

TECHNICAL SPECIFICATIONS

SODIUM CYCLAMATE ANHYDROUS

Sweetener for food E-952

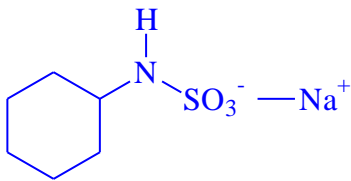
Product Code: 1021 (boxes 25 kg); 1023 (drums 50 kg); 1025 (big bags 500 kg); 1027 (big bags 1.000 kg).

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| CHARACTERISTIC | SPECIFICATION | METHOD |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------|----------|
| Formula | C ₆ H ₁₂ NSO ₃ Na  | |
| Chemical name | Sodium N-cyclohexylsulphamate. | |
| CAS Number | [139-05-9] | |
| Ph. Eur. Monograph | Nr 0774 | |
| Relative molecular mass | 201.2 | |
| Appearance | White or almost white crystalline powder or colourless crystals, odourless. | |
| Taste | Very sweet. | |
| Appearance of solution | Clear and colourless. | Eur. Ph. |
| Identification | A. IR Spectrophotometry. E. Reaction of sodium. | Eur. Ph. |
| Solubility | Freely soluble in water, slightly soluble in ethanol. | |
| Loss on drying | ≤ 1.0 % | PRO.27 |
| Content | 98.5 – 101.0% | PRO.28 |
| pH (solution 10% in water) | 5.5 – 7.5 | Eur. Ph. |
| Absorbance at 270 nm | ≤ 0.10 | Eur. Ph. |

| CHARACTERISTIC | SPECIFICATION | METHOD |
|--------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------|------------------------------|
| Sulphates | ≤ 0.1 % | Eur. Ph. |
| Elemental impurities: conform | ICH Guideline Q3D | ICP-MS |
| Lead | ≤ 0.5 ppm | ICP-MS |
| Selenium | ≤ 15 ppm | ICP-MS |
| Arsenic | ≤ 1.5 ppm | ICP-MS |
| Cyclohexylamine | < 8 ppm | Eur. Ph. |
| N,N-dicyclohexylamine | < 0.5 ppm | Eur. Ph. |
| ⁽¹⁾ N,N'-dicyclohexylsulfamide | < 1 ppm | Eur. Ph. |
| Aniline | < 0.5 ppm | Eur. Ph. |
| Sulphamic acid | ≤ 0.1 % | Eur. Ph. |
| Microbiology Total aerobic mesophilic bacteria Total coliform bacteria Salmonella spp. Mould and yeast | < 1000 cfu/g Absence / 0.1 g Absence / 25 g < 100 cfu/g | Eur. Ph. |
| Residual solvents: conform ICH Guideline Xylene | ICH Q3C < 1 ppm (ICH < 2170 ppm) | GC Headspace GC Headspace |
| Shelf life | Five years | |

⁽¹⁾ European Pharmacopoeia: no limit.

USE: FOOD and DRINKS according to the Regulation (EU) 1333/2008 and Regulation (EU) 1129/2011, and subsequent modifications. PHARMACY according to European Pharmacopoeia 10th edition.

PURITY Conform to European Pharmacopoeia 10th edition, to ICH Guidelines Q3C on Residual Solvents and Q3D on Elemental Impurities, and to Regulation (EU) 231/2012 and amendments on Specification for Food Additives.