



Specification

Concerning Product:	
Article number	31900
Trade name / designation / denomination	Natriumcyclamat krist.
CAS number	139-05-9
Other names / synonyms	•CYCLOHEXYLSULFAMIC ACID; •Cyclamic Acid; •Cyclamic Acid-d11; •N-Cyclohexylsulfamic Acid; •N-Cyclohexylsulfamic acid; •Sodium Cyclamate; •Sodium Cyclamate (Sodium N-cyclohexylsulfamate) crystalline; •Sodium Cyclamate (Sodium N-cyclohexylsulfamate) powder; •Sodium N-Cyclohexylsulfamate; •Sodium N-cyclohexylsulfamate;
EC number	205-348-9
Customs tariff number / CN code / TARIC	29299000
Molecular weight [g / mol]	201.219
Formula	C ₆ H ₁₂ NO ₃ SNa

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution	Ph.Eur.	clear and colourless	
Colour		white or almost white	
Flavor and taste		very sweet: approximately 30 to 40 times sweeter than sucrose	
Odour		odourless	
Physical parameter			
Form		crystalline powder or crystals	
Loss on drying	PRO.333	≤ 1,0	%
pH value	Ph.Eur.	(10% in H ₂ O): 5,5 – 7,5	
Solubility		in water: soluble; in ethanol: slightly soluble	
Identity			
Assay	PRO.333	98,5 – 101,0	%
Identification	Ph.Eur.	(A) I.R. spec.: conforms with standard	
Identification	Ph.Eur.	(E) Sodium reaction: positive	
UV spectroscopy	Ph.Eur.	@ 270 nm: ≤ 0,10	
Impurities			
Sulphates (SO ₄)	Ph.Eur.	≤ 0,1	%
Impurity	Ph.Eur.	Aniline ⁽¹⁾ : ≤ 0,5	ppm
Impurity	Ph.Eur.	Cyclohexylamine ⁽¹⁾ : ≤ 8	ppm
Impurity	Ph.Eur.	NN-Dicyclohexylamine ⁽¹⁾ : ≤ 0,5	ppm
Impurity	Ph.Eur.	NN-Dicyclohexylsulfamide ⁽¹⁾ : ≤ 1	ppm
Impurity	Ph.Eur.	Sulphamic acid: ≤ 0,1	%

Residual Solvents			
Residual solvents	GC	according to ICH Guideline Q3C (*)	
Residual solvents	GC	Xylene ^(1, *) : ≤ 1	ppm
Elemental Impurities			
Arsenic (As)	ICP-MS	(^{1, *}) ≤ 1,5	ppm
Lead (Pb)	ICP-MS	(*) ≤ 0,5	ppm
Selenium (Se)	ICP-MS	(^{1, *}) ≤ 15	ppm
Microbiological data			
Aerobic microorganisms	Ph.Eur.	(^{1, *}) ≤ 1000	CFU/g
Coliform bacteria	Ph.Eur.	absence ^(1, *)	/0,1 g
Salmonella	Ph.Eur.	absence ^(1, *)	/25 g
Yeast and Mould	Ph.Eur.	(^{1, *}) ≤ 100	CFU/g

Annotation:

* n.d. = not detectable / nicht messbar

*: Periodically tested

(¹): Limit of the European Pharmacopoeia: higher or not defined.

Regulatory information:

Elemental Impurities (ICP-MS): according to ICH Guideline Q3D (*)

Registration status: This product is manufactured using excipient Good Manufacturing Practices (GMP).

Supplemental information:

Shelf life: 5 years

Complies with monographie: Ph.Eur. 10th edition, monograph No. 0774

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.

Packing: 25 kg cardboard; 50 kg drum; 500 kg big bag

Regional origin: EU

Usage: 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.

Sweetener for food E-952

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 22. Dec. 2022

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