Potassium sorbate

Botanical Source

Synonyms SORBIC ACID, POTASSIUM SALT;
POTASSIUM HEXA-2,4-DIENOATE;
HEXADIENOIC ACID, POTASSIUM SALT (2,4-)

IUPAC Name

CAS Reference 590-00-1

E Number E202

Food Legislation

Council of Europe (CoE)	
Number	Comment
-	-

US Food and Drug Administration	
Number	Comment
182.3640	Approved by the US FDA. FDA 21 CFR 182.3640

Joint FAO/WHO Expert Committee on Food Additives (JECFA)		
Number	ADI	Comment
-	ADI 0-25 MG/KG BW	-

FEMA	
FEMA No.	Comment
2921	Generally recognised as safe as a flavour ingredient:GRAS List Number 3

Natural Occurrence and Use in Food
Found in mountain ash berries; used in cheese, gravies, snacks, fruit juices.

Estimated Intake from Food and Drink	
Daily Intake mg/kg/day	FEMA Possible Average Daily Intake mg
2.3446	0.411

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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	0.60000	At maximum application level this ingredient is not associated with significant increases in levels of Hoffmann analytes in smoke.
Philip Morris	0.08370	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	0.60000	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	0.08370	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	0.60000	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	0.60000	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	0.08370	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	0.60000	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	0.08370	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 vivo

Species	Test conditions	Endpoint	Results	Reference
Rat (8 per group [sex not specified in expert review])	Intraperitoenal injection with up to 1.2 g potassium sorbate/kg bw. Liver examined for DNA damage using alkaline elution.	DNA damage	-ve	Jung et al. 1992
Mouse (4 males per group)	Comet assay with a single oral dose of sorbic acid or potassium sorbate of 2 g/kg bw. Many organs assessed for DNA damage 3 and 24 hr after treatment.	DNA damage	-ve	Sasaki et al. 2002
Mouse (5 per group [sex not specified in expert review])	Animals dosed with sorbic acid at up to 5 g/kg bw/day by gavage. Bone marrow examined for micronuclei.	Chromosome damage	-ve	Jung et al. 1992
Mouse (5 per group [sex not specified in expert review])	Animals dosed with sorbic acid at up to 5 g/kg bw/day by gavage. Bone marrow examined for sister chromatid exchanges.	Chromosome effects	-ve	Jung et al. 1992
Mouse (10 per group [sex not specified in expert review])	Animals dosed with sorbic acid at 15 mg/kg bw/day by gavage for 30 days. Bone marrow examined for chromosome aberrations.	Chromosome damage	-ve	Bannerjee & Giri, 1986

Mouse [group size not specified in expert review]	Animals dosed at doses equivalent to up to 200 mg sorbic acid/kg bw. Gavage: 1. & 2. freshly-prepared sodium or potassium sorbate; 3. stored sodium sorbate; 4. stored potassium sorbate Intraperitoneal injection: 5. & 6. fresh or stored potassium sorbate; 7. stored sodium sorbate Bone marrow examined for micronuclei.	Chromosome damage	1. & 2. -ve 3. +ve (small, but statistically significant increase at 200 mg/kg bw) 4. –ve 5. & 6. -ve 7. +ve (slight increase at 200 mg/kg bw)	Munzner et al. 1990
Mouse [group size not specified in expert review]	Intraperitoneal injection of sorbic acid at 150 mg/kg bw. Bone marrow examined for micronuclei.	Chromosome damage	+ve	Mukherjee et al. 1988
Mouse [group size not specified in expert review]	Intraperitoneal injection of sorbic acid at 75 mg/kg bw. Bone marrow examined for sister chromatid exchanges.	Chromosome effects	+ve	Mukherjee et al. 1988

Hamster [group size not specified in expert review]	Animals administered (by gavage or by intraperitoneal injection) doses equivalent to up to 200 mg sorbic acid/kg bw of freshly-prepared or stored sodium or potassium sorbate. Bone marrow examined for micronuclei.	Chromosome damage	+ve with fresh or stored sodium sorbate by injection -ve with all other dosing regimens	Munzner et al. 1990
Hamster [group size not specified in expert review]	Animals administered (by gavage or by intraperitoneal injection) doses equivalent to up to 200 mg sorbic acid/kg bw of freshly-prepared or stored sodium or potassium sorbate. Bone marrow examined for chromosome aberrations.	Chromosome damage	+ve with fresh or stored sodium sorbate by injection -ve with all other dosing regimens	Munzner et al. 1990
Hamster [group size not specified in expert review]	Animals administered (by gavage or by intraperitoneal injection) doses equivalent to up to 200 mg sorbic acid/kg bw of freshly-prepared or stored sodium or potassium sorbate. Bone marrow examined for sister chromatid exchanges.	Chromosome effects	-ve	Munzner et al. 1990

In vitro

Test system	Test conditions	Endpoint	Activation status	Results	Reference
Human cells [test system not further specified in expert review]	Treatment with sorbic acid. Assay for unscheduled DNA synthesis. [No further details in expert review.]	DNA damage	With and without S9	-ve	Jung et al. 1992
Human cells [test system not further specified in expert review]	Treatment with potassium sorbate. [No further details in expert review.]	Single stranded DNA breaks	With and without S9	-ve	Jung et al. 1992
Hamster cells [test system not further specified in expert review]	Treatment with sorbic acid, potassium sorbate, freshly-prepared sodium sorbate, or sodium sorbate that had been heated to 80ºC and then stored for 48 hr. Cells examined for micronuclei or transformation [No further details in expert review.]	Chromosome damage and cell transformation [Transformed cells exhibit cancer-like characteristics]	Without S9	Heated and stored sodium sorbate: +ve All other testing regimens: -ve	Schiffmann & Schlatter, 1992

Hamster cells [test system not further specified in expert review]	Treatment with potassium sorbate or freshly-prepared or stored (2-4 wk at room temperature) sodium sorbate. Cells assessed for point mutation and sister chromatid exchanges. [No further details in expert review.]	Mutation; chromosome effects	With and without S9	Stored sodium sorbate: +ve for point mutation with S9 All other testing regimens: -ve	Munzner et al. 1990
Mammalian cells [test system not further specified in expert review]	Sorbic acid, sodium sorbate or potassium sorbate. [No further details in expert review.]	Mutation	[Not specified in expert review]	Sodium sorbate: +ve Sorbic acid and potassium sorbate: -ve	Budayova, 1985; Hasegawa et al. 1984
Mammalian cells [test system not further specified in expert review]	High concentrations of sorbic acid, sodium sorbate or potassium sorbate. Cells examined for chromosome damage and sister chromatid exchanges. [No further details in expert review.]	Chromosome damage and effects	[Not specified in expert review]	+ve	Abe & Sasaki, 1977; Hasegawa et al. 1984; Ishidate & Odashima, 1977; Ishidate et al. 1984; 1988

Mammalian cells [test system not further specified in expert review]	Treatment with stored freshly-prepared sodium sorbate or stored sodium or potassium sorbate. Cells examined for aneuploidy. [No further details in expert review.]	Change in chromosome number	[Not specified in expert review]	+ve	Schlatter et al. 1992
Salmonella typhimurium strains TA98, TA98, TA100, TA1535	Ames test with sorbic acid at up to 6.6 mg/plate	Mutation	With and without rat and hamster liver S9	-ve [Good quality study.]	NTP, undated
Salmonella typhimurium [strain not specified in expert review]	Ames tests with the intestinal contents of mice fed sorbic acid or potassium sorbate at approximately 5 or 16 g/kg bw/day for 1 yr.	Mutation	[Not stated in expert review whether tested also without S9]	+ve at the top dose (with S9)	Tsuchiya & Yamaha, 1984
Salmonella typhimurium [strains not specified in expert review]	Ames test with sodium sorbate. [No further details in expert review.]	Mutation	[Not stated in expert review whether tested also with S9]	Weakly +ve (without S9)	Yoshida, 1982
Salmonella typhimurium strains TA98, TA100	Ames test with potassium sorbate [concentration not stated].	Mutation	With and without S9	-ve	Kitano et al. 2002

Salmonella typhimurium [strains not specified in expert review]	Ames tests with sorbic acid or potassium sorbate. [No further details in expert review.]	Mutation	With and without S9	-ve	Jung et al., 1992; Nonaka, 1989; Ishidate et al. 1984 & 1988; Morita et al. 1981; Kawachi et al. 1980; d'Aquino & Santini, 1977; LBI, 1974
Salmonella typhimurium [strains not specified in expert review]	Ames tests with freshly-prepared or stored sodium or potassium sorbate. [No further details in expert review.]	Mutation	[Not stated in expert review whether tested also with S9]	-ve	Munzner et al. 1990
Bacillus subtilis strains M45, H17	Rec assay with potassium sorbate [concentration not stated].	DNA damage [indicative test]	Not stated	-ve	Kitano et al. 2002
Bacillus subtilis [strains not specified in expert review]	Rec assay with potassium sorbate [no further details in expert review]	DNA damage [indirect indicator]	Not stated	Weakly +ve	Nonaka, 1989
Bacillus subtilis [strains not specified in expert review]	Rec assay with sorbic acid. [No further details in expert review.]	DNA damage [indirect indicator]	Not stated	-ve	Morita et al. 1981; Namiki et al. 1980; Khoudokormoff & Gist-Brocades, 1978; Hayatsu et al. 1975; Kada, 1974

Saccharomyces cerevisiae	Test with potassium sorbate. [No further details in expert review.]	Mutation	Not stated	-ve	LBI, 1974
Drosophila melanogaster	Wing spot test with sodium or potassium sorbate. [No further details in expert review.]	Mutation	N/A	-ve	Schlatter et al. 1992

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