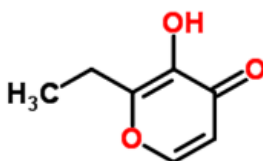


INGREDIENT IDENTITY

Name	Ethyl maltol
IUPAC name	2-Ethyl-3-hydroxy-4H-pyran-4-one
CAS no	4940-11-8
EINECS no.	225-582-5
Molecular formula	C ₇ H ₈ O ₃
Structural formula	



Molecular weight (g/mol)	140.1
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REGULATORY OR AUTHORITATIVE STATUS

FEMA no.	3487 FEMA GRAS
CoE no.	692 Category A (may be used in foodstuffs).
Flavis no.	07.047
JECFA no.	1481
ADI	0-2 mg/kg bw "No safety concern" from use as a food flavouring agent current estimated levels of intake (approximately 1580 µg/day in Europe and 6692 µg/day in the USA).
FDA	21 CFR 172.515 (Food additives permitted for direct addition to food for human consumption—;synthetic flavoring substances and adjuvants.
Food level	Reported uses: usual levels of 0.0025 (imitation dairy) to 160 ppm (non-alcoholic beverages); maximum levels of 0.0025 (imitation dairy) to 1000 ppm (seasonings/ flavourings and non-alcoholic beverages).
Natural status	"Not reported found in nature."

DATA ON UNBURNT INGREDIENT

Species	Rat
End-point	Mortality.
Conditions	Single oral dose of ethyl maltol.
Dose	Not specified
Result	LD ₅₀ 1220 mg/kg bw.
Reference	Opdyke, 1975

Species	Rabbit
End-point	Mortality.
Conditions	Single dermal application of ethyl maltol to one animal.
Dose	5000 mg/kg bw.
Result	LD ₅₀ >5000 mg/kg bw.
Reference	Opdyke, 1975

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

Smoke Chemistry		
Published Source	Level Tested %	Comment
BAT	0.01000	At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.
Philip Morris	0.02880	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	0.01000	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	0.02880	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	0.01000	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	0.01000	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	0.02880	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	0.01000	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Lorillard	0.00040	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Philip Morris	0.02880	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	0.00040	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.

References:

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Opdyke, D.L.J., 1975 Monographs on fragrance raw materials: Ethyl maltol. *Fd Cosmet. Toxicol.*, 13, 805-806.

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.

Vanschaeuwijck 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.