

D-Biotin**5011655**

Version 4.0

Revision Date 04/30/2024

Date of last issue: 04/20/2022

SECTION 1. IDENTIFICATION

Product name : D-Biotin

Substance name : (3aS,4S,6aR)-Hexahydro-2-oxo-1H-thieno[3,4-d]-imidazolevalerianic acid

Manufacturer or supplier's details

Company name of supplier : DSM Nutritional Products LLC

Address : 250 Plainsboro Rd
Plainsboro NJ 08536

Telephone : (609) 452-1000

Emergency telephone number : 1-800-424-9300 (24 HR CHEMTREC, CA & US); Outside CA & US +1-703-572-3887 (COLLECT CALLS ACCEPTED)

E-mail address of person responsible for the SDS : sds.nutritionalproducts@dsm.com

Recommended use of the chemical and restrictions on useRecommended use : Dietary supplement
For the fortification of foods
Ingredient for personal care products**SECTION 2. HAZARDS IDENTIFICATION****GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Combustible dust

GHS label elements

Signal word : Warning

Hazard statements : May form combustible dust concentrations in air.

Other hazards

Risk of dust explosion.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Synonyms : Co-N'Zyme R

Molecular formula : C10-H16-N2-O3-S

Brief description of the product : Substance

Substance name : (3aS,4S,6aR)-Hexahydro-2-oxo-1H-thieno[3,4-d]-imidazolevalerianic acid

CAS-No. : 58-85-5

Hazardous components

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Chemical name	CAS-No.	Concentration (% w/w)
biotin	58-85-5	>= 90 - <= 100

Actual concentration is withheld as a trade secret

SECTION 4. 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 : Rinse mouth with water.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : No specific symptoms known.
- Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Water
Foam
- Specific hazards during fire-fighting : None known.
- Further information : Consider dust explosion hazard.
- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Avoid dust formation.
- Environmental precautions : Try to prevent the material from entering drains or water courses.
- Methods and materials for containment and cleaning up : Sweep up and shovel.

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SECTION 7. HANDLING AND STORAGE

- 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.
- Advice on safe handling : For personal protection see section 8.
- Conditions for safe storage : To maintain product quality, do not store in heat or direct sunlight.
Keep container tightly closed and dry.
- Materials to avoid : No special restrictions on storage with other products.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components with workplace control parameters**

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

Personal protective equipment

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**Information on basic physical and chemical properties**

- 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

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Flammability (solid, gas)	: Not classified as flammable as defined by the transport regulations. (Method: Flammability (solids)) May form combustible dust concentrations in air.
Vapour pressure	: < 0.001 hPa (calculated value)
Relative vapour density	: Not applicable
Density	: 1.41 g/cm ³ (23.9 °C)
Water solubility	: 271 mg/l (20 °C, pH ca. 4.0; OECD Test Guideline 105)
Solubility in other solvents	: Ethanol 96%: ca.800 mg/l (25 °C) various organic solvents: practically insoluble
Partition coefficient: n-octanol/water	: log Pow ca. 0.81 (23 °C; OECD Test Guideline 117)
Auto-ignition temperature	: No self ignition observed in the Greiner oven at temperatures below melting point.
Thermal decomposition	: Not relevant
Explosive properties	: Not explosive
Oxidizing properties	: Not oxidizing

Other information

Combustibility index for deposited dust	: 3 (23 °C, VDI 2263-1)
	: 3 (100 °C, VDI 2263-1)
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 (Product sample, Median value of the tested sample 0.007 mm, Loss on drying 0.1 %, EN 13821) 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.
Powder volume resistivity	: ca. 3E+13 Ohmm (Product sample, Median value of the tested sample 0.007 mm, Loss on drying 0.1 %) The material can accumulate static charge and can therefore cause electrical ignition.
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

Reactivity	: No hazards to be specially mentioned.
Chemical stability	: Stable under recommended storage conditions.

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Possibility of hazardous reactions : Dust may form explosive mixture in air.

Conditions to avoid : Heat

Incompatible materials : Strong acids and strong bases
Strong oxidizing agents

Hazardous decomposition products : Nitrogen oxides (NO_x)
Sulphur oxides

SECTION 11. TOXICOLOGICAL INFORMATION

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.

IARC : No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA : No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP : No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity : No indication for adverse effects on fertility known.
(Rat, females)

Teratogenicity : not teratogenic
not embryotoxic

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(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.

Aspiration toxicity : No aspiration toxicity classification

Experience with human exposure**Product:**

- : No adverse effects known.
- : RDA (Recommended Daily Allowance) 0.15 mg

SECTION 12. ECOLOGICAL INFORMATION**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 daphnia and other aquatic invertebrates : Daphnia magna (Water flea)
EC50 (48 h) > 100 mg/l
(OECD Test Guideline 202)
- Toxicity to algae : Pseudokirchneriella subcapitata (green algae)
EC50 (72 h) > 100 mg/l
(OECD Test Guideline 201)
- 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)

Persistence and degradability

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

Bioaccumulative potential

- Partition coefficient: n-octanol/water : log Pow ca. 0.81 (23 °C ; OECD Test Guideline 117)

Mobility in soil

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Distribution among environmental compartments : No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

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

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : User must determine if any wastes generated exhibit hazardous characteristics as per 40 CFR Part 261 or other national / local legislation.

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**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**49 CFR**

Not regulated as a dangerous good

Special precautions for user

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

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SECTION 15. REGULATORY INFORMATION**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : Combustible dust

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

biotin

58-85-5

Maine Chemicals of High Concern

Product does not contain any listed chemicals

Vermont Chemicals of High Concern

Product does not contain any listed chemicals

Washington Chemicals of High Concern

Product does not contain any listed chemicals

The components of this product are reported in the following inventories:

TCSI : On the inventory, or in compliance with the inventory

TSCA : All substances listed as active on the TSCA inventory

AIIC : On the inventory, or in compliance with the inventory

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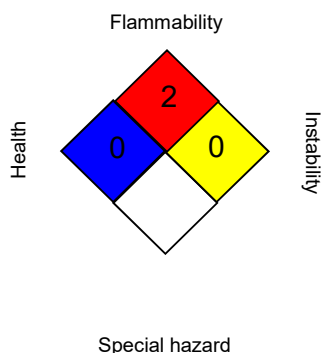
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DSL	: All components of this product are on the Canadian DSL
ENCS	: On the inventory, or in compliance with the inventory
ISHL	: On the inventory, or in compliance with the inventory
KECI	: On the inventory, or in compliance with the inventory
PICCS	: On the inventory, or in compliance with the inventory
IECSC	: On the inventory, or in compliance with the inventory
NZIoC	: On the inventory, or in compliance with the inventory
TECI	: Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION**Further information****NFPA 704:****HMIS® IV:**

HEALTH	/	0
FLAMMABILITY		2
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport

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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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

ACGIH = American Conference of Governmental Industrial Hygienists. CFR = Code of Federal Regulations. EPA = Environmental Protection Agency. NIOSH = National Institute of Occupational Safety and Health. OSHA = Occupational Safety and Health Administration. STEL = Short term exposure limit. TLV = Threshold Limit Value. TLV-C = Ceiling Limit Value. TWA = Time Weighted Average.

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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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