Undecalactone (gamma-)

Botanical Source

Synonyms UNDECANOLIDE (4-)
UNDECANOLACTONE (1,4-)
ALDEHYDE C-14 (SO CALLED)
PEACH ALDEHYDE
UNDECAN-4-OLIDE
ALDEHYDE C-14

IUPAC Name

CAS Reference 104-67-6

E Number

Food Legislation

Council of Europe (CoE)	
Number	Comment
179	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
233	ADI 0-1.25 MG/KG BW	No safety concern at current levels of intake when used as a flavouring agent.

FEMA	
FEMA No.	Comment
3091	Generally recognised as safe as a flavour ingredient:GRAS List Number 3

Natural Occurrence and Use in Food
Found in apple, apple juice, apricot, heated butter, peach, plum, pork, rice; used in chewing gum, candy, ice cream, baked goods.

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

0.008968	2.142

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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	0.00030	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	0.00030	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	0.00030	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	0.00030	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 vivo

Species	Test conditions	Endpoint	Result	Reference
Mouse Groups of 6 male ddY mice	Single ip doses of 0, 250, 500, 1000 or 2000 mg/kg bw/day or 4 daily ip doses of 500 mg/kg bw. Micronuclei were scored in the polychromatic erythrocytes in the bone marrow 24 hours after treatment.	chromosome damage	-ve A good quality study	Hayashi et al. 1988

In vitro

Test system	Test conditions	Endpoint	Activation	Result	References
Chinese hamster lung fibroblast cells	Up 48 hours exposure to a maximum of 0.5 mg/mL. Cells examined for structural and numerical chromosome aberrations	chromosome damage	without	-ve a limited study, as not tested in the presence of an activation fraction	Ishidate *et al.* 1984
Salmonella typhimurium strains TA92, TA94, TA98, TA100, TA1535 and TA1537 (and possibly also TA2367)	Ames assay, tested at up to 5 mg/plate	mutation	with and without rat liver S9	-ve a good quality study	Ishidate *et al.* 1984

Salmonella typhimurium strains TA97 and TA102	Up to 0.1 mg/plate (it is unclear why these investigators reportedly used much lower doses than were reportedly used by Ishidate *et al.* 1984)	mutation	with S9	-ve a limited assay, as only 2 strains were tested	Fujita & Sasaki, 1987
Bacillus subtilis H17 and M45	Tested at up to 19 µg/disk in a rec assay monitoring differential toxicity	DNA damage (indicative test)	without	No test (reported as -ve but no clear toxicity was seen in either strain)	Oda *et al*. 1978
Bacillus subtilis H17 and M45	Tested at up to 10 mg/plate in a rec assay monitoring differential toxicity [JECFA, 1998 mis-cited the dose as 10 ug/plate]	DNA damage (indicative test)	without	+ve	Yoo, 1986
Bacillus subtilis H17 and M45	Tested at up to 10 µg/disk in a rec assay monitoring differential toxicity [accuracy uncertain, as JECFA mis-cited the dose from the Yoo, 1986 study]	DNA damage	With and without S9	+ve in the presence of S9	Kuroda et al. 1984 as cited in JECFA, 1998
Escherichia coli WP2 *uvrA*	Tested at 0.025-0.2 mg/plate	Mutation	without	-ve	Yoo, 1986

References

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Hayashi M *et al* (1988). Micronucleus tests in mice on 39 food additives and eight miscellaneous chemicals. Food and Chemical Toxicology, 26, 487-500.

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

JECFA (1998). Safety evaluation of certain food additives and contaminants. (Forty-ninth report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Food Additives Series, No. 40. Available on the internet at http://www.inchem.org/documents/jecfa/jecmono/v040je12.htm

Kuroda K et al. (1984). Rec-assay of food additives. Nippon Kosnu Eisei Zasshi, 31, 277-281 (cited in JECFA, 1998).

Oda Y *et al* (1978). Mutagenicity of food flavors in bacteria. Shokuhin Eisei Hen, 9, 177-181.

Yoo YS (1986). Mutagenic and antimutagenic activities of flavoring agents used in foodstuffs. Journal of Osaka City Medical Center, 34, 267-288.