

Isoamyl butyrate

Botanical Source

Synonyms ISOPENTYL BUTYRATE;
METHYL BUTYL BUTYRATE (3-);
ISOAMYL BUTANOATE;
ISOPENTYL BUTANOATE

IUPAC Name

CAS Reference 106-27-4

E Number

Food Legislation

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

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
45	4000	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
2060	Generally recognised as safe as a flavour ingredient:GRAS List Number 3

Natural Occurrence and Use in Food
Found in banana, blue cheese, grape, apple, apricot, beer, apple brandy, grape brandy, guava, honey, mango; used in non-alcoholic beverages, ice cream, baked goods, chewing gum.

Estimated Intake from Food and Drink	
Daily Intake mg/kg/day	FEMA Possible Average Daily Intake mg
0.3163	9.645

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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	0.00200	At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.
Philip Morris	0.00050	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	0.00200	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	0.00050	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	0.00200	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	0.00200	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	0.00050	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	0.00200	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Philip Morris	0.00050	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.
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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 lung fibroblast cells	Up to 1 mg/ml (the highest non-toxic concentration) for 48 hr, cells examined for chromosome aberrations and polyploidy.	Chromosome damage	Without	-ve limited study as not tested in presence of activation	Ishidate <i>et al</i> 1984
<i>Salmonella typhimurium</i> , strains TA92, TA94, TA98, TA100, TA1535 and TA1537	Up to 10 mg/plate (the highest non-toxic concentration)	Mutation	With and without S9	-ve good quality study	Ishidate <i>et al</i> 1984
<i>Salmonella typhimurium</i> , strains TA97 and TA102	Up to 0.1 mg/plate	Mutation	with and without S9	-ve limited study as only tested in two strains	Fujita <i>et al</i> 1992
<i>Bacillus subtilis</i> ('Rec' assay)	Tested at up to 17 µg/disc in an assay measuring differential toxicity	DNA damage	without	-ve	Oda <i>et al</i> 1978

<i>Escherichia coli</i> PQ37	Up to 0.5 mg/ml, assessed effect on induction of SOS by UV light	DNA damage	without	-ve	Ohta <i>et al</i> 1986
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References

Fujita H *et al* (1992). Mutagenicity test of food additives with *Salmonella typhimurium* TA97 and TA102. Kenkyu Nenpo – Tokyo-Toritsu Eisei Kenkyusho (Annual Report of the Tokyo Metropolitan Research Laboratory of Public Health), 43, 219-227 (in Japanese, English abstract and tables).

Ishidate M Jr *et al* (1984). Primary mutagenicity screening of food additives currently used in Japan. Food and Chemical Toxicology, 22, 623-636.

Oda Y *et al* (1978). Mutagenicity of food flavours in bacteria (1st report). Osaka-Furitsu Koshu Eisei Kenkyu Hokoku Shokuhin Eisei Hen, 9, 177-181.

Ohta T *et al* (1986). Antimutagenic effects of 5-fluorouracil and 5-fluorodeoxyuridine on UV-induced mutagenesis induced in *Escherichia coli*. Mutation Research, 173, 19-24.