Orange oil, sweet

Botanical Source	Citrus sinensis (L.) Osbeck Citrus aurantium var. dulcis L.
Synonyms	ORANGE OIL; ORANGE PEEL OIL, SWEET; Orange Oil,Sweet,Expressed
IUPAC Name	
CAS Reference	8008-57-9 8028-48-6
E Number	

Food Legislation

Council of Europe (CoE)	
Number	Comment
143	Listed by the Council of Europe as acceptable for use in food.

US Food and Drug Administration	
Number	Comment
182.20	Approved by the US FDA. FDA 21 CFR 182.20

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

FEMA	
FEMA No.	Comment
2825	Generally recognised as safe as a flavour ingredient:GRAS List Number 3

Natural Occurrence and Use in Food
Found in oranges; used in non-alcoholic beverages, ice cream, ices, baked goods, condiments, candy, gelatin and puddings, chewing gum.

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

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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	0.01000	At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.
Philip Morris	0.00430	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	0.00430	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	0.00430	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	0.00001	The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.
Philip Morris	0.00430	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	0.00001	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.

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Tobacco Product Related Chemical and Biological Studies for Ingredients Tested Singly

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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
Human lymphocyte cells	In a test for the induction of sister chromatid exchanges, "essence of orange (not further defined) tested at 0.1 ul/ml	Chromosome effects	Without	+ve (weak)	Xing & Zhang, 1990
Chinese hamster lung cells	Orange oil (8008-57-9) up to 125 ug/ml. Treatment for 48 hr. [Brief citation only.]	Chromosome damage	Without	-ve	Ishidate et al. 1988
Mouse lymphoma cells, L5178Y	Only an abstract was published. Additional details from EPA (2002) indicates that cells were exposed to around 40-200 ug sweet orange peel oil (8008-57-9) /ml for 4 hr. Colonies were counted 10-14 days later.	Somatic cell mutation	With and without S9	+ve (Positive responses were seen with and without S9, the latter only at highly toxic concentrations when survival was <10%. The authors are said to have suggested that the low pH of the test material may have contributed to the genotoxic effect.)	Heck et al. 1989 (with extra detail from EPA, 2002).

Mammalian cells	*d*-Limonene (present at up to 97% in sweet orange peel oil, CAS 8008-57-9) tested in a range of genotoxicity studies in mammalian cells.	Various	Probably some with and some without S9	-ve	IARC, 1993
Salmonella typhimurium, strains TA98, TA100, TA1535, TA1537, TA1538	An Ames test with sweet orange peel oil (8008-57-9). Only an abstract was published. Additional details from EPA (2002) indicate that up to 5 mg/plate was tested.	Mutation	With and without S9	-ve	Heck et al. 1989 (with extra detail from EPA, 2002).
Salmonella typhimurium, strains TA98, TA100	Various commercial flavouring preparations including bitter orange (soluble essence and tincture) and sweet orange (hydroalcoholic extract, soluble essence and essential oil). Ames tests at up to 100 ul/plate [around 100 mg/plate].	Mutation	With and without S9	-ve	Crebelli et al. 1990

Escherichia coli, strains H17, M45	Sweet orange peel oil (8008-57-9) was tested at 5-30 ul/plate in rec assay monitoring differential toxicity. [Information obtained from tables in this Japanese paper. Additional details from EPA (2002).]	DNA damage (indicative test)	With and without	-ve	Kuroda et al. 1989 (with extra detail from EPA, 2002)

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