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

1.1 Product identifier

Product name: Cyanocobalamin

Cyanocobalaminum Cyanocobalamine Cyanocobalamine Cyanocobalamin

N° CAS: 68-19-9 N° EC: 200-680-0

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

Not classified.

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s):

Not applicable.

Not applicable.

Not applicable.

Precautionary statements:

Not applicable.

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Additional applicable label

elements:

Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Cyanocobalamin

IUPAC name: Cobalt(3+);[(2R,3S,4R,5S)-5-(5,6-dimethylbenzimidazol-1-yl)-4-hydroxy-2-

(hydroxymethyl)oxolan-3-yl] [(2R)-1-[3-

[(1*R*,2*R*,3*R*,5*Z*,7*S*,10*Z*,12*S*,13*S*,15*Z*,17*S*,18*S*,19*R*)-2,13,18-tris(2-amino-2-oxoethyl)-7,12,17-tris(3-amino-3-oxopropyl)-3,5,8,8,13,15,18,19-octamethyl-2,7,12,17-tetrahydro-1*H*-corrin-24-id-3-yl]propanoylamino]propan-2-yl] phosphate;cyanide

Synonyms: Vitamin B12

Cyanocob(III)alamin

 N° CAS: 68-19-9 N° EC: 200-680-0 Molecular Formula: $C_{63}H_{88}CoN_{14}O_{14}P$

Content: 96.0 per cent to 102.0 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Transport the victim to fresh air, away from the places of exposure which must be

ventilated. If breathing is difficult, practice artificial respiration.

After skin contact: Flush with copious amounts of water and soap. Remove contaminated clothing.

Consult a doctor if an irritation appears.

After eye contact: Assure adequate flushing by separating the eyelids with fingers. Flush with copious

amounts of water for at least 15 minutes. Consult an ophthalmologist if an irritation

appears.

After ingestion: If the person is conscious; rinse the mouth with water. Do not induce vomiting. Seek

medical advice.

4.2 Most important symptoms and effects, both acute and delayed

Any symptoms or effects proved from exposure.

4.3 Indication of any immediate medical attention and special treatment needed

No special treatment.

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SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Dry chemical, foam, CO₂.

Use appropriate extinguishers with the risks in the proximity.

Unsuitable extinguishing media: Water jet.

5.2 Special hazards arising from the substance/mixture

May produce toxic fumes of carbon monoxide if burning.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Don't penetrate or stay in the danger zone without protective

clothing and without 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

Prevent the access of unnecessary persons. Wear protective clothing.

For emergency responders

Prevent the access of unnecessary persons. Wear protective clothing.

6.2 Environmental precautions

Avoid the discharge into natural waters, sewers or soil.

6.3 Methods and material for containment and cleaning up

Transfer to suitable, labelled containers for disposal. Use of absorbent material. Ventilate and wash area.

6.4 Reference to other sections

Personal protective equipment, see section 8.

Waste treatment, see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: In any event don't drink, eat or smoke in the workplace.

Personal protection: Avoid inhalation. Avoid contact with eyes, skin and clothing. Avoid

prolonged or repeated exposure (see section 8).

Technical protective measures: Not available.

Handling: Wash hands after use. Remove the contaminated clothes and clean

them before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities

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Storage: Store in an airtight container.

Conditions for safe storage, including any

incompatibilities:

Store in a cool and dry place.

Storage – away from: Store protected from light.

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

General and extractive ventilation is usually required.

Individual protection measures

Eye/face protection: Glasses, masks with side protection.

Skin protection: Suitable protective clothing.

Hand protection: Gloves type neoprene.

Respiratory protection: Dust masks and filter P2.

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: Dark red, crystalline powder or dark red crystals.

Odour: Not available. Odour threshold: Not available. pH: Not available. Melting/freezing point: Not available. Initial boiling point: Not available. Not available. Boiling range: Flash point: Not available. Evaporation rate: Not available. Flammability (solid/gas): Not available.

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Upper/lower flammability or

explosive limits:

Not available.

Not available. Vapour pressure: Vapour density: Not available.

Relative density: Not available.

Sparingly soluble in ethanol (96%), practically insoluble in acetone. Solubility:

Sparingly soluble in water. Solubility in water:

Partition coefficient Not available.

(n-octanol/water):

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

9.2 Other information

The anhydrous substance is very hygroscopic.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No reactivity known.

10.2 Chemical stability

The substance is stable under normal and predictable environmental conditions of storage and handling.

10.3 Possibility of hazardous reactions

No hazardous reactions known.

10.4 Conditions to avoid

Light, excessive heat.

10.5 Incompatible materials

Strong oxidising agents.

10.6 Hazardous decomposition products

Carbon oxides, nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Oral LD50 (rat): > 5 000 mg/kg Acute toxicity:

Skin corrosion/irritation: Not available. Serious eye damage/irritation: Not available. Not available. Respiratory/skin sensitisation:

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Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: Not available.

Summary of evaluation of the Not available.

CMR properties:

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

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: May be irritating to eyes.

Skin contact: May be irritating to skin.

Inhalation: May be harmful by inhalation.

May be irritating to mucous membrane and respiratory tracts.

Ingestion: May be harmful by ingestion.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

The substance doesn't meet the criteria for PBT or vPvB in accordance with Annex XIII of regulation EC N° 1907/2008 (REACH).

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

It is recommended to avoid or to reduce as much as possible the production of waste.

Eliminate residues and packaging according to the current local or national security regulations.

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Avoid the dispersal of the poured materials, as well as their discharge and any contact with the soil, the streams, the

SECTION 14: TRANSPORT INFORMATION

sewers and the exhaust canals.

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

Personal protective equipment is required. See section 6 and 8.

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

Transport in bulk isn't intended to be used.

14.8 Additional transport information

The product isn't submitted to transport regulations.

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: S7 Keep container tightly closed.

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: OTHER INFORMATION

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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 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.

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

Quality Department FAC SECUNDUM ARTEM NV info@magis-pharma.be