

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

Name: Biotin

Bulk code: 94307

Internal code: 401338

Valid from batch: 0121361

**1.2 Synonyms.**

Biotin . D- biotin . Coenzyme R. Biotinum . Vitamin B8. Vitamin H. \_

**2. DESCRIPTION**

Appearance: crystalline powder or crystals.

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

Origin: synthetic.

Geographic origin: China

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

Chemical name: 5-[(3aS,4S,6aR)-2-oxohexahydrothieno [3,4-d]imidazole-4-yl] pentanoic acid

CAS: 58-85-5

EINECS/EC: 200-399-3

Formula: C<sub>10</sub>H<sub>16</sub>N<sub>2</sub>O<sub>3</sub>S

Molecular weight: 244.3 g/mol.

**4. PHYSICAL-CHEMICAL DATA.**

For more detailed information, consult the analysis bulletin.

**Solubility:** Very slightly soluble in water and alcohol. Insoluble in acetone. It is soluble in dilute solutions of alkaline acids.**Incompatibility:** Nitrous acid, strong oxidizing substances, formaldehyde, chloramine T, and strong H<sup>+</sup> and OH<sup>-</sup>.

**94307-BIOTIN****5. PROPERTIES/USES.**

Pharmaceutical use excipient.

Alimentary use.

Cosmetic use.

**6. DOSAGE.**

The usual dose is 0.005 g/dose, 0.02 g/24 h, orally.

Maximum dose: 0.02 g/dose, 0.04 g/24 h orally,

**7. OBSERVATIONS.**

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

**STORAGE:**

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

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

**BSE/TSE:**

The product does not contain and is not derived from BSE/TSE risk materials.

**GMO:**

The product does not contain GMO and complies with EC Regulation 1830/2003 and No. 1829/2003/EC.

**CMR:**

The product does not contain carcinogenic, mutagenic and toxic substances in accordance with Reg. (EC) 1223/2009.

**SVHC:**

The product does not contain SVHC substances according to Reg. (EC) 1272/2008.

**NANOMATERIALS:**

The product complies with Reg. (EU) n.1169/2011.

**94307-BIOTIN****IRRADIATION:**

The product has not been irradiated or ionized in accordance with Reg. 1999/2/EC; Reg. 1999/3/EC .

**PESTICIDES:**

The product complies with Reg. 396/2005/EC

**PRESERVATIVES:**

The product does not contain preservatives.

**RESIDUAL SOLVENTS:**

The product complies with Reg.2009/32/EC.

**CONTAMINANTS/IMPURITIES:**

The product complies with Reg. EC 1881/2006.

The product is free of:

- Aflatoxins
- Dioxins
- Melamine
- Nitrosamines

Other products:

- Pyrrolizidine alkaloids ; In accordance with Reg. (EU) 2020/2040.
- PAH 4: < 50 ppm. The product complies with EU Reg. 1933/2015
- Benzopyrene : < 10 ppm. The product complies with EU Reg. 1933/2015
- Ethylene oxide: Absent according to Reg. 396/2005/EC.

**HEAVY METALS:**

≤ 10ppm

**ALLERGENS:**

- **Food allergens:** The product does not contain any of the food allergens listed in Annex II of Regulation (EC) No. 1169/2011. The product does not contain gluten.

**HALAL:**

Halal certified .

**KOSHER:**

Kosher certified .

**VEGAN/VEGETARIAN:**

The product is suitable for vegan/vegetarian consumption.



GUINAMA. Laboratory distributor of raw materials for the pharmacy and cosmetics sectors .

Document type:

**DATA SHEET**

Review date:

**17.11.2023**

Version:

**11.0**

## 94307-BIOTIN

### DOPANTING SUBSTANCES:

The product complies with the WADA list of prohibited substances.

### TESTED ON ANIMALS:

The product has not been tested on animals.

### RSPO:

The product does not contain palm oil.