



Specification

Concerning Product:	
Article number	68199NLE
Trade name / designation / denomination	Vitamin B12, EP (Cyanocobalmin)
CAS number	68-19-9
Other names / synonyms	•Vitamin B12; •cyanocobalamin;
EC number	200-680-0
Customs tariff number / CN code / TARIC	29362600
Molecular weight [g / mol]	1355.37 g/mol
Formula	C ₆₃ H ₈₈ CoN ₁₄ O ₁₄ P

Parameter	Specification	Unit
Organoleptic test		
Colour	dark red	
Physical parameter		
Form	crystalline powder	
Loss on drying	≤ 12	%
Identity		
Assay	96 – 102,0	%
Identification	A: A361nm / A278nm 1,70 – 1,90	
Identification	A: A361nm / A547- 559nm 3,15 – 3,45	
Identification	B: the principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with reference solution (c)	
Impurities		
Related substances	≤ 3	%
Related substances	32-carboxycyanocobalamin ≤ 0,5	% [w/w]
Related substances	34-methylcyanocobalamin ≤ 1,5	% [w/w]
Related substances	50-carboxycyanocobalamin ≤ 0,5	% [w/w]
Related substances	7β, 8β-Lactone-cyanocobalamin ≤ 0,7	% [w/w]
Related substances	8-epi-cyanocobalamin ≤ 0,5	% [w/w]
Related substances	Impurity F: ≤ 0,5	% [w/w]
Related substances	Total impurities: ≤ 3,0	% [w/w]
Related substances	Unspecified impurities ≤ 0,2	% [w/w]
Residual Solvents		
Residual solvents	Aceton: ≤ 0,5	%
Microbiological data		
Escherichia Coli.	n.d.* in 1g	
Salmonella	n.d.* in 25g	
Total Plate Count	≤ 1000	CFU/g
Yeast and Mould	≤ 200	CFU/g

Annotation:

* n.d. = not detectable / nicht messbar

Regulatory information:

Allergens statement: According to Annex II of Regulation (EU) No **1169/2011** of the European Parliament and of the Council of 25th October 2011 and its amendment (EU) No **78/2014** on substances or products the above mentioned product does NOT cause allergies or intolerances and does NOT contain any allergens which have to be labelled according to these regulations.

BSE/TSE statement: Risk of BSE/TSE contamination can be excluded.

GMO statement: Genetic engineering:

For the above mentioned product there is no obligation of g.m.o. labelling as defined by the Regulations (EC) No **1829/2003** and **1830/2003** of the European Parliament and the Council of 22nd September 2003.

Supplemental information:

Shelf life: 60 Mon.

Derivation: Fermentation. The product contains NO animal ingredients.

Note: Traceability

According to Regulation (EC) No **178/2002** the traceability of the raw materials for the product is guaranteed one step backwards and of produced batches one step forward. All instructions, which are necessary to take these steps, are implemented in the Quality manual and management system according to IFS and BRC.

The product contains NO raw materials, ingredients or additives in nanoparticle size as per definition of Regulation (EU) No **1169/2011**.

Storage conditions: Protect from light and store cool and dry in well-closed original packaging. The temperature should not exceed 25 °C.

The primary packaging of the above mentioned product is suitable for food.

Complies with monographie: EP 10.3

Usage: The product is suitable for a vegetarian nutrition.

The product is suitable for a vegan nutrition.

The product is suitable for lactose intolerance diet.

The product is suitable for people with coeliac disease and sprue.

The product is in compliance with Jewish dietary laws.

The product is in compliance with Islamic dietary laws.

Chemische Werke Hommel GmbH & Co.KG

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Waltrop, 25. Sep. 2024

LF-Basis: 2.0 (2023-12-12)

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