

Nutrinova® Potassium Sorbate - Pharma Grade – Chemical and physical properties according to European Pharmacopoeia 10.0* and US Pharmacopoeia 43-NF 38*

Definition

Chemical name	2,4-Hexadienoic acid, (<i>E,E</i>)-, potassium salt; Potassium (<i>2E,4E</i>)-hexa-2,4-dienoate; Potassium (<i>E,E</i>)-sorbate
CAS number	24634-61-5; 590-00-1
Chemical formula	C ₆ H ₇ KO ₂
Relative molecular mass	150.22

Description

White to yellowish-white crystalline powder or spherical granules
 Freely soluble in water (approx. 1400 g/L at 20 °C);
 less soluble in ethyl alcohol (approx. 1 g/L at 20 °C)

Identification

Ultra-violet absorption	UV-Maximum 264 ± 2 nm (solution of 0.002 g/L in water at pH <3)
IR-spectrum	Complies with reference spectrum
Test for potassium	Positive

Pharma specific tests

Appearance of solution	Clear and colourless
Acidity (calc. as Sorbic Acid)	Not more than 0.1 %
Alkalinity (calc. as K ₂ CO ₃)	Not more than 0.1 %
Aldehyde	Not more than 0.15 %, as acetaldehyde (C ₂ H ₄ O)
Identification (double bonds)	Positive (USP)
Residual solvents	According to the requirements of the USP

Purity

Assay	99,0 % to 101,0 % of C ₆ H ₇ KO ₂ , on dry weight basis (Ph Eur) 98,0 % to 102,0 % of C ₆ H ₇ KO ₂ , on dry weight basis (USP-NF)
Loss on drying	Not more than 0.5 % (Karl Fischer method)
pH-value	8.5 – 10.5 (10 % water solution)
Heat resistance	No discoloration after 90 minutes at 105 °C
Melting range	132 - 135 °C (USP-NF) - based on the range of sorbic acid
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
Potassium	24,5 % - 27,6 %
Chloride	Not more than 100 ppm
Sulphate	Not more than 150 ppm

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

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

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

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® Potassium Sorbate is solely responsible for investigating whether existing patents are infringed by the use of Nutrinova® Potassium Sorbate. Additionally, the user is solely responsible for investigating and checking the regulatory approval status with respect to any intended use of Nutrinova® Potassium Sorbate. Any sales and/or the deliveries of Nutrinova® Potassium Sorbate 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.

Technical Note

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

* amended version

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Celanese Sales Germany GmbH
Am Unisys-Park 1
65843 Sulzbach (Taunus)
Germany
Phone: +49 (0)69 45009-1378
Fax: + 49 (0)69 45009- 58294
Email: foodingredients-emea@celanese.com
Web: www.celanese.com/food-ingredients/about-us.aspx