Sorbic Acid

1 Nonproprietary Names

BP: Sorbic Acid

PhEur: Sorbic Acid

USP–NF: Sorbic Acid

2 Synonyms

Acidum sorbicum; (2-butenylidene) acetic acid; crotylidene acetic acid; E200; hexadienic acid; hexadienoic acid; 2,4-hexadienoic acid; 1,3-pentadiene-1-carboxylic acid; 2-propenylacrylic acid; (*E*,*E*)-sorbic acid; *Sorbistat*.

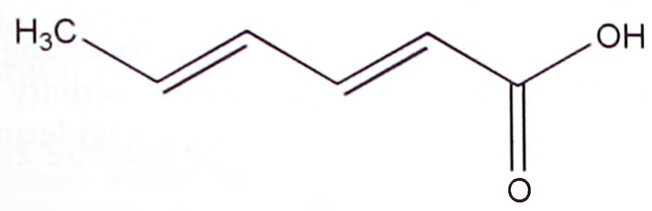
3 Chemical Name and CAS Registry Number

(*E*,*E*)-Hexa-2,4-dienoic acid [110–44–1] and [22500-92-1]

4 Empirical Formula and Molecular Weight

$C_6H_8O_2$ 112.13

5 Structural Formula



6 Functional Category

Antimicrobial preservative.

7 Applications in Pharmaceutical Formulation or Technology

Sorbic acid is an antimicrobial preservative[1,2] with antibacterial and antifungal properties used in pharmaceuticals and enteral preparations. Generally, it is used at concentrations of 0.05–0.2% in oral and topical pharmaceutical formulations, especially those containing nonionic surfactants. Sorbic acid has been used in pluronic lecithin organogel formulations investigated for topical drug delivery[3] and is also used with proteins, enzymes, gelatin, and vegetable gums.[4] It has been shown to be an effective preservative for promethazine hydrochloride solutions in a concentration of 1 g/L.[5]

Sorbic acid is primarily used as an antifungal agent, although it also possesses antibacterial properties. The optimum antibacterial activity is obtained at pH 4.5; and practically no activity is observed above pH 6.[6,7] Sorbic acid has limited stability and activity against bacteria and is thus frequently used in combination with other antimicrobial preservatives or glycols, when synergistic effects appear to occur.[8]

8 Description

Sorbic acid occurs as a tasteless, white to yellow-white crystalline powder with a faint characteristic odor.

9 Pharmacopeial Specifications

See Table I.

10 Typical Properties

Antimicrobial activity Reported minimum inhibitory concentrations (MICs) at pH 6 are shown in Table II.[9]

SEM 1: Excipient: sorbic acid; manufacturer: Pfizer Ltd.; magnification: 60×.

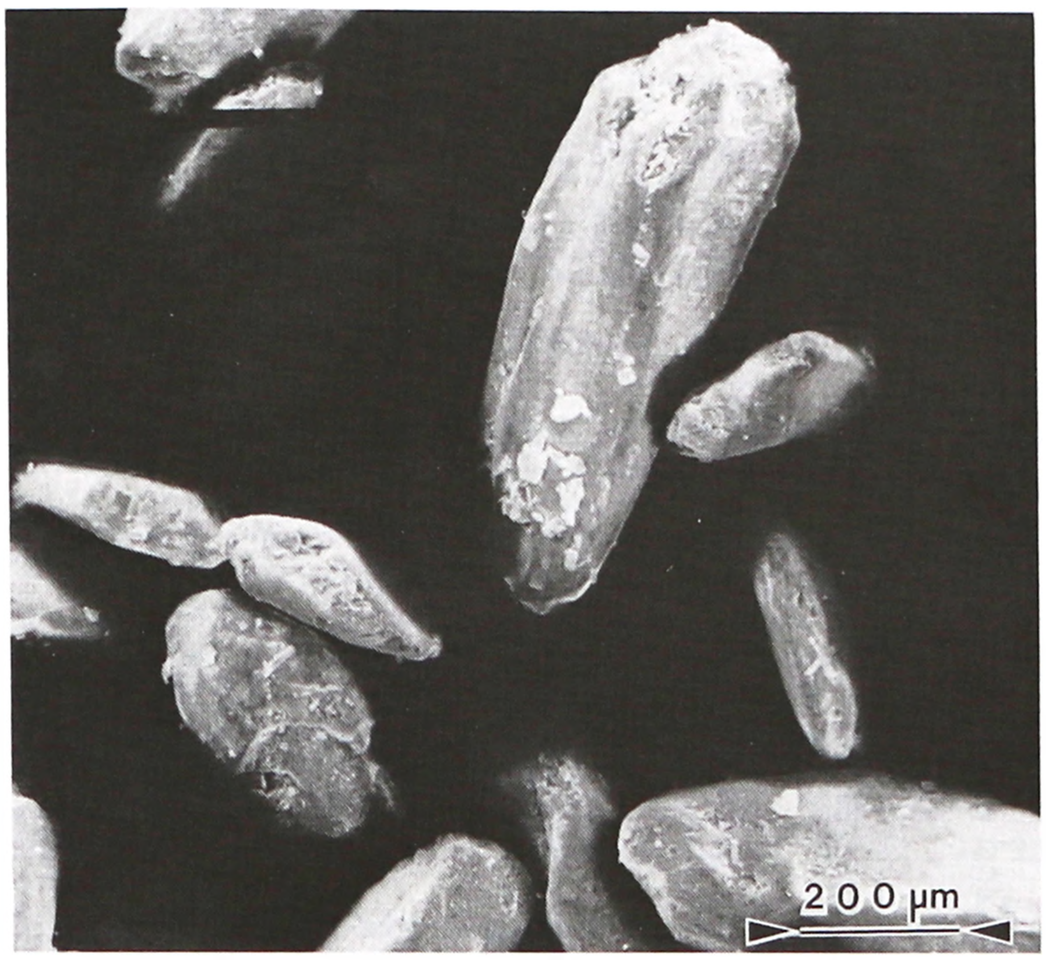


Table I: Pharmacopeial specifications for sorbic acid.

Test	PhEur 9.2	USP 40–NF 35 S1
Identification	+	+
Characters	+	—
Appearance of solution	+	—
Melting range	132–136°C	132–135°C
Water	≤1.0%	≤0.5%
Residue on ignition	—	≤0.2%
Sulfated ash	≤0.2%	—
Heavy metals	—	≤10 ppm
Aldehyde (as C_2H_4O)	≤0.15%	—
Assay (anhydrous basis)	99.0–101.0%	99.0–101.0%

Table II: Minimum inhibitory concentrations (MICs) of sorbic acid at pH 6.

Microorganism	MIC (µg/mL)
Aspergillus niger	200–500
Candida albicans	25–50
Clostridium sporogenes	100–500
Escherichia coli	50–100
Klebsiella pneumoniae	50–100
Penicillium notatum	200–300
Pseudomonas aeruginosa	100–300
Pseudomonas cepacia	50–100
Pseudomonas fluorescens	100–300
Saccharomyces cerevisiae	200–500
Staphylococcus aureus	50–100

Boiling point 228°C with decomposition.
Density 1.20 g/cm^3
Dissociation constant pK_a = 4.76
Flash point 127°C
Melting point 134.5°C