

Fumarated Rosin

Botanical Source

Synonyms Rosin Size,Aqueous dispersion of modified rosin size

IUPAC Name

CAS Reference 65997-04-8

E Number

Food Legislation

Council of Europe (CoE)	
Number	Comment

US Food and Drug Administration	
Number	Comment

Joint FAO/WHO Expert Committee on Food Additives (JECFA)		
Number	ADI	Comment

FEMA	
FEMA No.	Comment

Natural Occurrence and Use in Food

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

Tobacco Legislation

Tobacco				
Country	Cigarettes	RYO	Cigars	Pipe
Afghanistan				
Algeria				
Argentina				
Australia				
Bahrain				
Brazil				
Burundi				
Canada				
Comoros				
Djibouti				
EEC				
Egypt				
Eritrea				
EU TPD2				
Fiji				
France				
GCC (Bahrain,				
Germany				
Hong Kong				
Hungary				
Iceland				
Iran				
Iraq				
Jordan				
Kazakhstan				
Kuwait				
Latvia				
Libya				
Macedonia				
Madagascar				

Fumarated Rosin

Malaysia				
Maldives				
Mexico				
Moldova				
Montenegro				
New Zealand				
Nigeria				
Norway				
Pakistan				
Palestine				
Papua New Guinea				
Rwanda				
Samoa				
Saudi Arabia				
Serbia				
Solomon Island				
Somalia				
Somaliland				
South Sudan				
Sri Lanka				
Sweden				
Switzerland				
Syria				
Taiwan				
Tunisia				
Turkey				
UK				
United Arab				
Uzbekistan				
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

Ames Activity		
Published Source	Level Tested %	Comment

Micronucleus		
Published Source	Level Tested %	Comment

Neutral red		
Published Source	Level Tested %	Comment

Inhalation		
Published Source	Level Tested %	Comment

Mouse Skin Painting		
Published Source	Level Tested %	Comment

Fumarated Rosin

Tobacco Product Related Chemical and Biological Studies for Ingredients Added in a Mixture

No studies identified

Fumarated Rosin

Tobacco Product Related Chemical and Biological Studies for Ingredients Tested Singly

No studies identified

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 Status	Results	Reference
Chinese hamster ovary (CHO) cells.	Chromosome aberration test in which rosin, fumarated was tested with and without metabolic activation. The study was conducted to OECD test guideline 472 and was GLP compliant. Dose: Up to 0.08 mg/ml (+S9). Up to 0.12 mg/ml (-S9).	Chromosome damage	With and without	Negative. The top concentration tested was limited by cytotoxicity. Polyploidy was induced at the toxic concentration (0.12 mg/ml).	EPA, 2015
Mouse lymphoma L5178Y cells.	Mammalian cell gene mutation assay in which rosin, fumarated was tested in the presence and absence of metabolic activation (S9). Study conducted to OECD test guideline 476 under GLP compliant conditions. Dose: 0.005 – 0.16 mg/ml (+S9). 0.0025 – 0.08 mg/ml (-S9).	Mutation	With and without	Negative. The top concentration tested was limited due to toxicity.	ECHA, 2014
Salmonella typhimurium, strains TA98, TA100, TA102, TA1535 and TA1537; Escherichia coli, WP2uvrA.	Bacterial reverse mutation (Ames) assay in which “fumarated rosin” was tested with and without metabolic activation. Study conducted to OECD test guideline 471 and GLP compliant. Dose: 0.017, 0.05, 0.167, 0.5, 1.67 and 5 mg/plate.	Mutation	With and without	Negative.	EPA, 2015
Salmonella typhimurium .	Bacterial reverse mutation (Ames) assay in which fumarated rosin was tested with and without metabolic activation. Study conducted to OECD test guideline 471 and under GLP conditions. Dose: Not specified .	Mutation	With and without	Negative.	IUCLID, 2000

In vivo

Test System	Test Conditions	Endpoint	Results	Reference
Rabbit	Rosin, fumarated was tested in a study conducted to OECD test guideline 404 and GLP compliant . Dose not specified.	Skin irritation.	Not irritation.	IUCLID, 2000
Rabbit, New Zealand White.	100% Rosin, fumarated was applied to the clipped skin of 6 rabbits (males and females), under semi-occluded contact, for 4 hours. Observations were made up to 72 hours. This study was conducted to OECD test guideline 404 and was GLP compliant.	Skin irritation.	No irritation was observed. On the basis of these results, rosin, fumarated is not classifiable according to the EU criteria .	ECHA, 2014
Rabbit	Rosin, fumarated was tested in a study conducted to OECD test guideline 405 and under GLP compliant conditions . Dose not specified.	Eye irritation.	Highly irritating	IUCLID, 2000
Guinea pig	A maximization test with rosin, fumarated, conducted according to "Directive 84/449/EEC, B.6" and under GLP conditions . [The test procedure typically involves an initial induction phase of five 48-hour covered patch tests, followed 10-14 days later by a 48-hour covered challenge patch.] Dose not specified.	Skin sensitization.	Sensitizing	IUCLID, 2000
Mouse	Local lymph node assay (LLNA) conducted in accordance with OECD test guideline 429 . The test substance was described as a "reaction product of gum rosin with 9% fumaric acid" [CAS RN not specified]. Dose: 0.5, 5 or 50%.	Skin sensitization.	Moderate sensitizer. Stimulation indices (SI) were 1.2, 7 and 12.8 with increased concentration. The EC3 was reported to be 5%, indicating positive sensitization. [OECD test guideline 429 defines stimulation index (SI) as the ratio of lymphocyte proliferation in a treated group to that in the vehicle control group. An SI of ≥ 3 is considered positive and the estimated concentration three (EC3) is the estimated concentration of a test substance needed to produce an SI of 3.]	Illing et al, 2009
Rat, Sprague-Dawley	Rosin, fumarated was administered by oral gavage to 5 females per dose and observations were made for up to 14 days. The study was conducted to OECD test guideline 425 and was GLP compliant. Dose: Up to 2000 mg/kg bw	Mortality, body weight, clinical signs of toxicity, necropsy examination.	LD50 >2000 mg/kg bw. No adverse effects were noted; there were no findings at necropsy.	EPA, 2015
Rat, Sprague-Dawley.	Fumarated rosin in methylcellulose, was administered to 5 males and 5 females (top dose only, lower doses were administered to groups of 1 male and 1 female) by oral gavage and animals were observed for 14 days. This study was conducted to OECD test guideline 401 under GLP compliance. Dose: 200, 400, 800 and 2000 mg/kg bw	Mortality, body weight, clinical signs of toxicity, gross pathology.	LD50 >2000 mg/kg bw. Staggered gait, piloerection, ungroomed appearance, hunched position and a single case of diarrhoea was observed at 2000 mg/kg bw. All animals were normal by day 4 and there were no deaths. Gross pathology examination revealed large mandibular lymph nodes in 2 females at the top dose.	ECHA, 2014

Rat, Sprague-Dawley.	Rosin, fumarated was applied to the clipped skin of 5 males and 5 females under semi-occlusive cover for 24 hours, observations were made up to day 14. Study was conducted to OECD test guideline 402 and GLP compliant. Dose: 2000 mg/kg bw	Mortality, clinical signs of toxicity, behavioural effects, body weight, gross and microscopic examination.	LD50 >2000 mg/kg bw. No deaths occurred in the study, no toxic signs were reported except erythema and yellow colour at the test site 24 hours after dosing (normal by day 8).	ECHA, 2014
Rat, Sprague-Dawley.	Groups of 10 rats (both male and female) were administered a diet containing "rosin, fumarated" for 28-38 days; the study started 2 weeks prior to mating with females dosed until at least day 4 of lactation. Study conducted to OECD test guideline 422 and GLP compliant. Dose: 0, 1000, 3000 or 10,000 ppm (approximately 90, 260 or 900 mg/kg bw/day, respectively).	General Systemic Effects – Repeated Exposure Clinical signs of toxicity, body weight, food consumption, haematology, necropsy examination, organ weights, histopathology examination. Reproductive and Developmental Toxicity Reproductive toxicity: mating and litter performance.	General Systemic Effects – Repeated Exposure NOAEL 86 mg/kg bw/day (paternal). NOAEL 94 mg/kg bw/day (maternal). Abnormal coloured urine was observed. In the mid and high dose groups soft faeces were observed as well as decreased body weight gain and food consumption. In the highest dose groups, total bilirubin was "significantly increased" and haemoglobin, red blood cell count and haematocrit (% red blood cells in the blood) was slightly decreased. In high dose females there was a "significant decrease" in adrenal gland weight and thymic atrophy was seen at histopathological examination (considered by the investigators to be possibly due to the condition of the animals rather than any specific toxic effect). Reproductive and Developmental Toxicity NOAEL 260 mg/kg bw/day (reproductive/developmental). At the highest dose level, there were slight effects on mating performance and duration of gestation. The mean number of implants per pregnancy was slightly decreased, and the litter size and litter weight was slightly reduced; the effects likely to be secondary to the maternal toxicity. There were no effects on mating performance, duration of gestation, litter size and pup weight at 260 mg/kg bw/day or below.	EPA, 2015

References

ECHA, 2014

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EPA, 2015

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IUCLID, 2000

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