Propyl acetate (n-)

Botanical Source

Synonyms n-PROPYL ACETATE

IUPAC Name

CAS Reference 109-60-4

E Number

Food Legislation

Council of Europe (CoE)

Number	Comment
192	Listed by the Council of Europe as acceptable for use in food at up to 15 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
126	No Safety concern @ intake	No safety concern at current levels of intake when used as a flavouring agent.

FEMA

FEMA No.	Comment
2925	

Natural Occurrence and Use in Food

Found in banana, grape, apple juice, beer, wheat bread, cantaloupe, capers, cocoa, guava, honey, fig, honeydew melon, heated corn oil; used in beverages, ice cream, baked goods.

Estimated Intake From Food and Drink

Daily Intake mg/kg/day	FEMA Possible Average Daily Intake mg
15	2.196

Tobacco Legislation

Tobacco Ingredients

Country	Cigarettes	RYO	Cigars	Pipe

Propyl acetate (n-)

Afghanistan				
Algeria				
Argentina				
Australia				
Brazil				
Burundi				
Canada				
Comoros				
Djibouti				
EEC				
Egypt				
Eritrea				
EU TPD2				
Fiji				
France	Y	Y	Y	Y
GCC (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, UAE)				
Germany	Y	Y	Y	Y
Hong Kong				
Hungary	Y	Y	Y	Y
Iceland				
Iran				
Iraq				
Jordan				
Kazakhstan				
Lebanon				
Libya				
Macedonia				
Madagascar				
Malaysia				
Maldives				
Mexico				
Moldova				
Montenegro				
New Zealand				
Nigeria				

Propyl acetate (n-)

Norway				
Pakistan				
Palestine				
Papua New Guinea				
Rwanda				
Samoa				
Serbia				
Solomon Island				
Somalia				
Somaliland				
South Sudan				
Sri Lanka				
Sweden				
Switzerland	Y	Y	Y	Y
Syria				
Tunisia				
Turkey				
UK	0.0001	0.0001	0.0001	0.0001
United Arab Emirates				
Vietnam				

Y=Permitted for use in tobacco products. If use is limited, the maximum permitted level is given.

Tobacco Product related Chemical and Biological Studies

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.

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.

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.

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.

Mouse Skin Painting

Published Source	Level Tested %	Comment

Toxicological Data on the Unburnt Ingredient

[+ve positive; -ve, negative; ? equivocal

With, with metabolic activation; without, without metabolic activation]

In vivo Studies

Species	Test Conditions	End Point	Results	Reference
Rabbit	2/sex/group. Draize test on intact and abraded skin without occlusion with 0.5 ml of undiluted n-propyl acetate. 100%.	Skin Irritation	-ve	OECD, 2009
Rabbit, New Zealand White	Six rabbits treated with 0.01 ml undiluted n-propyl acetate without occlusion for 24 hours. 100%.	Skin Irritation	-ve	OECD, 2009
Rabbit	An unspecified number of rabbits were exposed to undiluted n-propyl acetate at 20 ml/kg bw (17,756 mg/kg bw), occluded for 24 hours, in an acute dermal toxicity study. 100%.	Skin irritation	+ve. Erythema and necrosis were observed	OECD, 2009
Guinea Pig	A number of rabbits were exposed to undiluted n-propyl acetate at 1-10 ml/kg bw (888-8,880 mg/kg bw) under an occluded patch for 24 hours. Observed for 14 days. 100%.	Skin irritation	Erythema and desquamation were observed which had disappeared after 14 days	OECD, 2009

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Species	Test Conditions	End Point	Results	Reference
Rabbit	0.5 ml of undiluted n-propyl acetate was instilled into the eye of five animals in a Draize test. 100%.	Eye irritation	Minor corneal injury (Grade 2 on a Draize scale) which quickly healed.	OECD, 2009
Rat Carworth-Wistar	Inhalation Groups of six females exposed to an atmosphere of n-propyl acetate vapour for 4 hours. Observed for 14 days. 4000, 8000 or 16,000 ppm (16,700, 33,400 or 66,800 mg/m^3).	Mortality, clinical signs of toxicity	4-hour LC_{50} >16,700 and <33,400 mg/m^3. At 66,700 mg/m^3, were unconscious at 1 hour and dead within 2.5 hours; at 33,400 mg/m^3, all were unconscious and 4/6 died during or immediately after exposure; at 16,700 mg/m^3, animals were inactive but conscious during exposure and there were no deaths. Animals that died during exposure had pulmonary haemorrhage; survivors showed signs of lung damage at necropsy.	OECD, 2009
Rat	Inhalation 6 rats exposed for 4 hours to n-propyl acetate vapour. 8000 ppm (33,400 mg/m3).	Mortality	4-hour LC50 <33,400 mg/m3. Mortality 4/6.	OECD, 2009
Rat, wistar	Inhalation Four males exposed for 4 hours. Inhibition of the duration of maximal tonic extension was measured after applying a short electrical impulse through ear electrodes within 1 minute of the end of exposure. Animals were tested on two separate occasions Unspecified dose	Mortality, neurotoxicity	The concentration which resulted in a 30% decrease in hindlimb extension (EC30) was 6600 ppm (90% confidence interval (CI) 1200 ppm) (27,500 mg/m3 (90% CI 5000 mg/m3)). There were no mortalities and no evidence of toxicity.	OECD, 2009
Mouse, H-strain	Four females exposed for 2 hours. Inhibition of the duration of maximal tonic extension was measured after applying a short electrical impulse through ear electrodes within 1 minute of the end of exposure. Animals were tested on two separate occasions. Unspecified dose	Mortality, neurotoxicity	The concentration which resulted in a 30% decrease in hindlimb extension (EC_{30}) was 6200 ppm (90% confidence interval (CI) 830 ppm (25,900 mg/m^3 (90% CI 3500 mg/m^3)). There were no mortalities and no evidence of toxicity	OECD, 2009

Propyl acetate (n-)

Species	Test Conditions	End Point	Results	Reference
Cat	Inhalation exposure for 30 minutes (higher concentration) or 5.5 hours (lower concentration). Dose 24,000 or 7400 ppm [100,200 or 30,900 mg/m^3] (for shorter and longer exposure durations respectively	Mortality, clinical signs of toxicity, narcotic effects	Both exposures described as "near-lethal" and the animals "began to stagger and lost consciousness" according to the citing source.	Lundberg, 1977
Rat, Osborne-Mendel	5/sex/group fasted for 16 hours before being dosed by gavage Unspecified dose	Mortality, clinical signs of toxicity	LD_{50} 9370 mg/kg bw. Depression occurred soon after treatment, rough fur, and scrawny appearance. Death occurred in 4-18 hours	Jenner et al, 1964
Rat, Carowrth-Wistar	Five males per group dosed by gavage with a 10% aqueous solution. Observed for 14 days Dose Approximately 3550,7100 or 14200 mg/kg bw	Mortality, clinical signs of toxicity, gross necropsy.	LD_{50} 8700 mg/kg bw (95% confidence interval 6600-11,450 mg/kg bw). Signs of toxicity included sluggish behaviour, laboured breathing. Necropsy of animals that died during the study – congestion of abdominal organs and surface "burns" of viscera in contact with stomach.	OECD, 2009
Rat	Groups of three rats were dosed by gavage with undiluted n-propyl acetate and observed for 14 days. 50 - 3200 mg/kg bw.	Mortality, clinical signs of toxicity	LD50 >3200 mg/kg bw. Moderate weakness was the only sign of toxicity, no deaths.	OECD, 2009
Mouse	Dosed by gavage without being fasted, dose not specified	Mortality, clinical signs of toxicity	LD_{50} 8300 mg/kg bw. Depression soon after treatment. Died within a few minutes to 18 hours.	Jenner et al, 1964
Rabbit	10-35 animals.groups given n-propyl acetate by gavage Dose not specified	Mortality, clinical signed of toxicity	LD_{50} 6630 mg/kg bw. Narcotic effect was observed with animals lying down on their sides at lower doses, accompanied by disappearance of corneal reflexes, nystagmus [uncontrolled eye movement], dyspnea [shortness of breath] and bradycardia [slow heart rate] at higher doses.	Munch, 1972
Rabbit	Not specified Dose up to 5000mg/kg bw	Mortality	LD_{50} >5000 mg/kg bw	CIR, 2012

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Species	Test Conditions	End Point	Results	Reference
Rabbit, New Zealand	4 males/group. n-Propyl acetate applied undiluted to clipped intact dorsal trunk under an occluded patch for 24 hours. Observed for 14 days. Dose – up to 20ml/kg bw (17,800 mg/kg bw)	Mortality	LD50 >17,800 mg/kg bw.	OECD, 2009
Guinea Pig	Applied undiluted to clipped intact skin of the dorsal trunk under an occluded patch for 24 hours. Observed for 14 days. Up to 10 ml/kg bw (8880 mg/kg bw).	Mortality, clinical signs of toxicity	LD50 >8880 mg/kg bw. No evidence of systemic toxicity	OECD, 2009
Cat	Exposure to atmospheres containing n-propyl acetate for 6 hours/day for 5 days Dose 5200ppm	Not specified	Inflammation of the bronchi and trachea (bronchitis and tracheitis). Fatty deposits developed in the liver	Lundberg, 1995
Rat, Osborne-Mendel	5/sex/group dosed by gavage at a dose of one-third of the LD50 for 4 days. 3120 mg/kg bw/day.	Macroscopic examination	No toxicity	Jenner et al, 1964

In vitro Studies

Test System	Test Conditions	Endpoint	Activation Status	Results	Reference
Salmonella typhimurium, strains TA98, TA100, TA1535, TA1537 and TA1538.	Bacterial reverse mutation (Ames) assay with and without metabolic activation Dose up to 10mg/plate	Mutation	With and without	-ve	OECD, 2009
Saccharomyces cerevisiae, strain D61.M.	Assay for aneuploidy. Incubated with n-propyl acetate for 4 hours without metabolic activation, followed by treatment on ice for about 17 hours, and then incubation for a further 4-5 hours. Up to about 1.23% [12.3 mg/ml].	Changes in chromosome number	without	+ve (weak)	Zimmermann et al, 1985
Saccharomyces cerevisiae, strain D61.M.	Assay for chromosome loss (chromosomal malsegregation) using the cold-shock regimen, without metabolic activation Up to 9.5mg/ml	Changes in chromosome number	without	+ve (weak)	Zimmermann et al, 1989

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