



Specification

Concerning Product:	
Article number	6132043LPEY
Trade name / designation / denomination	Tri-Natriumcitrat-2-hydrat EP, Krist.
CAS number	6132-04-3
Other names / synonyms	•1,2,3-Propanetricarboxylic acid, 2-hydroxy-, sodium salt, hydrate (1:3:2); •Sodium Citrat crystalline; •Sodium Citrat powder; •trisodium 2-hydroxypropane-1,2,3-tricarboxylate dihydrate; •trisodium citrate dihydrate;
EC number	612-118-5
Customs tariff number / CN code / TARIC	29181500
Molecular weight [g / mol]	294.09957
Formula	C ₆ H ₉ Na ₃ O ₉

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution	10%	complies	
Appearance		white crystals	
Physical parameter			
Acidity/Alkalinity	PE	complies	
Loss on drying		11,0 – 13,0	%
Identity			
Assay	on anhydrous substance	99,0 – 101,0	%
Identification	citrat	positiv	
Identification	Na	positiv	
Impurities			
Oxalate (as anhydros Oxalic Acid)		≤ 0,03	%
Sulphates (SO ₄)		≤ 0,015	%
Elemental Impurities			
Chlorides (Cl)		≤ 0,005	%
Microbiological data			
Total Plate Count	TAMC	≤ 2000	CFU/g
Yeast and Mould	TYMC	≤ 200	CFU/g

Annotation:

Unless otherwise stated or specified, the presence of the elements of class 1-3 (classification according to ICH Q3D) above the Q3D Option 1 limit value is unlikely according to our review. No further elements are knowingly added. The specification includes monograph-specific element impurities. These will continue to be taken into account in the specification in accordance with the monograph requirement.

Behavior against sulfuric acid comply

We confirm that the product is in production, bottling and Storage with the Ph.Eur. (I 283/95) called organic Solvents ("Residual Solvents") does not come into contact. Heavy metal parameters of this specification were determined in accordance with ICH guideline Q3D on elementary impurities on the basis of a product-related risk assessment. The risk assessment was carried out taking into account option 1 (max. Daily dose 10g / d) for oral use.

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 14. Dec. 2021

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