

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : D-Biotin
Substance name : (3aS,4S,6aR)-Hexahydro-2-oxo-1H-thieno[3,4-d]-imidazolevalerianic acid
CAS-No. : 58-85-5

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : For the fortification of foods, Ingredient for pharmaceutical products, Ingredient for personal care products, For use in fermentation

1.3 Details of the supplier of the safety data sheet

Company : DSM Nutritional Products Europe Ltd
PO Box 2676
CH-4002 Basel

Telephone : +41618157777
Telefax : +41618157770
E-mail address of person responsible for the SDS : sds.nutritionalproducts@dsm.com

1.4 Emergency telephone number

+41 848 00 11 77 (Carechem 24 International)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.3 Other hazards

Risk of dust explosion.

SECTION 3: Composition/information on ingredients

Synonyms : Co-N'Zyme R
Brief description of the product : Substance
EINECS-No. : 200-399-3
Molecular formula : C10-H16-N2-O3-S

3.1 Substances

Hazardous components

Chemical name	CAS-No. EC-No.	Concentration (% w/w)
Substances with a workplace exposure limit :		

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biotin	58-85-5 200-399-3	>= 90 - <= 100
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SECTION 4: First aid measures**4.1 Description of first aid measures**

- General advice : No hazards which require special first aid measures.
- If inhaled : Move to fresh air.
If symptoms persist, call a physician.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and plenty of water.
- In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms : No specific symptoms known.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : Treat symptomatically.

SECTION 5: Firefighting measures**5.1 Extinguishing media**

- Suitable extinguishing media : Water
Foam

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : None known.

5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
- Further information : Consider dust explosion hazard.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

- Use personal protective equipment.
Avoid dust formation.

6.2 Environmental precautions

- Try to prevent the material from entering drains or water courses.

6.3 Methods and material for containment and cleaning up

Sweep up and shovel.

6.4 Reference to other sections

For personal protection see section 8.
For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : For personal protection see section 8.
- Advice on protection against fire and explosion : Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed. Take precautionary measures against static discharges.
- Hygiene measures : General industrial hygiene practice.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : To maintain product quality, do not store in heat or direct sunlight.
Keep container tightly closed and dry.
- Advice on common storage : No special restrictions on storage with other products.

7.3 Specific end use(s)

- Specific use(s) : Not applicable

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
biotin	58-85-5	TWA	0.4 mg/m ³	DSM Internal Limit

8.2 Exposure controls

Personal protective equipment

- Eye protection : Safety glasses
- Hand protection : Glove material: for example nitrile rubber
- Skin and body protection : Lightweight protective clothing
- Respiratory protection : No personal respiratory protective equipment normally required.
In case of high dust concentration use a dust mask applicable to local conditions.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

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Appearance	: Crystalline powder
Colour	: white
Odour	: odourless
Odour Threshold	: No information available.
pH	: 4.5 (0.1 g/l) (as aqueous solution)
Melting point/range	: 229 - 232 °C with decomposition
Boiling point/boiling range	: not determined
Flash point	: Not applicable
Flammability (solid, gas)	: May form combustible dust concentrations in air.
Vapour pressure	: < 0.001 hPa (calculated value)
Relative vapour density	: Not applicable
Density	: not determined
Water solubility	: ca. 220 mg/l (25 °C)
Solubility in other solvents	: Ethanol 96%: ca.800 mg/l (25 °C) various organic solvents: practically insoluble
Partition coefficient: n-octanol/water	: log Pow 0.39 (calculated (citation from literature))
Auto-ignition temperature	: No self ignition observed in the Grewer oven at temperatures below melting point.
Thermal decomposition	: Not relevant
Explosive properties	: Not explosive
Oxidizing properties	: No data available

9.2 Other information

Combustibility index for deposited dust	: 1 (ca. 21 °C)
Dust explosion properties	: KSt value: 126 bar-m/s (36 % > 0.063 mm)
Dust explosion class	: St1 (36 % > 0.063 mm)
Maximum explosion over-pressure	: 7.7 bar (36 % > 0.063 mm)
Minimum ignition energy	: 3 - 10 mJ (36 % > 0.063 mm) The Minimum ignition energy (MIE) of a dust/air mix depends on the particle size the water content and the temperature of the dust. The finer and the dryer the dust the lower the MIE.
	: General remark: The indicated dust explosion characteristics are only valid for this product and are sensitive to the sample's parameters.
Minimum ignition temperature of a dust/air mix	: ca. 370 °C determined in the BAM oven
Molecular weight	: 244.31 g/mol

SECTION 10: Stability and reactivity

10.1 Reactivity

No hazards to be specially mentioned.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Dust may form explosive mixture in air.

10.4 Conditions to avoid

Heat

10.5 Incompatible materials

Strong acids and strong bases
Strong oxidizing agents

10.6 Hazardous decomposition products

Nitrogen oxides (NO_x)
Sulphur oxides

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity	: LD50 (Rat): > 20,000 mg/kg
	: LD50 (Mouse): > 10,000 mg/kg
Skin irritation	: No skin irritation (Rabbit, OECD Test Guideline 404, 4 h)
	: no phototoxic skin reaction (Guinea pig, OECD Test Guideline 432, 24 d)
Eye irritation	: No eye irritation (Rabbit, OECD Test Guideline 405, 72 h)
	: Dust contact with the eyes can lead to mechanical irritation.
Sensitisation	: Did not cause sensitisation on laboratory animals. (Guinea pig, Maximisation Test, OECD Test Guideline 406)
	: no photoallergenic skin reaction (Guinea pig)
Genotoxicity in vitro	: not mutagenic (Ames test)
Carcinogenicity	: No indication for carcinogenicity known.
Reproductive toxicity	: No indication for adverse effects on fertility known. (Rat, females)

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Teratogenicity	: not teratogenic not embryotoxic (Mouse)
STOT - single exposure (Acute exposure)	: The substance or mixture is not classified as specific target organ toxicant, single exposure.
STOT - repeated exposure	: The substance or mixture is not classified as specific target organ toxicant, repeated exposure.
Experience with human exposure	: No adverse effects known. : RDA (Recommended Daily Allowance) 0.15 mg
Aspiration toxicity	: No aspiration toxicity classification

SECTION 12: Ecological information**12.1 Toxicity**

Toxicity to fish	: Oncorhynchus mykiss (rainbow trout) LC0 (48 h) 500 mg/l suspension (OECD Test Guideline 203) : Danio rerio (zebra fish) LC0 (96 h) > 104 mg/l
Toxicity to bacteria	: activated sludge Concentration of the substance 100 mg/l No inhibition was observed under the biodegradation test conditions. (OECD Test Guideline 301C)

12.2 Persistence and degradability

Biodegradability	: Not readily biodegradable. 38 % (28 d) (OECD Test Guideline 301C)
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12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water	: log Pow 0.39 (calculated (citation from literature))
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12.4 Mobility in soil

Distribution among environmental compartments	: No data available
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12.5 Results of PBT and vPvB assessment

Assessment	: The substance does not fulfill the PBT criteria. : The substance does not fulfill the vPvB criteria.
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12.6 Other adverse effects

Additional ecological information : There is no data available for this product.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

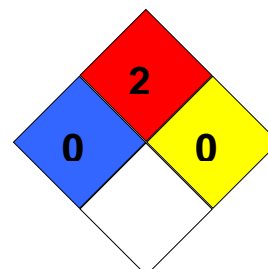
14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

NFPA Classification : Health hazard: 0
Fire Hazard: 2
Reactivity Hazard: 0



15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance.

SECTION 16: Other information

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



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Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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