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PENICILLAMINUM

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

1.1 PRODUCT IDENTIFIER

Product name: EN: Penicillamine

LAT: Penicillaminum
NL: Penicillamine
FR: Pénicillamine
DE: Penicillamin
52-67-5

N° CAS: 52-67-5 N° EC: 200-148-8

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: Magis-Pharma NV

Neerlandweg 24 2610 Wilrijk 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

 Skin Irrit. 2
 H315

 Eye Irrit. 2
 H319

 STOT SE 3
 H335

2.2 LABEL ELEMENTS

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Warning

Hazard statements:

H315 Causes skin irritation.

H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Precautionary statements:

P261 Avoid breathing (dust/fume/gas/mist/vapors/spray)

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MATERIAL SAFETY DATA SHEET

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Wash hands thoroughly after handling. P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P312 Call a POISON CENTER/doctor if you feel unwell. P332+P313 If skin irritation occurs: Get medical advice/attention. P337+P313 If eye irritation persists: Get medical advice/attention. P362 Take off contaminated clothing and wash before reuse.

Additional applicable label

elements:



2.3 OTHER HAZARDS

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Product name: Penicillamine

IUPAC name: (2S)-2-Amino-3-methyl-3-sulfanylbutanoic acid

Synonyms: D-penicillamine

> 3,3-dimethylcysteine 3-mercapto-D-valine

N° CAS: 52-67-5 200-148-8 N° EC: Molecular Formula: C₅H₁₁NO₂S

Content: 98.0 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

After inhalation: Allow the victim to rest in a well-ventilated area. Seek immediate medical attention. Serious inhalation: Evacuate the victim to a safe area as soon as possible. Loosen tight clothing such as a

collar, tie, belt or waistband. If breathing is difficult, administer oxygen. If the victim is not breathing, perform mouth-to-mouth resuscitation. Seek medical attention.

After skin contact: After contact with skin, wash immediately with plenty of water. Gently and

> thoroughly wash the contaminated skin with running water and non-abrasive soap. Be particularly careful to clean folds, crevices, creases and groin. Cover the irritated skin with an emollient. If irritation persists, seek medical attention. Wash

contaminated clothing before reusing.

Serious skin contact: Wash with a disinfectant soap and cover the contaminated skin with an anti-bacterial

cream. Seek immediate medical attention.



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After eye contact: Check for and remove any contact lenses. Immediately flush eyes with running water

for at least 15 minutes, keeping eyelids open. Cold water may be used. Do not use an

eye ointment. Seek medical attention.

After ingestion: Do not induce vomiting. Examine the lips and mouth to ascertain whether the tissues

are damaged, a possible indication that the toxic material was ingested; the absence of such signs, however, is not conclusive. Loosen tight clothing such as a collar, tie, belt or waistband. If the victim is not breathing, perform mouth-to-mouth

resuscitation. Seek immediate medical attention.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

Potential acute health effects: May cause gastrointestinal effects, signs and symptoms may include nausea, vomiting, diarrhoea, constipation, cramps, and loss of appetite.

Potential chronic health effects: Not available.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media: SMALL FIRE: Carbon dioxide, dry chemical powder or appropriate

foam, water spray. Wear self-contained breathing apparatus for

firefighting if necessary.

LARGE FIRE: Use water spray, alcohol-resistant foam, dry chemical or

carbon dioxide.

Unsuitable extinguishing media: Not available.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE/MIXTURE

During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

5.3 ADVICE FOR FIREFIGHTERS

Surrounding fires: Not available. Protection against fire: Not available.

Hazardous combustion products: Carbon oxides, nitrogen oxides (NO_x), hydrogen chloride gas,

hydrogen fluoride.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

FOR NON-EMERGENCY PERSONNEL

Not available.

FOR EMERGENCY RESPONDERS

Not available.

6.2 ENVIRONMENTAL PRECAUTIONS

Not available.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Small spill: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

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Large spill: Sweep-up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete. Ensuring personal safety, mark out contaminated area with signs and prevent unauthorized access. Turn leaking containers up to prevent further. Evacuate area.

6.4 REFERENCE TO OTHER SECTIONS

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Precautions for safe handling: Avoid contact with skin and eyes.

Personal protection: Not available.

Technical protective measures: Avoid formation of dust and aerosols. Provide appropriate exhaust

ventilation at places where dust is formed. Normal measures for

preventive fire protection.

Handling: Not available.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep container tightly closed in a dry (protected from moisture) and Storage:

well-ventilated place. Store at room temperature.

Conditions for safe storage, including any

incompatibilities:

Not available.

Storage – away from: Not available.

7.3 SPECIFIC END USE(S)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Not available.

8.2 EXPOSURE CONTROLS

APPROPRIATE ENGINEERING CONTROL

Use process enclosures, local exhaust ventilation. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit. Contains no substances with occupational exposure limit values.

INDIVIDUAL PROTECTION MEASURES

Eye/face protection: Splash goggles.

In case of a large spill: Splash goggles.

Skin protection: Lab coat.

In case of a large spill: Full suit. Boots.

Hand protection: In case of a large spill: Gloves

Respiratory protection: Not determined. Thermal hazards: Not determined.

Suggested protective clothing might not be sufficient; consult a specialist BEFORE handling this product.



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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.

Odour: Not available. Odour threshold: Not available. 4.5 to 5.5 pH: Melting/freezing point: 210 °C

Initial boiling point: Not available. Not available. Boiling range: Flash point: Not available. Evaporation rate: Not available. Flammability (solid/gas): Not available. Upper/lower flammability or Not available.

explosive limits:

Vapour pressure: Not applicable. Vapour density: Not available. Not available. Relative density:

Solubility: Slightly soluble in ethanol (96 per cent). Practically slightly insoluble in chloroform

and in ether.

Freely soluble in water. Solubility in water:

Partition coefficient

(n-octanol/water):

Not available.

Auto-ignition temperature: Not available. Decomposition temperature: Not available. Not available. Viscosity: Explosive properties: Not available. Not available. Oxidising properties:

9.2 OTHER INFORMATION

Molecular weight: 149.20 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

Hazardous decomposition products: Carbon monoxide, carbon dioxide, nitrogen oxides, sulphur oxides.

Polymerisation: Will not occur.

10.2 CHEMICAL STABILITY

Conditions of instability: None known.

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10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Not available.

10.4 CONDITIONS TO AVOID

Not available.

10.5 INCOMPATIBLE MATERIALS

Not available.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity: Acute oral toxicity (LD₅₀): 6170 mg/kg (rat)

Skin corrosion/irritation: Not available.
Serious eye damage/irritation: Not available.
Respiratory/skin sensitisation: Not available.
Germ cell mutagenicity: Not available.
Carcinogenicity: Not available.

Reproductive toxicity: Possible risk of congenital malformation in the fetus.

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: Not available.
STOT-repeated exposure: Not available.
Aspiration Hazard: Not available.

Other: Routes of entry: Eye contact, inhalation, ingestion.

Special remarks on chronic effects on humans: To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly

investigated.

11.2 ADDITIONAL INFORMATION ON POTENTIAL ADVERSE HUMAN HEALTH EFFECTS AND SYMPTOMS

Eye contact:

Skin contact:

Inhalation:

Ingestion:

Aspiration:

Not available.

Not available.

Not available.

Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 TOXICITY

Not available.

12.2 PERSISTENCE AND DEGRADABILITY

Not available.



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12.3 BIOACCUMULATIVE POTENTIAL

Not available.

12.4 MOBILITY IN SOIL

Not available.

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

Not available.

12.6 OTHER ADVERSE EFFECTS

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Contact a licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chem scrubber.

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 dangerous goods. 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), No. IATA/ICAO (Air):

14.6 SPECIAL PRECAUTIONS FOR USER

Not applicable.

14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II OF MARPOL AND THE IBC CODE

Not available.

14.8 ADDITIONAL TRANSPORT INFORMATION

Not available.



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SECTION 15: REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE/MIXTURE

Hazard symbol:

Risk phrases: R36/37/38 Irritating to eyes, respiratory system and skin.

Safety phrases: S26 In case of contact with eyes, rinse immediately with plenty of water and seek

medical advice.

S27 Take off immediately all contaminated clothing.

S28 After contact with skin, wash immediately with plenty of soap and water. S36/37/39 Wear suitable protective clothing, gloves and eye/face protection. S45 In case of accident or if you feel unwell seek medical advice immediately (show

the label where possible).

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

15.2 CHEMICAL SAFETY ASSESSMENT

Not available.

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

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 Bioaccumalative

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.



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16.6 TRAINING ADVISEMENT

Not available.

16.7 NOTICE FOR USER(S)

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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