

Isobutyraldehyde

Botanical Source

Synonyms METHYL PROPANAL(2-);
ISOBUTYL ALDEHYDE;
ISOBUTANAL;
ISOBUTYRIC ALDEHYDE

IUPAC Name

CAS Reference 78-84-2

E Number

Food Legislation

Council of Europe (CoE)	
Number	Comment
92	Listed by the Council of Europe as acceptable for use in food at up to 1 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
252	130	No safety concern at current levels of intake when used as a flavouring agent.

FEMA	
FEMA No.	Comment
2220	Generally recognised as safe as a flavour ingredient:GRAS List Number 3

Natural Occurrence and Use in Food
Found in apple, banana, barley, beans, beef, beer, blue cheese, brandy, bread, wheat, butter; used in gelatin and puddings, candy, frozen dairy products.

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

0.001624	0.734
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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	0.00100	At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.
Philip Morris	0.00020	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	0.00100	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	0.00020	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	0.00100	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	0.00020	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.
Lorillard	0.00120	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Philip Morris	0.00020	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	0.00120	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.

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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.

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Tobacco Product Related Chemical and Biological Studies for Ingredients Tested Singly

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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	Result	Reference
<i>Drosophila melanogaster</i> (this assay can be classed as <i>in vivo</i> or <i>in vitro</i>)	Wild-type males fed isobutylaldehyde (80,000 ppm) or given it by injection (50,000 ppm) (concentrations producing roughly 30% mortality), and then mated with unexposed females to produce 3 broods, which were examined for the frequency of sex-linked recessive lethal mutations	Mutation (Sex-linked recessive lethal mutation)	-ve	Woodruff <i>et al.</i> 1985

In vitro

Test system	Test conditions	Endpoint	Activation	Result	References
Human lymphocytes	Cells exposed at 0.002%, examined for sister chromatid exchanges after 24 and 48 hr	Chromosome effects	without	-ve limited study as S9 was not used	Obe & Beek, 1979 (cited in JECFA, 1998 and IUCLID, 2000)
Chinese hamster ovary cells	Test conditions not specified in the citation, exposed cells examined for sister chromatid exchanges	Chromosome effects	without	+ve	NTP, 1985 (cited in IUCLID, 2000)

Chinese hamster ovary cells	Test conditions not specified in the citation, exposed cells examined for chromosome aberrations	Chromosome damage	unspecified	+ve	NTP, 1985 (cited in IUCLID, 2000)
Mouse lymphoma cells (L5178Y)	Test conditions not specified in the citation	Mutation	unspecified	+ve	NTP, 1986 (cited in IUCLID, 2000)
<i>Salmonella typhimurium</i> , strains TA98, TA100, TA1535 and TA1537	Tested at concentrations of up to 10 mg/plate, using a preincubation method	Mutation	with and without S9	-ve (a high quality study)	Mortelmans <i>et al.</i> 1986
<i>Salmonella typhimurium</i> , strains TA98, TA100 and TA102	Tested at concentrations of up to 8 mg/plate using a preincubation method	Mutation	with and without S9	-ve (limited study, only 3 strains used)	Aeschbacher <i>et al.</i> 1989 (cited in IUCLID, 2000)
<i>Salmonella typhimurium</i> , strains TA100, TA102 and TA104	Tested (using a preincubation step) at concentrations of up to 5 mg/plate	Mutation	with and without S9	-ve according to abstract and discussion, equivocal in 2 strains with S9 according to a table footnote	Dillon <i>et al.</i> 1998

<i>Salmonella typhimurium</i> , strains TA98, TA100, TA1535 and TA1537	Tested in a spot test at 0.2 mg/plate	Mutation	with and without S9	-ve (a spot test is a relatively limited study)	Florin <i>et al.</i> 1980
<i>Salmonella typhimurium</i> , strains TA98 and TA100	Test involved a preincubation step, other conditions not specified in the brief abstract	Mutation	with and without S9	-ve (a limited study, only 2 strains used)	Sasaki & Endo, 1978
<i>Salmonella typhimurium</i> , strains TA98, TA100, TA1535, TA1537, TA1538, G46, C3076 and D3052	Tested at up to 1 mg/ml using a gradient plate technique	Mutation	with and without S9	+ve	McMahon <i>et al.</i> 1979
<i>Escherichia coli</i> , strains WP2 and WP2 uvrA ⁻	Tested at up to 1 mg/ml using a gradient plate technique	Mutation	with and without S9	+ve	McMahon <i>et al.</i> 1979
<i>Escherichia coli</i> Sd-4-73	Tested using a paper disc method at up to 25 µl/disc	Mutation	without	-ve (old test method of uncertain relevance)	Szybalski <i>et al.</i> 1958 (cited in IUCLID, 2000)

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