



Specification

Concerning Product:	
Article number	4468024LPEL
Trade name / designation / denomination	Zinkgluconat, Ph.Eur.
CAS number	4468-02-4
Other names / synonyms	•(2R,3S,4R,5R)-2,3,4,5,6-pentahydroxyhexanoic acid; zinc; •Zinc gluconate; •bis(D-gluconato-O1,O2)zinc;
EC number	224-736-9
Customs tariff number / CN code / TARIC	29181600
Molecular weight [g / mol]	457.71956
Formula	C ₁₂ H ₂₄ O ₁₄ Zn

Parameter	Specification	Unit
Organoleptic test		
Appearance of solution	(2 %): complies	
Appearance	almost white powder	
Physical parameter		
Loss on drying	≤ 12,0	%
Identity		
Assay	calculated on anhydrous substance 98,0 – 102,0	%
Identification	Zn (Ph.Eur.): complies	
Identification	A (DC): complies	
Impurities		
Residual solvents	The product comes in the production, filling and storage with the Ph.Eur. (ICH 283/95) organic solvents ("Residual Solvents") not in contact.	
Sulphates (SO ₄)	≤ 0,05	%
Elemental impurities		
Cadmium (Cd)	≤ 0,0002	ppm
Cadmium (Cd)	ICH-Q3D: ≤ 5	ppm
Chlorides (Cl)	≤ 0,05	%
Lead (Pb)	≤ 5	ppm
Nutritional data		
Sugar	Saccharose, reduzierende Zucker: complies	
Microbiological data		
Total Plate Count	(TAMC): ≤ 2000	CFU/g
Yeast and Mould	(TYMC): ≤ 200	CFU/g

Regulatory information:

Elemental Impurities: Other elements are not knowingly added. The specification includes monograph-specific element contaminants. These will continue to be considered in the specification according to the monograph specification.

Unless otherwise specified, the presence of Class 1-3 elements (classification according to ICH Q3D) above the Q3D Option 1 limit is unlikely according to a review.

Supplemental information:

Note: Heavy metal parameters of this specification were gem. ICH guideline Q3D to elemental impurities based on a product-related Risk assessment determined. The risk assessment was carried out considering Option 1 (maximum daily dose 10g / d) for an oral application performed.

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 02. Oct. 2019

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