



GUINAMA. Laboratory distributor of raw materials for the pharmaceutical and cosmetics industries.

Type of document:

TECHNICAL DATA SHEET

Review date:

26.12.2022

Version:

15.0

93398-VITAMIN B12

1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION

1.1 Identification of the substance or preparation

Name: Vitamin B12

Bulk code: 93398

Internal code: 405352

1.2 Synonyms

Cyanocobalamin.

2. DESCRIPTION

Appearance: Crystalline powder or crystals.

Colour: Dark red.

Geographical origin: Asia.

Origin: Plant. The product is obtained by fermentation and extraction. The source materials are glucose, corn steep liquor, inorganic chemical salts and a production strain (*Ensifer Adhaerens*).

3. COMPOSITION/INFORMATION ON COMPONENTS

Formula: $C_{63}H_{88}CoN_{14}O_{14}P$

CAS: 68-19-9

EC: 200-680-0

Molecular weight: 1355.38 g/mol

Method of production: The raw source material goes through several processes which involve preparing the seeds, the cultivation thereof, fermentation, isolation by successive filtration, transformation and extraction to a second desorption solution. Finally, a refining process is performed until a crystalline crude substance is obtained, which undergoes crystallisation and drying processes to produce cyanocobalamin. Throughout the entire manufacturing process, several critical points are controlled.

4. PHYSICO-CHEMICAL DATA

For more information, see the analysis report.

Solubility: Sparingly soluble in water and ethanol (96%), practically insoluble in acetone.

The product is highly hygroscopic, thermolabile and photosensitive.

5. PROPERTIES/USES

Excipient for pharmaceutical use.

Food use.



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6. DOSAGE

No information available.

7. REMARKS

The product has been handled in a NON-sterile room; for batches suitable for sterile use, check availability.

STORAGE:

Store at room temperature in a cool, dry, well-ventilated place away from sunlight, in a tightly closed container.

The documentation available related to the product's regulatory compliance is included below.

BSE/TSE:

The product does not contain ingredients of ruminant origin or materials derived from or exposed to ruminants affected by or quarantined for transmissible spongiform encephalopathy (TSE)/transmissible bovine spongiform encephalopathy (BSE) and is compliant with EU Regulation 999/2001.

GMOs:

The product or any of its ingredients:

- Are not GMOs and do not contain any GMOs, and no GMOs are used in their production.
- GMOs do not have to be labelled on the ingredients we supply in accordance with Commission Regulation (ECC) No 49/2000 of 10 January and (ECC) No 1829/2003 and (ECC) No 1830/2003 of the European Parliament and of the Council.
- This product has not been genetically modified and thus there is no requirement to label GMOs as defined by the above-mentioned regulations.

NANOMATERIALS:

According to the definition of "nanomaterials" in EU Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, we hereby declare that there are no nanomaterials and these are not used in the formulation or packaging material of the product.



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IRRADIATION/IONISATION:

The product has not been treated with irradiation or ionised.

The product has not been sterilised by ionising radiation at any point in the manufacturing process and therefore is fully compliant with the relevant legislated regulations (Directive 1999/2/EC).

ETHYLENE OXIDE (ETO):

Ethylene oxide (ETO), 2-Chloroethanol or any other chemical sterilising agents are not used during product manufacture, storage or transportation. Nor are subcontractors involved in manufacturing, storage and transport permitted to use these agents.

PESTICIDES/EXTERMINATORS:

Based on the production process, the raw materials and equipment used, the potential pesticide residues in the above-mentioned product comply with European legislation on pesticide residues, esp. Regulation (EC) No 149/2008 and Regulation (EU) 2015/868 of 26 May 2015 amending Annexes II, III and V to Regulation (EC) No 396/2005.

CONTAMINANTS:

Based on the production process, raw materials and equipment used, no contaminants are expected: dioxins, melamine, polycyclic aromatic hydrocarbons (PAHs) and polychlorinated biphenyls (PCBs). (Regulation 2015/1933/EC amending Regulation 1881/2006/EC).

RESIDUAL SOLVENTS:

The product is compliant with: Directive E 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC of the European Parliament and of the Council on the approximation of the laws of the Member States on extraction solvents used in the production of foodstuffs and food ingredients.

ALLERGENS:

- **Food allergens:** The product does not contain any of the allergens referred to in Annex II to Regulation (EU) No 1169/2011, nor is there a possibility that the product is cross contaminated with them. The product does not contain gluten.



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NUTRITIONAL COMPOSITION:

ENERGY/NUTRIENT	UNITS	TYPICAL VALUES PER 100 g OF PRODUCT
Energy (total calories): - Energy from fat	Kcal or kJ	N/A
Protein	g	N/A
Carbohydrates (total) of which: - Sugar - Polyols - Starch	g	N/A
Total fat (of which): - Saturated - Monounsaturated - Polyunsaturated - Trans fat - Cholesterol	g Cholesterol (mg)	N/A
Dietary fibre	g	N/A
Sodium	mg	N/A
Potassium	mg	N/A
Calcium	mg	N/A
Ash	g	N/A
Moisture	g	2-8%
Vitamin A	ug	N/A
Vitamin B	mg	N/A
Vitamin C	mg	N/A
Vitamin D	IU	N/A
Vitamin E	IU	N/A

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian uses.

DOPING SUBSTANCES (WADA):

According to the current World Anti-Doping Agency list, the ingredient is not a doping substance, nor is it a combination of doping substances. The ingredient does not contain any doping substances. The ingredient is not derived from a doping substance.