# Chemische Werke Hommel GmbH & Co. KG

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# **Specification**

Concerning Product:			
Article number	3344181LPEG		
Trade name / designation / denomination	Tri-Magnesiumdicitrat wasserfrei,EP ASMF		
CAS number	3344-18-1		
Other names / synonyms	•Magnesium citrate; •trimagnesium 2-hydroxypropane- 1,2,3-tricarboxylate; •trimagnesium dicitrate;		
EC number	222-093-9		
Customs tariff number / CN code / TARIC	29181500		
Molecular weight [g / mol]	451.1144		
Formula	$C_{12}H_{10}Mg_3O_{14}$		

Parameter	Test Method	Specification	Unit				
Organoleptic test							
Appearance of solution	(5%)	complies					
Colour		white					
Physical parameter							
Form		powder					
Loss on drying	(180° C/ 5h)	≤ 3,5	%				
pH value	(5%)	6,0 - 8,5					
Identity							
Assay		Mg (o.d.b.*) 14,0 - 16,0 %					
Identification	Ph.Eur.	Citrate: complies					
Identification	Ph.Eur.	Magnesium: complies					
Impurities							
Oxalate (as anhydros Oxalic Acid)	(C <sub>2</sub> H <sub>2</sub> O <sub>4</sub> )	≤ 280 ppm					
Sulphates (SO <sub>4</sub> )		≤ 0,2	%				

Elemental Impurities						
Calcium (Ca)		≤ 0,2	%			
Iron (Fe)		≤ 100	ppm			
Nickel (Ni)		≤ 20	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:**

**Residual solvents:** During production, filling and storage the product does not come in contact with the in Ph.Eur. (I 283/95) mentioned organic solvents.

### **Supplemental information:**

**Note:** Heavy metal parameters of this specification were set according to I-Guideline Q3D on elementary contaminants based on a product-related risk assessment. The risk assessment was carried out considering option 1 (maximum daily dose 10 g/d) for oral use. Unless otherwise mentioned or specified, the presence of Class 1-3 elements (classification according to ICH Q3D) above the Q3D Option 1 limit is not likely to occur.

Other items are not knowingly added.

The specification includes monograph-specific element impurities. These will continue to be considered in the specification according to the monograph specification.

#### Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 24. Jun. 2019

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