT	0.00450	At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.		
Philip Morris	0.01240	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	0.00450	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	0.01240	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	0.00450	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	0.00450	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	0.01240	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	0.00450	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.		
Lorillard 0.00230		The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.		
Philip Morris	0.01240	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	0.00230	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.

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.

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.

# 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	Result	References
Salmonella typhimuriu m, strains TA98, TA100, TA1535, TA1537, TA1538	Ames test. Tested up to 10 mg/plate.	Mutation.	With and without S9.	-ve	Heck et al. 1989, additional data cited in JECFA, 1999
Rat liver cells	Unscheduled DNA synthesis assay. Tested up to 0.5 mg/plate.	DNA damage.	Not applicable (although cited in JECFA as with S9).	-ve	Heck et al. 1989, additional data cited in JECFA, 1999
Human leucocytes	Tested at a concentration of 3.5 x 10 <sup>-4</sup> M. Examined for chromosome aberrations (abnormal metaphases and chromosome breaks).	Chromos ome damage.	Without.	+ve for abnormal metaphase s -ve for chromoso me breaks	Withers, 1966
Human lymphocyte s	Tested at concentrations of 0-3.0 mM. Examined for sister chromatid exchanges.	Chromos ome effects.	Without.	+ve (weak)	Jansson et al. 1986

### References

Heck J.D. et al. (1989). Toxicologist 9, 257 (and additional data cited in JECFA, 1999),

Jansson T. et al. (1986). Mutation Res. 169, 129.

- JECFA (1999). Prepared by the Fifty-First Meeting of the Joint FAO/WHO Expert Committee on Food Additives. WHO Fd Add. Ser. 42.
- Withers R.F.J. (1966). Mechanisms of Mutation and Inducing Factors. Proc. Symp. 1965. Landa Z. (Ed.), p359.