Acesulfame Potassium

1 Nonproprietary Names

PhEur: Acesulfamum kalicum

2 Synonyms

Acesulfame K; E950; 6-methyl-3,4-dihydro-1,2,3-oxathiazin-4(3*H*)-one 2,2-dioxide potassium salt; *Sunett*.

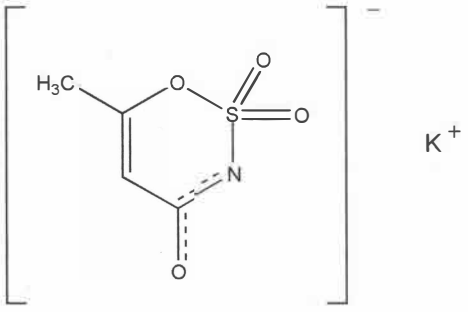
3 Chemical Name and CAS Registry Number

6-Methyl-1,2,3-oxathiazin-4(3H)-one-2,2-dioxide potassium salt [55589-62-3]

4 Empirical Formula and Molecular Weight

$C_4H_4KNO_4S$ 201.24

5 Structural Formula



6 Functional Category

Sweetening agent.

7 Applications in Pharmaceutical Formulation or Technology

Acesulfame potassium is used as an intense sweetening agent in cosmetics, foods, beverage products, table-top sweeteners, vitamin and pharmaceutical preparations, including powder mixes, tablets, and liquid products. It is widely used as a sugar substitute in compounded formulations,[1] and as a toothpaste sweetener.[2]

The approximate sweetening power is 180–200 times that of sucrose. It enhances flavor systems and can be used to mask some unpleasant taste characteristics.

8 Description

Acesulfame potassium occurs as a colorless to white-colored, odorless, crystalline powder with an intensely sweet taste.

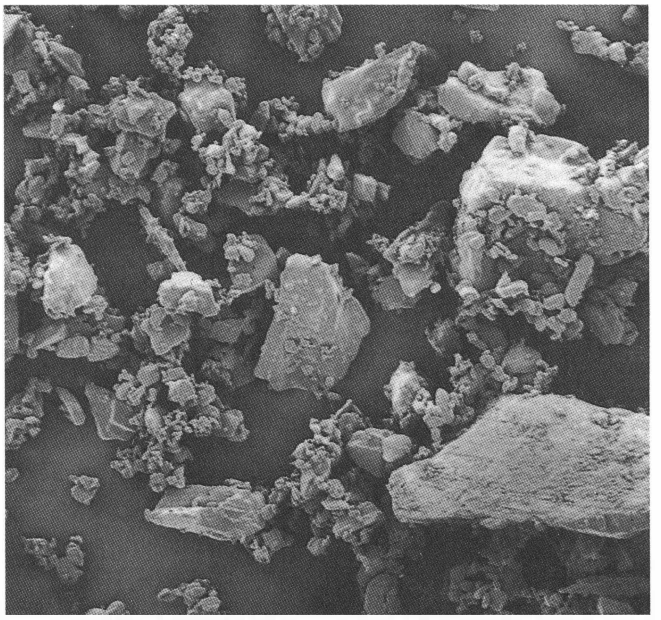
9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for acesulfame potassium.

Test	PhEur 2002
Characters	+
Identification	+
Appearance of solution	+
Acidity or alkalinity	+
Acetylacetamide	+
Impurity B and related substances	≤20 ppm
Fluorides	≤3 ppm
Heavy metals	≤5 ppm
Loss on drying	≤1.0%
Assay	99.0–101.0%

SEM: 1
Excipient: Acesulfame potassium
Magnification: 150×
Voltage: 5 kV



10 Typical Properties

Density (bulk): 1.1–1.3 g/cm^3
Melting point: 250°C, decomposition can be observed at 225°C if slowly heated.
Solubility: *see* Table II.

Table II: Solubility of acesulfame potassium.

Solvent	Solubility at 20°C unless otherwise stated
Ethanol	1 in 1000
Ethanol (50%)	1 in 100
Water	1 in 7.1 at 0°C
	1 in 3.7
	1 in 0.77 at 100°C

11 Stability and Storage Conditions

Acesulfame potassium possesses good stability. In the bulk form it shows no sign of decomposition at ambient temperature over many years. In aqueous solutions (pH 3.0–3.5 at 20°C) no reduction in sweetness was observed over a period of approximately 2 years. Stability at elevated temperatures is good, although some decomposition was noted following storage at 40°C for several months. Sterilization and pasteurization do not affect the taste of acesulfame potassium.[3]

The bulk material should be stored in a well-closed container in a cool, dry place.

12 Incompatibilities

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13 Method of Manufacture

Acesulfame potassium is synthesized from acetoacetic acid *tert*-butyl ester and fluorosulfonyl isocyanate. The resulting compound is transformed to fluorosulfonyl acetoacetic acid amide, which is then cyclized in the presence of potassium hydroxide to form the oxathiazinone dioxide ring system. Because of the strong acidity of this compound, the potassium salt is produced directly.

An alternative synthesis route for acesulfame potassium starts with the reaction between diketene and amidosulfonic acid. In the presence of dehydrating agents, and after neutralization with potassium hydroxide, acesulfame potassium is formed.

14 Safety

Acesulfame potassium is widely used in beverages, cosmetics, foods, and pharmaceutical formulations and is generally regarded as a relatively nontoxic and nonirritant material. Pharmacokinetic studies have shown that acesulfame potassium is not metabolized and is rapidly excreted unchanged in the urine. Long-term feeding studies in rats and dogs showed no evidence to suggest acesulfame potassium is mutagenic or carcinogenic.[4]

The WHO has set an acceptable daily intake for acesulfame potassium of up to 15 mg/kg body-weight.[4]

LD_{50} (rat, IP): 2.2 g/kg[3]
LD_{50} (rat, oral): 6.9–8.0 g/kg

15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Eye protection, gloves, and a dust mask are recommended.

16 Regulatory Status

Accepted for use in Europe as a food additive. It is also accepted for use in certain food products in the USA and several countries in Central and South America, the Middle East, Africa, Asia, and Australia.

17 Related Substances

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18 Comments

The perceived intensity of sweeteners relative to sucrose depends upon their concentration, temperature of tasting, and pH, and on the flavor and texture of the product concerned.

Intense sweetening agents will not replace the bulk, textural, or preservative characteristics of sugar, if sugar is removed from a formulation.

Synergistic effects for combinations of sweeteners have been reported, e.g., acesulfame potassium with aspartame or sodium cyclamate.

Note that free acesulfame acid is not suitable for use as a sweetener.

19 Specific References

1 Kloesel L. Sugar substitutes. *Int J Pharm Compound* 2000; **4**(2): 86–87.
2 Schmidt R, Janssen E, Haussler O, *et al.* Evaluating toothpaste sweetening. *Cosmet Toilet* 2000; **115**: 49–53.
3 Lipinski G-WvR, Huddart BE. Acesulfame K. *Chem Ind* 1983; **11**: 427–432.
4 FAO/WHO. Evaluation of certain food additives and contaminants. Thirty-seventh report of the joint FAO/WHO expert committee on food additives. *World Health Organ Tech Rep Ser* 1991; No. 806.

20 General References

Anonymous. Artificial sweetners. *Can Pharm J* 1996; **129**: 22.
Lipinski G-WvR, Lück E. Acesulfame K: a new sweetener for oral cosmetics. *Manuf Chem* 1981; **52**(5): 37.
Marie S. Sweeteners. In: Smith J, ed. *Food Additives User's Handbook*. Glasgow: Blackie, 1991: 47–74.
Nutrinova. Technical literature: *Sunett in Pharmaceuticals*, 1998.

21 Author

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22 Date of Revision

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