



Specification

Concerning Product:	
Article number	927208LPE
Trade name / designation / denomination	Magnesiumglycerophosphat, EP
CAS number	927-20-8
Other names / synonyms	•Magnesium Glycerophosphate 50% solution; •magnesium glycerophosphate;
EC number	213-149-3
Customs tariff number / CN code / TARIC	29199000
Formula	$C_3H_7MgO_6P \cdot x H_2O$

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance of solution	5% in H ₂ O	complies	
Appearance		white crystalline powder	
Physical parameter			
Acidity/Alkalinity	0.1 M NaOH	≤ 1.5	ml
Loss on drying	@ 150 °C; 4 h	≤ 12.0	%
Identity			
Assay		Mg (o.d.b.): 11.0 – 12.5	%
Identification	Ph.Eur.	A: positive	
Identification	Ph.Eur.	B (Phosphat): positive	
Identification	Ph.Eur.	Magnesium: positive	
Impurities			
Heavy Metals (as Pb)		≤ 20	ppm
Soluble part		Glycerol in Ethanol: ≤ 1,5	%
Phosphate (PO ₄)		≤ 0.5	%
Sulphates (SO ₄)		≤ 0.1	%
Residual Solvents			

Residual solvents		The product never comes in the production, filling and storage with the organic solvents ("Residual Solvents") mentioned in the Ph.Eur. (ICH 283/95) in contact.	
Elemental Impurities			
Chlorides (Cl)		≤ 0.15	%
Iron (Fe)		≤ 150	ppm
Nickel (Ni)	ICH-Q3D	≤ 50	ppm
Microbiological data			
Total Plate Count		≤ 2000	CFU/g
Yeast and Mould		≤ 200	CFU/g

Annotation:

o.d.b. = on dried basis / auf getrockneter Basis

Regulatory information:

Elemental Impurities: Heavy metal parameters of this specification were acc. ICH guideline Q3D for elemental contaminants based on a product-related risk assessment. The risk assessment was carried out considering option 1 (max. Daily dose 10 g/d) for oral use.

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:

Released by manufacturer: 2020-01-30

Complies with monographie: Ph.Eur. 10.Ed.

Packing: 25 kg fiber drums on palettes

Usage: e.g. pharmaceutical industry

Chemische Werke Hommel GmbH & Co.KG

This document was generated electronically and is valid without signature.

Waltrop, 30. Jan. 2020

We only confirm that we took over the data from our supplier accordingly. Despite careful working, errors in the takeover are not totally excluded. Some or all parts of the document may be translated due to our best knowledge from the original to give a better understanding. If you have any questions about specific details, please call us directly. Unless otherwise marked, these data do not originate from us and have not been tested by us on the correctness. The above information corresponds to the present state of our knowledge and is intended as a general description of our products and their possible applications. We make no warranties, expressed or implied, as to the information's accuracy, adequacy, sufficiency or freedom from defect and assumes no liability in connection with any use of this information. Any user of this product is responsible for determining the suitability of our products for its particular application. The foregoing information does not absolve the buyer of its own tests. Observing existing laws and regulations, is the responsibility of the buyer of our product. Nothing included in this information waives any of our General Terms and Conditions of Sale, which control unless it agrees other in writing. Any existing intellectual/industrial property rights must be observed. Due to possible changes in our products and applicable national and international regulations and laws, the status of our products could change. Material Safety Data Sheets providing safety precautions, that should be observed when handling or storing our products, are available upon request and are provided in compliance with applicable law. The user should obtain and review the applicable Material Safety Data Sheet information before handling any of these products. For additional information, please contact us.