Botanical Source

Synonyms

HYDROXY PROPANOIC ACID(2-)

IUPAC Name

CAS Reference 598-82-3;

50-21-5 17092-92

E Number E270

Food Legislation

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

US Food and Drug Administration		
Number	Comment	
184.1061	Approved by the US FDA. FDA 21 CFR 184.1061	

Joint FAO/WHO Expert Committee on Food Additives (JECFA)				
Number	ADI	Comment		
930		No safety concerns at current levels of intake when used as a flavouring agent.		

FEMA	
FEMA No.	Comment
2611	Generally recognised as safe as a flavour ingredient:GRAS List Number 3

Natural Occurrence and Use in Food

Found in apple juice, beef, beer, bread, cocoa, coffee, wheat bread, cherry, grape, guava, mango, milk, papaya, dry salami, sherry, tomato; used in cheese, candy, chewing gum, baked goods.

Estimated Intake from Food and Drink				
Daily Intake mg/kg/day FEMA Possible Average Daily Intake mg				
4.4915 0.924				

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

Smoke Chemistry			
Published Source	Level Tested %	Comment	
BAT 1.24000		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	
ВАТ	1.24000	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		
ВАТ	1.24000	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		
ВАТ	1.24000	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 1.24000		The results indicate that the addition of the ingredient had no discernible effect on the inhalation toxicity of mainstream smoke.		
Lorillard	0.20000	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		
Lorillard	0.20000	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

Baker RR, Pereira da Silva JR, Smith G. The effect of tobacco ingredients on smoke chemistry. Part I: Flavourings and additives. Food Chem Toxicol. 2004; 42 Suppl:S3-37

Baker RR, Pereira da Silva JR, Smith G. The effect of tobacco ingredients on smoke chemistry. Part II: casing ingredients. Food Chem Toxicol. 2004; 42 Suppl:S39-52.

Baker RR, Massey ED, Smith G. An overview of the effects of tobacco ingredients on smoke chemistry and toxicity. Food Chem Toxicol. 2004; 42 Suppl:S53-83.

Gaworski CL, Dozier MM, Heck JD, Gerhart JM, Rajendran N, David RM. Brennecke LH, Morrissey R. Toxicologic evaluation of flavor ingredients added to cigarette tobacco: 13 week inhalation exposures in rats. Inhal. Toxicol. 1998; 10:357-381

Gaworski CL, Heck JD, Bennett MB, Wenk ML. Toxicologic evaluation of flavor ingredients added to cigarette tobacco: skin painting bioassay of cigarette smoke condensate in SENCAR mice. Toxicology. 1999; 139(1-2):1-17.

Tobacco Product Related Chemical and Biological Studies for Ingredients Tested Singly

References

Baker RR, Bishop LJ. The pyrolysis of tobacco ingredients. J. Anal. Appl. Pyrolysis 2004, 71, 223-311.

Toxicological Data on the Unburnt Ingredient

GENOTOXICITY

[+ve, positive; -ve, negative; ?, equivocal; with, with metabolic activation; without, without metabolic activation]

In vivo

No relevant data identified.

In vitro

Test system	Test	Endpoint	Activation	Results	Reference
	conditions		status		
Chinese hamster lung fibroblasts	Treatment with lactic acid [not further specified] at 2 mg/ml. Cells examined for chromosome aberrations.	Chromosome damage	Without	+ve [Other reports by these investigators (see below) found no chromosome damage. The positive result might be due to the acidity of the test culture (BIBRA, 1990)]	Ishidate, 1981 and 1983
Chinese hamster fibroblast ("CHL") cells	Treated with up to 1 mg "unspecified" lactic acid (CAS 50-21-5)/ml for 48 hours. Cells examined for polyploidy and chromosome aberrations.	Chromosome damage and changes in chromosome numbers	Without	-ve (limited assay, not tested with S9)	Ishidate, 1987; Ishidate et al. 1984
Salmonella typhimurium	Good quality Ames test	Mutation	With and without S9	-ve	NTP

strains TA97, TA98, TA100, TA1535	using up to 10 mg/plate.		derived from rat or hamster liver		
Salmonella typhimurium strains TA92, TA94, TA98, TA100, TA1535, TA1537, (and possibly TA2637)	Ames test conducted at up to 10 mg/plate.	Mutation	With and without	-ve	Ishidate 1983; Ishidate et al. 1984, 1988
Saccharomyces cerevisiae	A review reports briefly a study in yeast. [No further details given in the citation.]	Mutation	With and without S9	-ve	Anon, 1980

References

Anon (1980). Lactic acid and calcium lactate; affirmation of GRAS status for lactic acid and calcium lactate for direct human food ingredients. Federal Register 45, 32324 (cited in BIBRA, 1990).

BIBRA (1990). Toxicity Profile, lactic acid. BIBRA International Ltd, Carshalton, Surrey, SM5 4DS.

Ishidate M (1981). In: Quo Vadis – short-term tests for carcinogenesis. Garattini S et al. (Eds). Centre de Recherches Clin-Midy. Published 1983 (cited in BIBRA, 1990).

Ishidate M Jr (1983). Application of chromosome aberration tests in vitro to the primary screening for chemicals with carcinogenic and/or genetic hazards. Tests Carts Cancerog. Quo Vadis (Symp.), 57-79.

Ishidate M et al. (1984). Primary mutagenicity screening of food additives currently used in Japan. Food and Chemical Toxicology 22, 623-636.

Ishidate M (1987). Chromosomal aberration test *in vitro*, L.I.C., Inc., Tokyo (cited in Ishidate et al. 1988).

Ishidate M et al. (1988). A comparative analysis of data on the clastogenicity of 951 chemical substances tested in mammalian cell cultures. Mutation Research 195, 151-213.

NTP [undated]. Unpublished NTP study data (study A10575) available via National Toxicology Program Database Search, at http://ntp-apps.niehs.nih.gov/ntp_tox/index.cfm