Isoamyl acetate

Botanical Source	
Synonyms	ISOPENTYL ACETATE; METHYL BUTYL ACETATE (3-)
IUPAC Name	ISOPENTYL ACETATE
CAS Reference	123-92-2
E Number	

Food Legislation

Council of Europe (CoE)	
Number	Comment
214	Listed by the Council of Europe as acceptable for use in food at up to 500 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	ADI	Comment
43	23000	Group ADI 0-3 mg/kg bw (1979)
		Comments: No safety concern at current levels of intake when used as a flavouring agent. The 1979 group ADI of 0-3 mg/kg bw for isoamyl acetate and isoamyl butyrate, expressed as isoamyl alcohol, was maintained at the forty-sixth meeting

FEMA	
FEMA No.	Comment
2055	Generally recognised as safe as a flavour ingredient:GRAS List Number 3

Natural Occurrence and Use in Food
Found in apple, banana, beer, apricot, blackberry, blackberry brandy, wheat bread, butter; 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
0.1652	24.491

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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	0.00600	At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.
Philip Morris	0.00350	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	0.00600	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	0.00350	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	0.00600	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	0.00600	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	0.00350	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	0.00600	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Philip Morris	0.00350	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

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.

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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.

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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.

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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
Hamster fibroblasts	Incubated for 48 hr at up to 2 mg/ml, cells assessed for chromosome aberrations	Chromosome damage	Without	-ve	Ishidate *et al.* 1984
Mouse lymphoma cells	No details given, only available as an abstract	Somatic cell mutations	With and without S9	-ve	McCarroll *et al.* 1985
Salmonella typhimurium strains TA97, TA98, TA100, TA1535, TA1537	Up to 10 mg/plate Met OECD guideline	Mutation	With and without S9 from rat and hamster liver	-ve	Zeiger *et al.* 1992
Salmonella typhimurium strains TA98, TA100, TA1535, TA1537	Up to 10 mg/plate	Mutation	With and without S9	-ve	McCarroll *et al.* 1985
Salmonella typhimurium strains TA92, TA94, TA98, TA100, TA1535, TA1537	Up to 5 mg/plate	Mutation	With and without S9	-ve	Ishidate *et al.* 1984

Bacillus subtilis and *Escherichia coli*	No details given, only available as an abstract, differential killing assay	DNA damage (indicative test)	With and without S9	-ve (both tests)	McCarroll *et al.* 1985
Yeast *Saccharomyces cerevisiae*	No details given in expert review	Mutation?	Not specified in expert review	-ve	CIR, 1988 citing Zimmerman *et al.* 1985
Drosophila melanogaster	Males fed at 4800 ppm in diet for 3 days, or injected at 14,000 ppm, mated to untreated females, offspring (3 broods) examined for induction of sex-linked recessive lethal mutations	Mutation	Not applicable	-ve	Foureman *et al.* 1994

References

CIR (1988). J. Am. Coll. Toxicol. 7, 705.

Foureman P. *et al.* (1994). Envir. molec. Mutagen. 23, 51.

Ishidate M. *et al.* (1984). Fd Chem. Toxicol. 22, 623.

McCarroll N.E. *et al.* (1985). Envir. Mutagen. 7(suppl. 3), 63.

Zeiger E. *et al.* (1992). Envir. molec. Mutagen. 19(Suppl. 21), 2.