

# Potassium Sorbate

## 1 Nonproprietary Names

BP: Potassium sorbate  
PhEur: Kalii sorbas  
USPNF: Potassium sorbate

## 2 Synonyms

E202; 2,4-hexadienoic acid (*E,E*)-potassium salt; potassium (*E,E*)-hexa-2,4-dienoate; potassium (*E,E*)-sorbate; sorbic acid potassium salt; *Sorbistat K*.

## 3 Chemical Name and CAS Registry Number

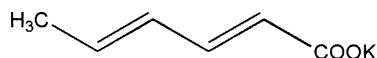
2,4-Hexadienoic acid potassium salt [24634-61-5]

## 4 Empirical Formula Molecular Weight

C<sub>6</sub>H<sub>7</sub>O<sub>2</sub>K

150.22

## 5 Structural Formula



## 6 Functional Category

Antimicrobial preservative.

## 7 Applications in Pharmaceutical Formulation or Technology

Potassium sorbate is an antimicrobial preservative, with antibacterial and antifungal properties used in pharmaceuticals, foods, enteral preparations, and cosmetics. Generally, it is used at concentrations of 0.1–0.2% in oral and topical formulations, especially those containing nonionic surfactants.

Potassium sorbate is used in approximately twice as many pharmaceutical formulations as is sorbic acid owing to its greater solubility and stability in water. Like sorbic acid, potassium sorbate has minimal antibacterial properties in formulations above pH 6.

## 8 Description

Potassium sorbate occurs as a white crystalline powder with a faint, characteristic odor.

## 9 Pharmacopeial Specifications

See Table I.

Table I: Pharmacopeial specifications for potassium sorbate.

Test	PhEur 2002	USPNF 20
Identification	+	+
Characters	+	—
Appearance of solution	+	—
Acidity or alkalinity	+	+
Loss on drying	≤ 1.0%	≤ 1.0%
Heavy metals	≤ 10 ppm	≤ 0.001%
Organic volatile impurities	—	+
Aldehydes (as C <sub>2</sub> H <sub>4</sub> O)	≤ 0.15%	—
Assay (dried basis)	99.0–101.0%	98.0–101.0%

## 10 Typical Properties

**Antimicrobial activity:** potassium sorbate is predominantly used as an antifungal preservative although it also has antibacterial properties. Similarly to sorbic acid, the antimicrobial activity is dependent on the degree of dissociation; there is practically no antibacterial activity above pH 6. Preservative efficacy is increased with increasing temperature,<sup>(1)</sup> and increasing concentration of potassium sorbate.<sup>(1)</sup> The efficacy of potassium sorbate is also increased when used in combination with other antimicrobial preservatives or glycols since synergistic effects occur.<sup>(2)</sup> Reported minimum inhibitory concentrations (MICs) at the pH values indicated are shown in Table II.<sup>(2)</sup>

Table II: Minimum inhibitory concentrations (MIC) of potassium sorbate.

Microorganism	MIC (μg/mL) at the stated pH		
	5.5	6.0	7.0
<i>Escherichia coli</i>	1400	1500	3800
<i>Pseudomonas aeruginosa</i>	1600–2300	1900–2500	5600–9000
<i>Staphylococcus aureus</i>	1200	1000	3800

**Density:** 1.363 g/cm<sup>3</sup>

**Melting point:** 270 °C with decomposition.

**Solubility:** see Table III.

## 11 Stability and Storage Conditions

Potassium sorbate is more stable in aqueous solution than sorbic acid; aqueous solutions may be sterilized by autoclaving.

The bulk material should be stored in a well-closed container, protected from light, at a temperature not exceeding 40 °C.

## 12 Incompatibilities

Some loss of antimicrobial activity occurs in the presence of nonionic surfactants and some plastics. See also Sorbic Acid.

**Table III:** Solubility of potassium sorbate.

Solvent	Solubility at 20 °C unless otherwise stated
Acetone	1 in 1000
Benzene	Practically insoluble
Chloroform	Very slightly soluble
Corn oil	Very slightly soluble
Ethanol	1 in 50
Ethanol (95%)	1 in 35
Ethanol (5%)	1 in 1.7
Ether	Very slightly soluble
Propylene glycol	1 in 1.8 1 in 2.1 at 50 °C 1 in 5 at 100 °C
Water	1 in 1.72 1 in 1.64 at 50 °C 1 in 1.56 at 100 °C

### 13 Method of Manufacture

Potassium sorbate is prepared from sorbic acid and potassium hydroxide.

### 14 Safety

Potassium sorbate is used as an antimicrobial preservative in oral and topical pharmaceutical formulations and is generally regarded as a relatively nontoxic material. However, some adverse reactions to potassium sorbate have been reported, including irritant skin reactions which may be of the allergic, hypersensitive type. There have been no reports of adverse systemic reactions following oral consumption of potassium sorbate.

The WHO has set an estimated total acceptable daily intake for sorbic acid, calcium sorbate, potassium sorbate, and sodium sorbate expressed as sorbic acid at up to 25 mg/kg body-weight.<sup>(3,4)</sup>

LD<sub>50</sub> (mouse, IP): 1.3 g/kg<sup>(5)</sup>

LD<sub>50</sub> (rat, oral): 4.92 g/kg

See also Sorbic Acid.

### 15 Handling Precautions

Observe normal precautions appropriate to the circumstances and quantity of material handled. Potassium sorbate is irritant to the skin, eyes, and mucous membranes; eye, protection and gloves are recommended. In areas of limited ventilation, a respirator is also recommended.

### 16 Regulatory Status

GRAS listed. Accepted for use as a food additive in Europe. Included in the FDA Inactive Ingredients Guide (oral capsules,

solutions, suspensions, syrups, tablets, and topical creams and lotions). Included in nonparenteral medicines licensed in the UK.

### 17 Related Substances

Sorbic acid.

### 18 Comments

Much of the information contained in the sorbic acid monograph on safety, incompatibilities, and references also applies to potassium, calcium, and sodium sorbates. See Sorbic Acid for further information.

Potassium sorbate has less antimicrobial activity than sorbic acid, but is more water soluble. Most potassium sorbate compounds will contain sorbic acid.

The EINECS number for potassium sorbate is 246-376-1.

### 19 Specific References

- 1 Lusher P, Denyer SP, Hugo WB. A note on the effect of dilution and temperature on the bactericidal activity of potassium sorbate. *J Appl Bacteriol* 1984; 57: 179–181.
- 2 Woodford R, Adams E. Sorbic acid. *Am Perfum Cosmet* 1970; 85(3): 25–30.
- 3 FAO/WHO. Toxicological evaluation of certain food additives with a review of general principles and of specifications. Seventeenth report of the joint FAO/WHO expert committee on food additives. *World Health Organ Tech Rep Ser* 1974; No. 539.
- 4 FAO/WHO. Evaluation of certain food additives and contaminants. Twenty-ninth report of the joint FAO/WHO expert committee on food additives. *World Health Organ Tech Rep Ser* 1986; No. 733.
- 5 Lewis RJ, ed. *Sax's Dangerous Properties of Industrial Materials*, 10th edn. New York: Wiley, 2000: 3042.

### 20 General References

- Smolinske SC, ed. *Handbook of Food, Drug, and Cosmetic Excipients*. Boca Raton, FL: CRC Press, 1992: 363–367.
- Sofos JN, Busta FF. Sorbates. In: Branen AL, Davidson PM, eds. *Antimicrobials in Foods*. New York: Marcel Dekker, 1983: 141–175.
- Walker R. Toxicology of sorbic acid and sorbates. *Food Add Contam* 1990; 7(5): 671–676.

### 21 Author

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### 22 Date of Revision

8 May 2002.