

Dodecalactone (gamma-)

Botanical Source

Synonyms DODECANOLACTONE (1,4-),DODECANOLIDE (4-),DODECAN-4-OLIDE,DODECANOLIDE (1,4-)

IUPAC Name

CAS Reference 2305-05-7

E Number

Food Legislation

Council of Europe (CoE)

Number	Comment
2240	Listed by the Council of Europe as acceptable for use in food at up to 10 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
235	No Safety concern @ intake	No safety concern at current levels of intake when used as a flavouring agent.

FEMA

FEMA No.	Comment
2400	

Natural Occurrence and Use in Food

Found in apricot, beef, beer, blackberry, blue cheese, butter, carambola (starfruit), cheddar cheese, chervil, chicken; used in baked goods, beverages, ice cream, candy.

Estimated Intake From Food and Drink

Daily Intake mg/kg/day	FEMA Possible Average Daily Intake mg
10	4.39

Tobacco Legislation

Dodecalactone (gamma-)

Tobacco Ingredients

Country	Cigarettes	RYO	Cigars	Pipe
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				

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Moldova				
Montenegro				
New Zealand				
Nigeria				
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	0.001	0.001	0.001	0.001
United Arab Emirates				
Vietnam				

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

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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	0.00120	At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.
Philip Morris	0.00010	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	0.00120	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	0.00010	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	0.00120	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	0.00120	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	0.00010	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	0.00120	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Philip Morris	0.00010	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
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Toxicological Data on the Unburnt Ingredient

In vivo Studies

Skin Irritation

Species	Test Conditions	End Point	Results	Reference
Human	48 hour occluded patch test performed on human volunteers Dose = 12%	Skin Irritation	No irritation	Opdyke, 1976
Rabbit	Rabbits given a 24-hour occlusive application of gamma-dodecalactone to intact or abraded skin. Dose = 100%	Skin Irritation	Moderately irritating	Opdyke, 1976

General Systemic Effects – Single Exposure

Species	Test Conditions	End Point	Results	Reference
Rat	Rats given an acute oral treatment Dose = not specified	Mortality	LD ₅₀ >5000 mg/kg bw	Opdyke, 1976

Species	Test Conditions	End Point	Results	Reference
Rabbit	Rabbit given an acute dermal treatment Dose = not specified	Mortality	LD ₅₀ >5000 mg/kg bw	Opdyke, 1976

References

Opdyke, D.L.J., 1976
Monographs on Fragrance Raw Materials: γ -Dodecalactone. *Fd Cosmet. Toxicol.*, 14, 751.

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