

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

Valid from batch: 0129973

1.2 Synonyms

Cyanocobalamin.

2. DESCRIPTION

Appearance: crystalline powder or crystals.

Color: dark red.

Origin: Vegetable.

Geographical origin: Asia.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient: Cyanocobalamin 97%-102%

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

CAS: 68-19-9

CE: 200-680-0

Molecular weight: 1355.38 g/mol

Production method: 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*). The raw material undergoes several processes, including seed preparation, cultivation, fermentation, isolation through successive filtrations, processing, and extraction to a second desorption solution. Finally, a refining process occurs until a crystalline raw substance is obtained, which, after crystallization and drying processes, will give rise to cyanocobalamin. Several critical points are monitored throughout the entire manufacturing process.

4. PHYSICAL-CHEMICAL DATA

For more detailed information, please refer to the analysis bulletin.

Solubility: Sparingly soluble in water and ethanol (96%), practically insoluble in acetone. The product is very hygroscopic, thermolabile and photosensitive.

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5. PROPERTIES/USES

Excipient for pharmaceutical use.

Food use.

6. DOSAGE

No data available.

7. OBSERVATIONS

The product has been handled in a NON-sterile room, so the product is NOT sterile.

The documentation corresponding to the regulatory part of the product that is available for it is the one we reflect below.

NUTRITIONAL INFORMATION:

ENERGY/NUTRIENT	UNITS	TYPICAL VALUES PER 100 g OF PRODUCT
Energy (total calories):	Kcal or kJ	N/A
- Energy from fats		
Proteins	g	N/A
Carbohydrates (total) of which:		
- Sugars	g	N/A
- Polyols		
- Starch		
Total fat (of which):	g	
- Saturated		
- Monounsaturated		
- Polyunsaturated		
- Trans Fats		
- Cholesterol	Cholesterol (mg)	N/A
Dietary fiber	g	N/A
Sodium	mg	N/A
Potassium	mg	N/A
Calcium	mg	N/A
Ashes	g	N/A
Humidity	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

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ALLERGENS:

- **Food allergens:** The product is gluten-free. The product does not contain any of the allergens listed in Annex II of Regulation 1169/2011:

Allergens	Added as a base raw material or in a derivative form		Cross contamination ⁽¹⁾	
	Yes	No	Yes	No
Cereals containing gluten (i.e. wheat, rye, barley, oats, spelt, kamut or their hybridised strains) and products thereof, except (*): (a) wheat-based glucose syrups including dextrose ; (b) wheat-based maltodextrins ; (c) glucose syrups based on barley; (d) Cereals used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.		No		No
Crustaceans and products thereof.		No		No
Eggs and products thereof.		No		No
Fish and products thereof, except (*): (a) Fish gelatine used as carrier for vitamin or carotenoid preparations; (b) Fish gelatine or Isinglass used as fining agent in beer and wine.		No		No
Peanuts and products thereof.		No		No
Soybeans and products thereof, except (*): (a) fully refined soybean oil and fat (And products thereof, insofar as the process that they have undergone is not likely to increase the level of allergenicity assessed by the EFSA for the relevant product from which they originated) (b) natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol acetate, natural D-alpha tocopherol succinate from soybean sources; (c) vegetable oils derived phytosterols and phytosterol esters from soybean sources; (d) plant stanol ester produced from vegetable oil sterols from soybean sources.		No		No
Milk and products thereof (including lactose), except (*): (a) whey used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages; (b) lactitol.		No		No

Allergens	Added as a base raw material or in a derivative form		Cross contamination ⁽¹⁾	
	Yes	No	Yes	No
Nuts, i.e. almonds (<i>Amygdalus communis</i> L.), hazelnuts (<i>Corylus avellana</i>), walnuts (<i>Juglans regia</i>), cashews (<i>Anacardium occidentale</i>), pecan nuts (<i>Carya illinoensis</i> (Wangenh.) K. Koch), Brazil nuts (<i>Bertholletia excelsa</i>), pistachio nuts (<i>Pistacia vera</i>), macadamia nuts and Queensland nuts (<i>Macadamia ternifolia</i>), and products thereof, except (*): (a) nuts used for making distillates or ethyl alcohol of agricultural origin for spirit drinks and other alcoholic beverages.		No		No
Celery and products thereof.		No		No
Mustard and products thereof.		No		No
Sesame seeds and products thereof.		No		No
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO ₂ .		No		No
Lupin and products thereof.		No		No
Molluscs and products thereof.		No		No

(1) Risk of cross contamination , may contain traces.

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STORAGE:

Store at room temperature in a cool, dry place, protected from light and with the container tightly closed, in a dry and ventilated area, away from sources of heat and humidity.

SHELF LIFE:

5 years. For more detailed information, see the analysis bulletin.

LEGAL REQUIREMENTS:

The product complies with:

- Regulation (EU) No 2231/2012 and its amendments.
- Regulation (EU) No 178/0002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.
- Regulation (EC) No 852/2004 on the hygiene of foodstuffs.

BSE/TSE:

The product does not contain ingredients of ruminant origin or materials derived from, or exposed to, ruminants affected by or quarantined with Transmissible Spongiform Encephalopathy (TSE) / Transmissible Bovine Spongiform Encephalopathy (BSE) and complies with EU legislation 999/2001.

GMO:

The product or any of its ingredients:

- They are not GMOs and do not contain any GMOs and no GMOs are used in their production.
- The ingredients we supply do not require any mention on their label about GMOs, in accordance with Commission Regulation (ECC) No. 49/2000 dated 10 January and Regulation (ECC) No. 1829/2003 and Regulation (ECC) No. 1830/2003 of the European Parliament and Council.
- This product has not been genetically modified, so there is no GMO labeling requirement as defined by the regulations mentioned above.

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, there are no nanomaterials and they are not used in the formulation or packaging of the product.

IRRADIATION/IONIZATION:

The product has not been irradiated or ionized.

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The product has not been sterilized by ionizing radiation at any point in the manufacturing process and is therefore in full compliance with the relevant legislative regulations (Directive 1999/2/EC and 1999/3/EC).

ETHYLENE OXIDE (ETO):

Ethylene oxide (ETO), 2-chloroethanol, or any other chemical sterilizing agent is not used during product manufacturing, storage, or transportation. Nor is their use permitted by subcontractors involved in manufacturing, storage, or transportation.

PESTICIDES:

Based on the production process, 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.

RESIDUAL SOLVENTS:

The product complies with: Directive E 2010/59/EU of 26 August 2010 amending Directive 2009/32/EC on the approximation of the laws of the Member States relating to extraction solvents used in the production of food and food ingredients (RD 1101/2011).

CONTAMINANTS/IMPURITIES:

Based on the production process, raw materials and equipment used, no contaminants are expected: dioxins, melamine , polycyclic aromatic hydrocarbons (PAHs) and biphenyls polychlorinated (PCB). (Regulation (EU) 2023/915).

HEAVY METALS:

- Pb: <0.5ppm
- Cd: <0.2ppm
- Hg: <0.1ppm
- As: <1.0 ppm

VEGAN/VEGETARIAN:

The product is suitable for vegan/vegetarian uses.

HALAL:

The product has Halal certification .

DOPING SUBSTANCES :

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



GUINAMA. Laboratory that distributes raw materials for the pharmaceutical and cosmetics sectors .

Document Type:

TECHNICAL SHEET

Review date:

07.04.2025

Version:

19.0

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REACH:

Not available.