

Specification

Magnesia 7775001
Potassium chloride
EP, USP, E 508

Article No.:	7775001
Specification Type:	API
Version:	6
Issue Date:	21/06/2021
Manufacturer's Designation:	Potassium chloride, EP, USP, E 508, pyrogen free, according specification no. 353
Manufacturing Site:	K+S Minerals and Agriculture GmbH In der Aue1 Heringen (Werra), Hessen 36266, Germany

Appearance (EP)	almost white or white, crystalline powder, or colourless crystals
Appearance (E 508)	colourless, elongated, prismatic or cubital crystals or white, granular powder
Solubility (EP)	freely soluble in water, practically insoluble in anhydrous ethanol
Solubility (E 508)	freely soluble in water, insoluble in ethanol
Odour	odourless
Assay (EP)	99.0 - 101.0 %
Assay (USP)	99.0 - 100.5 %
Assay (E 508) (on dried basis)	Min. 99 %
Identification (K)	complies
Identification (CI)	complies
Appearance of solution	clear and colourless
Acidity / alkalinity (USP)	complies
Acidity / alkalinity (EP)	max. 0,5 ml von 0,01 M HCl / NaOH
Pb	max. 2 ppm
Cd	max. 1 ppm
Hg	max. 1 ppm
As	max. 3 ppm
Fe	max. 20 ppm
Al	max. 1.0 ppm
I (EP)	complies
I (USP)	max. 0.005 %
Br	max. 0.1 %
SO4	max. 300 ppm
Na (EP)	max. 0.1 %
Na (USP)	complies

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Na (E 508)	negative
Ca, Mg	complies
Mg and alkali metals (calculated as Ca)	max. 200 ppm
Loss on drying (EP)	max. 1.0 %
Loss on drying (USP) (105 °C, 2 h)	max. 1.0 %
Loss on drying (E 508) (105 °C, 2 h)	max. 1 %
Residual solvents	no organic solvents are used in the production, the product meets the requirements of USP, EP and EMA/CHMP/ICH/82660/2006 for residual solvents
Total Plate Count	max. 1000 cfu/g
Yeasts / Moulds	max. 100 cfu/g
Bacterial endotoxins	max. 5 I.U./g

Released by: 21/06/2021, David Roether

Parameters indicated in this specification are based on our current, carefully determined knowledge. It is the users own responsibility to test and analyze materials and therefore corroborate that products are adequate for their applications.