

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## BIOTINUM

EN

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### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name: Biotin  
Biotinum  
Biotine  
Biotine  
Biotin

N° CAS: 58-85-5

N° EC: 200-399-3

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

#### 1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV  
Oostmalsebaan 1c (unit 5)  
2960 Sint-Lenaarts  
Belgium

Telephone: (+32) (0)3 457 11 76

Email: info@magis-pharma.be

Web page: www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Not a hazardous substance or mixture.

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s): Not applicable.

Signal word(s): Not applicable.

Hazard statements: Not applicable.

Precautionary statements: Not applicable.

Additional applicable label elements: Not applicable.

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### 2.3 Other hazards

Risk of dust explosion.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Biotin
IUPAC name:	5-[(3aS,4S,6aR)-2-oxo-1,3,3a,4,6,6a-hexahydrothieno[3,4-d]imidazol-4-yl]pentanoic acid
Synonyms:	D-biotin Coenzyme R
N° CAS:	58-85-5
N° EC:	200-399-3
Molecular Formula:	C <sub>10</sub> H <sub>16</sub> N <sub>2</sub> O <sub>3</sub> S
Content:	98.5 per cent to 101.0 per cent (dried substance).

### 3.2 Mixtures

Not applicable.

## SECTION 4: FIRST AID MEASURES

### 4.1 Description of first aid measures

General notes:	No hazards which require special first aid measures.
After inhalation:	Move to fresh air. If symptoms persist, call a physician.
After skin contact:	Take off contaminated clothing and shoes immediately. Wash off with soap and plenty of water.
After eye contact:	Flush eyes with water as a precaution. Remove contact lenses. Protect unharmed eye. Keep eye wide open while rinsing.
After ingestion:	Clean mouth with water and drink plenty of water afterwards. 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

No specific symptoms known.

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

Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

### 5.1 Extinguishing media

Suitable extinguishing media:	Water, foam.
Unsuitable extinguishing media:	Not available.

### 5.2 Special hazards arising from the substance/mixture

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None known.

### 5.3 Advice for firefighters

Surrounding fires:

Consider dust explosion hazard.

Protection against fire:

In the event of fire, wear self-contained breathing apparatus.

Hazardous combustion products:

Not available.

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### 6.1 Personal precautions, protective equipment and emergency procedures

#### For non-emergency personnel

Use personal protective equipment. Avoid dust formation.

#### For emergency responders

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

Precautions for safe handling:

Avoid dust formation. General industrial hygiene practice.

Personal protection:

For personal protection, see section 8.

Technical protective measures:

Provide appropriate exhaust ventilation at places where dust is formed. Take precautionary measures against static discharges.

Handling:

Not available.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:

Not available.

Conditions for safe storage, including any incompatibilities:

Keep container tightly closed and dry.

Storage – away from:

To maintain product quality, do not store in heat or direct sunlight. No special restrictions on storage with other products.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

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### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1 Control parameters

TWA: 0.4 mg/m<sup>3</sup> (Basis: DSM Internal Limit)

#### 8.2 Exposure controls

##### Appropriate engineering control

Not available.

##### Individual protection measures

Eye/face protection: Safety glasses.

Skin protection: Lightweight protective clothing.

Hand protection: Glove material: for example nitrile rubber.

Respiratory protection: No personal respiratory protective equipment normally required.  
In case of high dust concentration, use a dust mask applicable to local conditions.

Thermal hazards: Not determined.

##### Environmental exposure control

Not available.

### SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on basic physical and chemical properties

Appearance: White or almost white, crystalline powder or colourless crystals.

Odour: Odourless.

Odour threshold: Not available.

pH: 4.5 (0.1 g/l) (as aqueous solution)

Melting/freezing point: 229 - 232 °C with decomposition

Initial boiling point: Not determined.

Boiling range: Not determined.

Flash point: Not applicable.

Evaporation rate: Not available.

Flammability (solid/gas): May form combustible dust concentrations in air.

Upper/lower flammability or explosive limits: Not available.

Vapour pressure: < 0.001 hPa (calculated value)

Vapour density: Not available.

Relative density: Not available.

Solubility: Very slightly soluble in ethanol (96%): ca. 800 mg/l (25 °C)  
Practically insoluble in acetone. It dissolves in dilute solutions of alkali hydroxides.

Solubility in water: Very slightly soluble in water: ca. 220 mg/l (25 °C)

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Partition coefficient (n-octanol/water):	log Pow 0.39 (calculated (citation from literature))
Auto-ignition temperature:	No self-ignition observed in the Greuer oven at temperatures below melting point.
Decomposition temperature:	Not relevant.
Viscosity:	Not available.
Explosive properties:	Not explosive.
Oxidising properties:	Not 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 overpressure: 7.7 bar (36 % > 0.063 mm)  
Minimum ignition energy: 3 - 10 mJ ( 6 % > 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 oxidising agents.

### 10.6 Hazardous decomposition products

Nitrogen oxides (NO<sub>x</sub>), sulphur oxides.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity:	Oral LD <sub>50</sub> (Rat): > 20 000 mg/kg Oral LD <sub>50</sub> (Mouse): > 10 000 mg/kg
Skin corrosion/irritation:	No skin irritation (Rabbit, OECD Test Guideline 404, 4 h).

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	No phototoxic skin reaction (Guinea pig, OECD Test Guideline 432, 24 d)
Serious eye damage/irritation:	No eye irritation (Rabbit, OECD Test Guideline 405, 72 h). Dust contact with the eyes can lead to mechanical irritation.
Respiratory/skin sensitisation:	Did not cause sensitisation on laboratory animals. (Guinea pig, Maximisation Test, OECD Test Guideline 406). No photoallergenic skin reaction (Guinea pig).
Germ cell mutagenicity:	Not mutagenic (Ames test).
Carcinogenicity:	No indication for carcinogenicity known.
Reproductive toxicity:	No indication for adverse effects on fertility known. (Rat, females)
Summary of evaluation of the CMR properties:	Not available.
STOT-single 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 Hazard:	No aspiration toxicity classification
Other:	Experience with human exposure: No adverse effects known. RDA (Recommended Daily Allowance) 0.15 mg

### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

## 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)

### 12.3 Bioaccumulative potential

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log Pow 0.39 (calculated (citation from literature))

### 12.4 Mobility in soil

Not available.

### 12.5 Results of PBT and vPvB assessment

The substance does not fulfil the PBT criteria. The substance does not fulfil the vPvB criteria.

### 12.6 Other adverse effects

Not available.

## 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

### Transport information according to ADR/RID/IMDG/ICAO/IATA

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), Not classified.  
IATA/ICAO (Air) :

#### 14.6 Special precautions for user

Not available.

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

Not applicable for product as supplied.

#### 14.8 Additional transport information

Not classified as dangerous in the meaning of transport regulations.

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## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not applicable.

Risk phrases: Not applicable.

Safety phrases: Not applicable.

### 15.2 Chemical safety assessment

A chemical safety assessment is not required for this substance.

## SECTION 16: OTHER INFORMATION

### 16.1 Changes since the previous version

Not applicable.

### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

### 16.3 Key literature references/sources for data

European Chemicals Agency.

<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

### 16.4 Method of classification in case of mixture

Not applicable.

### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

### 16.6 Training advisement

Not available

### 16.7 Notice for user(s)



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The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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### 16.8 Department issuing MSDS

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