

Nutrinova® Sorbic Acid – Pharma Grade – Chemical and physical properties according to European Pharmacopoeia 11.0* and US Pharmacopoeia*

Definition

Chemical name (2E,4E)-Hexa-2, 4-dienoic acid; (E, E)-Sorbic Acid

CAS number 110-44-1 Chemical formula $C_6H_8O_2$

Relative molecular mass 112.13 (USP-NF)

Description White to yellowish-white crystalline powder

Freely soluble in methanol and ethyl alcohol (approx. 129 g/L at 20 °C);

less soluble in water (approx. 1.2 g/L at 20 °C)

Identification

UV-Maximum 264 + 2 nm (solution of 0.002 g/L in water at pH <3)

IR-spectrum Complies with reference spectrum

Pharma specific tests

Appearance of solution: Clear and colourless

Aldehydes Not more than 0.15 % (as acetaldehyde) (C₂H₄O)

Identification (double bonds) Positive (USP)

Residual solvents: According to the requirements of the USP

Purity

Assay 99,0 % to 101,0 % of C₆H₈O₂, on the anhydrous basis (Ph Eur)

98,0 % to 102,0 % of $C_6H_8O_2$, on the anhydrous basis (USP-NF)

Water content

Not more than 0.5 % (Karl Fischer method)

Heat resistance

No discoloration after 90 minutes at 105 °C

Melting range 132 - 135 °C (USP-NF) Sulfated ash Not more than 0.1 %

Heavy metals Not more than 10 ppm (expressed as lead)

Lead Not more than 0.1 ppm
Arsenic Not more than 0.1 ppm
Mercury Not more than 0.01 ppm
Cadmium Not more than 0.02 ppm
Zinc Not more than 0.1 ppm
Chloride Not more than 100 ppm
Sulphate Not more than 150 ppm

^{*} amended version PSoAcPh0200 October 2023



Microbiology

Total mesophilic counts	< 10 KBE in 1 g
Yeasts	< 10 KBE in 1 g
Moulds	< 10 KBE in 1 g
Enterobacteriaceae	< 10 KBE in 1 g
Staphylococcus aureus	negative in 1 g
Pseudomonas aeruginosa	negative in 1 g
Escherichia coli	negative in 1 g
Salmonellae	negative in 10 g

Shelf life 3 years from date of manufacture

provided that the product is stored in the originally closed packaging, protected from sunlight and at ambient temperature (max. 30 $^{\circ}$ C)

and under dry conditions (max. 65 % relative humidity)

Nutrinova® Sorbic Acid Pharma Grade meets the requirements of the European Pharmacopoeia, US Pharmacopoeia and other national Pharmacopoeias.

Nutrinova® Sorbic Acid Pharma Grade conforms also to the purity specifications published by FAO/WHO, those of the US Food Chemicals Codex, those of the JSFA, and/or the EC as well as to national specifications published in food regulations for Sorbic acid. Any existing legal restrictions for the use in foods, drugs and cosmetics must be observed by users of Nutrinova® Sorbic Acid.

The information presented herein is based on our present state of knowledge and is intended to provide general notes on our products and their uses. It must not be construed as guaranteeing specific properties of the products described herein or their suitability for a particular application. The user of Nutrinova® Sorbic Acid is solely responsible for investigating whether existing patents are infringed by the use of Nutrinova® Sorbic Acid. Additionally, the user is solely responsible for investigating and checking the regulatory approval status with respect to any intended use of Nutrinova® Sorbic Acid. Any sales and/or the deliveries of Nutrinova® Sorbic Acid are always subject to our General Terms and Conditions, unless otherwise agreed between the parties in writing. Any reference to laws, regulations, standards, guidelines etc. refers to such laws, regulations, standards, guidelines etc. as in force and effect as the date of this document. This product specification supersedes all provisions and concepts contained in any and all prior product specifications.

Technical Note

The product may contain traces of potassium sorbate. The user is responsible for the microbiological stability of its products. The water used in the production of aqueous Sorbic acid solutions should not contain any reactive substances, such as free chlorine. We recommend following the hygienic requirements according to "Good Manufacturing Practice" (GMP).

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