

**94307-BIOTIN****1. IDENTIFICATION OF THE SUBSTANCE OR PREPARATION.****1.1 Identification of the substance or preparation.**

Name: Biotin

Bulk code: 94307

Internal code: 405029

Valid from lot: 136109

**1.2 Synonyms.**

Biotin . D- biotin . (Vitamin H )

**2. DESCRIPTION**

Appearance: crystalline powder or crystals.

Color: white or almost white (powder) or colorless (crystals).

Origin: synthetic.

Geographical origin: China

**3. COMPOSITION/INFORMATION ON THE COMPONENTS.**

Ingredients: Biotin (98.5-101%)

Formula:  $C_{10}H_{16}N_2O_3S$ 

CAS: 58-85-5

EINECS/EC: 200-399-3

Molecular weight: 244.31 g/mol.

INCI: Biotin

**Method of production:** The product is obtained by chemical synthesis from Thioketone .**4. PHYSICAL-CHEMICAL DATA.**

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

**Solubility:** Very slightly soluble in water and alcohol. Practically insoluble in acetone. It is soluble in dilute solutions of alkaline acids.**5. PROPERTIES/USES.**

Cosmetic use.

Food use.

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### 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:

The approximate nutritional information of the product is as follows (per 100 g):

Energy / Nutrient	Unit	Typical values per 100 g product
<b>Energy</b> (total calories)	Kcal or kJ	
-Energy from fat	Kcal or kJ	0
<b>Protein</b>	g	0
<b>Carbohydrate</b> (total), of which:	g	
-sugars	g	0
-Polyols	g	0
-starch	g	0
<b>Fat</b> (total), of which:	g	
-Saturates	g	0
-mono-unsaturates	g	0
-polyunsaturates	g	0
-Trans-fats	g	0
-Cholesterol	mg	0
Dietary Fibre	g	0
Sodium	mg	0
Potassium	mg	0
Calcium	mg	0
Ash	g	0
Moisture	g	<1
Vitamin A	ug	0
Vitamin B	mg	0
Vitamin C	mg	0
Vitamin D	IU	0
Vitamin E	IU	0

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### ALLERGENS:

- **Food allergens:** The product does not contain any major allergens, nor have any major allergens been used at any time during the synthesis of the raw materials used. The product does not contain any of the ingredients listed in Annex II of Regulation 1169/2011, which are listed below:

Allergens	Added as a base raw material or in a derivative form		Cross contamination <sup>(1)</sup>	
	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.		X		
Crustaceans and products thereof.		X		
Eggs and products thereof.		X		
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.		X		
Peanuts and products thereof.		X		
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.		X		
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.		X		

 浙江圣达生物药业股份有限公司  
 ZHEJIANG SHENGDA  
 BIX-PHARM CO., LTD

 16/05/2025  
 Authorised Signa

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Allergens	Added as a base raw material or in a derivative form		Cross contamination <sup>(1)</sup>	
	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.		X		
Celery and products thereof.		X		
Mustard and products thereof.		X		
Sesame seeds and products thereof.		X		
Sulphur dioxide and sulphites at concentrations of more than 10 mg/kg or 10 mg/litre expressed as SO <sub>2</sub> .		X		
Lupin and products thereof.		X		
Molluscs and products thereof.		X		

### STORAGE:

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

### SHELF LIFE:

4 years from the date of production. For more detailed information, see the analysis bulletin.

### LEGAL REQUIREMENTS:

The product complies with:

- Regulation (EC) No. 231/2012
- Regulation (EC) 1169/2011 for food allergens.

### 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) / bovine spongiform encephalopathy (BSE) and is in compliance with EU legislation 999/2001.

**94307-BIOTIN****GMO:**

Neither the product nor any of its components:

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

**NANOMATERIALS:**

The product does not contain nanomaterials .

**IRRADIATION:**

The product has not been irradiated or ionized in accordance with Regulation 1999/2/EC.

The product has not been ionized or irradiated.

**ETHYLENE OXIDE:**

No ethylene oxide (ETO), 2-chloroethanol or any other sterilizing agent is used during the manufacturing, storage or transportation process of the product.

The manufacturer does not permit the use of these substances or other sterilizing products involved in the manufacturing, storage, and transportation processes.

**ADDITIVES:**

The product does not contain preservatives.

**PESTICIDES:**

Based on current knowledge of the manufacturing process, the starting materials used, the potential pesticide residues in the product comply with European legislation on pesticide residues, esp . Regulation (EC) No 149/2008 and Regulation (EU) 2015/868 of 26 May 2015 and its amendments in Annexes II, III and V to Regulation (EC) No 396/2005.

**RESIDUAL SOLVENTS:**

The product complies with Regulation 2009/32/EC and Directive 2010/59/EU.

**CONTAMINANTS/IMPURITIES:**

Based on current knowledge of the manufacturing process, the raw materials used, and the equipment, no contaminants of dioxins, melamine, PAHs , or PCBs are expected.

The product complies with EC Regulation 2023/915 for maximum levels of contaminants in food.

The product is free of:

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- Nitrosamines

**HEAVY METALS:**Lead (Pb)  $\leq$  2 ppmCadmium (Cd)  $\leq$  1 ppmMercury (Hg)  $\leq$  0.1 ppmArsenic (As)  $\leq$  1ppm**VEGAN/VEGETARIAN:**

The product is suitable for vegan/vegetarian use.

**DOPING SUBSTANCES:**

The product complies with the WADA list of prohibited substances. The product is not a doping substance and is not a combination of doping substances. The product does not contain any doping substances. The product is not the product of any doping substance.

**ANIMAL TESTED:**

The product has not been tested on animals.

**REACH:**

Exempt.