

浙江圣达生物药业股份有限公司

Zhejiang Shengda Bio-Pharm Co., Ltd.

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Safety Data Sheet

According to Regulation (EC) No 1907/2006

D-Biotin/Biotin

Version 2.0

Issue date: 06/05/2017

Revision date: 06/05/2017

Section 1 Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier:

Identification on the label/Trade name: D-Biotin/Biotin
Additional identification: Not available
Identification of the product: CAS# 58-85-5; EC# 200-399-3
Index Number: Not available
REACH registration No.: Not available

1.2 Relevant identified uses of the substance and uses advised against:

1.2.1 Identified uses:

Pharma, food, feed and veterinary.

1.2.2 Uses advised against:

Not available.

1.3 Details of the supplier of the safety data sheet:

Supplier(Manufacturer): Zhejiang Shengda Bio-Pharm Co., Ltd.
Address: No. 789, Renmin East Road, Tiantai, Zhejiang, China
Contact person(E-mail): export@sd-pharm.com
Telephone: +86-576-83881111/83966232/ 13758609918
Fax: +86-576-83993731/83993730

1.4 Emergency telephone Number:

86-576-83881111

Available outside office hours?

YES

NO

Section 2 Hazards Identification

2.1 Classification of the substance/mixture:

2.1.1 Classification:

The substance is classified as following according to 67/548/EEC and REGULATION (EC) No 1272/2008:

REGULATION (EC) No 1272/2008	
Hazard classes/Hazard categories	Hazard codes
N/A	N/A

For full text of H- phrases: see section 2.2.

67/548/EEC	
Hazards characteristics	R-Phrases
N/A	N/A

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For full text of R- phrases: see section 16.

2.2 label elements:

Hazard Pictograms: No hazard pictogram is used.
Signal Word(S): No signal word is used.
Hazard Statement: Not applicable.
Precautionary statement: Not applicable.

2.3 Other hazards:

Not available.

Section 3 Composition/information on ingredients

Substance/Mixture: Substance

Ingredient(s):

Chemical Name	Registration No.	CAS No.	EC No.	Concentration
biotin	N/A	58-85-5	200-399-3	97.5-102%

Section 4 First aid measures

4.1 Description of first aid measures:

In all cases of doubt, or when symptoms persist, seek medical attention.

4.1.1 In case of inhalation:

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

4.1.2 In case of skin contact:

Wash off with soap and plenty of water.

4.1.3 In case of eyes contact:

Flush eyes with water as a precaution.

4.1.4 In case of ingestion:

Never give anything by mouth to an unconscious person. Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed:

The product is not classified as harmful to human health effect.

4.3 Indication of any immediate medical attention and special treatment needed:

If skin irritation or rash occurs, get medical advice/attention.

Section 5 Fire-Fighting measures

5.1 Extinguishing media:

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released: Carbon oxides, nitrogen oxides (NOx), sulphur oxides.

5.3 Special fire fighting methods and special protective actions for fire-fighters:

Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

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Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

- 6.1.1 For non-emergency personnel: Provide adequate ventilation. Avoid dust formation. Avoid inhalation dust. Avoid skin and eye contact. Refer to section 8 of SDS for personal protection details.
- 6.1.2 For emergency responders: Wear an appropriate NIOSH/MSHA approved respirator if dust is generated.

6.2 Environmental Precautions:

Do not allow material to be released to the environment without proper governmental permits.

6.3 Methods for Containment and Cleaning up:

Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections:

See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for information on disposal.

6.5 Additional information:

Not applicable.

Section 7 Handling and storage

7.1 Precautions for safe handling:

- 7.1.1 Protective measures: Provide appropriate exhaust ventilation at places where dust is formed.
- 7.1.2 Advice on general occupational hygiene: Do not eat, drink and smoke in work areas. Wash hands after use. Remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities:

D-Biotin is fairly stable to air and heat. Protected from light. The shelf life is 36 months from the date of production when stored in the unopened original container at room temperature.

7.3 Specific end use(s):

Not applicable.

Section 8 Exposure Controls/Personal Protection

8.1 Control parameters:

- 8.1.1 Occupational exposure limits: Not available.
- 8.1.2 Additional exposure limits under the conditions of use: Not available.
- 8.1.3 DNEL/DMEL and PNEC-Values: Not available.

8.2 Exposure controls:

- 8.2.1 Appropriate engineering controls: General industrial hygiene practice.
- 8.2.2 Individual protection measures, such as personal protective equipment:

- Eyeface protection:** Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
- Hand protection:** Handle with gloves. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.
- Body protection:** Wear suitable protective clothing to prevent skin exposure.
- Respiratory protection:** Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).
- Thermal hazards:** Wear suitable protective clothing to prevent heat.

8.2.3 Environmental exposure controls: Avoid discharge into the environment.
According to local regulations, Federal and official regulations.

Section 9 Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance:	Solid (Crystalline powder or crystals)
Colour:	White or almost white or colorless
Odour:	Odorless
Odour threshold:	Not available
pH:	Not available
Melting point/range (°C):	229-232°C (with decomposition)
Boiling point/range (°C):	Not available
Flash point (°C):	Not available
Evaporation rate:	Not available
Flammability limit - lower (%):	Not available
Flammability (solid, gas):	Not available
Ignition temperature (°C):	Not available
Upper/lower flammability/explosive limits:	Not available
Vapour pressure (20°C):	Not available
Vapour density:	Not available
Relative Density:	Not available
Bulk density (kg/m ³):	Not available
Water solubility (g/l):	Very slightly soluble in water.
n-Octanol/Water (log Po/w):	Not available
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
Viscosity, dynamic (mPa.s):	Not available
Explosive properties:	Not available
Oxidising properties:	Not available
Molecular Formula:	C ₁₀ H ₁₆ N ₂ O ₃ S
Molecular Weight:	244.31

9.2. Other information:

Fat solubility(solvent– oil to be specified) etc:	Very slightly soluble in ethanol, practically insoluble in organic solvents.
Surface tension:	Not available
Dissociation constant in water(pKa):	Not available
Oxidation-reduction Potential:	Not available
Specific gravity:	Not available

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Section 10 Stability and reactivity

10.1 Reactivity:

The substance is stable under normal storage and handling conditions.

10.2 Chemical stability:

Stable at room temperature in closed containers under normal storage and handling conditions.

10.3 Possibility of hazardous reactions:	No dangerous reactions known.
10.4 Conditions to avoid:	Incompatible materials.
10.5 Incompatible materials:	Strong oxidizing agents.
10.6 Hazardous decomposition products:	In case of fire, the following can be released: Carbon oxides, nitrogen oxides (NOx), sulphur oxides.

Section 11 Toxicological information

11.1 Toxicokinetics, metabolism and distribution:

Non-human toxicological data: Not available

11.2 Information on toxicological effects:

Acute toxicity:

LD50(Oral, Rat): Not available

LD50(Dermal, Rabbit): Not available

LC50(Inhalation, Rat): Not available

Skin corrosion/Irritation: Not classified

Serious eye damage/Irritation: Not classified

Respiratory or skin sensitization: Not classified

Germ cell mutagenicity: Not classified

Carcinogenicity: Not classified

Reproductive toxicity: Not classified

STOT- single exposure: Not classified

STOT-repeated exposure: Not classified

Section 12 Ecological information

Toxicity:

Acute toxicity		Time	Species	Method	Evaluation	Remarks
LC50	N/A	96h	Fish	OECD 203	N/A	N/A
EC50	N/A	48h	Daphnia	OECD 202	N/A	N/A
EC50	N/A	72h	Algae	OECD 201	N/A	N/A

Persistence and degradability: Not available.

Bioaccumulative potential: Not available.

Mobility in soil: Not available.

Results of PBT&vPvB assessment: Not available.

Other adverse effects: Not available.

Section 13 Disposal considerations

13.1 Waste treatment methods: The material should be disposed by incineration in a chemical incinerator in compliance with national and regional requirements.

13.2 Product / Packaging disposal: If empty container retains product residues, all label precautions must be observed. Return for reuse or dispose according to national or local regulations.

Section 14 Transport information

Product name: D-Biotin/Biotin

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	Land transport(ADR/RID)	Sea transport (IMDG)	Air transport (ICAO/IATA)
UN-Number	Not regulated	Not regulated	Not regulated
UN Proper shipping name	Not regulated	Not regulated	Not regulated
Transport hazard Class	Not regulated	Not regulated	Not regulated
Packaging group	Not regulated	Not regulated	Not regulated
Environmental hazards	No	No	No
Special precautions for user	See section 2.2	See section 2.2	See section 2.2
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not regulated	Not regulated	Not regulated

Section 15 Regulation information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:

Relevant information regarding authorization: Not applicable.

Relevant information regarding restriction: Not applicable.

Other EU regulations: Employment restrictions concerning young person must be observed. For use only by technically qualified individuals.

Other National regulations: Not applicable

Chemical Safety Assessment has been carried out? YES NO

Section 16 Other information

16.1 Indication of changes:

Version 2.0 Amended by EU No 453/2010

16.2 Relevant R- phrases (number and full text):

Not applicable.

16.3 Training instructions:

Not applicable.

16.4 Further information:

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

16.5 Notice to reader:

Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.

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