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Specification

Concerning Product:	
Article number	13870901AL
Trade name / designation / denomination	Cobamamide Coenzym B12 (Adenosylcobalamin)
CAS number	13870-90-1
Other names / synonyms	•(2S,3S,4R)-2-(6-aminopurin-9-yl)-5-methanidyloxolane-3,4-diol; cobalt(3+); [(2R,5S)-5-(5,6-dimethyl-1-benzimidazolyl)-4-hydroxy-2-(hydroxymethyl)-3-oxolanyl] 1-[[1-oxo-3-[(2R,3R,4Z,7S,9Z,12S,13S,14Z,17S,18S,19R)-2,13,18-tris(2-amino-2-oxoethyl)-7,12,17-tr; •cobamamide;
EC number	237-627-6
Customs tariff number / CN code / TARIC	29362600
Molecular weight [g / mol]	1579.58176
Formula	$C_{72}H_{100}CoN_{18}O_{17}P$

Parameter	Test Method	Specification	Unit
Organoleptic test			
Appearance		Crystals or Powder	
Colour		dark red	
Physical parameter			
Loss on drying		60 °C ≤ 12	%
Identity			
Assay	HPLC	on anhydrous basis 98 – 102	%
Identification	UV	Identification 1: Dark Red Absorption exhibits maxima at 264 nm, 285 nm, 305 nm and 460 nm	
Identification	HPCL	Identification 2: The principal peak obtained with the Test solution for assay is consistent with the reference solution in retention time	
Identification	IR	Identification 3: The infrared absorption altas of this production should be consistent with the standard	
UV spectroscopy	UV	A460 nm / A352 nm ≥ 90	
Impurities			
Impurity	HACCP	Ethylene Oxide: Meet EC 396/2005	
Impurity	HPLC	total: ≤ 1	%
Residual Solvents			
Residual solvents	GC	Acetone ≤ 0,5	%
Elemental Impurities			
Arsenic (As)	HG-AFS	≤ 2,0	mg/kg
Cadmium (Cd)	ICP-MS	≤ 1,0	mg/kg

Mercury (Hg)	ICP-MS	≤ 0,1	mg/kg
Lead (Pb)	ICP-MS	≤ 3,0	mg/kg
Microbiological data			
Coliform bacteria		neg.	
Escherichia Coli.		Neg.	
Salmonella		neg.	
Staphylococcus Aureus		neg.	
Total Plate Count		≤ 1000	CFU/g
Yeast and Mould		≤ 100	CFU/g

Regulatory information:

Allergens statement: Product is free of allergens according to Regulation (EU) No. 1169/2011 Annex II.

BSE/TSE statement: Product conforms to TSE/BSE regulation EC Nr. 999/2001.

Food Grade Status: Product is suitable and safe for human consumption according to Regulation EC 178/2002.

GMO statement: GMO Free According to Reg. (EC) 1829/2003 and 1830/2003 and amendments

Irradiated Status: Product is irradiation free according to Directive EC 1999/2/EG and 1169/2011.

Nanoparticles: In accordance with the definition of the “engineered nanomaterial” of the European regulation 2015/2283 and on our supplier’s information, the product isn’t complying with the definition of “engineered nanomaterials”. So, this raw material, according to the European regulation 1169/2011, isn’t subject to labelling as an engineered nanomaterial.

Vegan Status: Product is suitable for vegetarian, vegan diets.

Supplemental information:

Derivation: Product is fermented in the fermentation step from corn derivatives, among others.

Note: Product can meet the Kosher and Halal food conditions.

Product does not meet the criteria for classification as dangerous in accordance with EU regulation (EC) No 1272/2008 and its modifications, therefore is not subject to the obligation to provide a Material Safety Data Sheet according to EU regulation (EC) No 1907/2006 and its modifications.

Storage conditions: The product contains compounds susceptible to degradation caused by improper storage or processing influenced by e.g. light, oxygen, heat, pressure. We do not assume responsibility for changes in quality, even during the specified best before date.

Packing: The packaging of the product conforms to the stipulations set forth in EC Regulation 1935/2004, EC Regulation 10/2011 and EC Regulation 2023/2006.

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Waltrop, 07. May. 2024

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