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POVIDONUM IODINATUM

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

1.1 PRODUCT IDENTIFIER

Product name: EN: Povidone, ionated

> LAT: Povidonum iodinatum NL: Povidon, gejodeerd FR: Povidone iodée DE: Povidon, jodiert

N° CAS: 25655-41-8 N° EC: 607-771-8

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 www.magis-pharma.be Web page:

1.4 EMERGENCY TELEPHONE NUMBER

Public utility foundation: Belgisch Antigifcentrum Centre Antipoisons Belge

Telephone: (+32) (0)70 245 245 (Service 24/7)

www.antigifcentrum.be www.centreantipoisons.be Web page:

SECTION 2: HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE/MIXTURE

Classification according to (EC) n° 1272/2008

Skin Irrit. 2 H315 H318 Eye Dam. 1 Aquatic Chronic 2 H411

2.2 LABEL ELEMENTS

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):







Signal word(s): Danger

Hazard statements:

H315 Causes skin irritation. H318 Causes serious eye damage.

H411 Toxic to aquatic life with long lasting effects.

Precautionary statements:

P264 Wash thoroughly after handling.

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P264+P265 Wash thoroughly after handling. Do not touch eyes.

P273 Avoid release to the environment.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

P305+P354+P338 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses

if present and easy to do. Continue rinsing.

P317 Get emergency medical help.

P321 Specific treatment (see on this label).

P332+P317 If skin irritation occurs: Get emergency medical help. P362+P364 Take off contaminated clothing and wash it before reuse.

P391 Collect spillage.

P501 Dispose of contents/container to... (see section 13).

Additional applicable label

elements:

Not applicable.

2.3 OTHER HAZARDS

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Product name: Povidone, ionated

IUPAC name: Polyvinylpyrrolidone iodine

Synonyms: Iodopovidone

1-ethenylpyrrolidin-2-one;molecular iodine

N° CAS: 25655-41-8 N° EC: 607-771-8 Molecular Formula: $C_6H_9I_2NO$

Content: 9.0 per cent to 12.0 per cent of available iodine (dried substance)

3.2 MIXTURES

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General notes: Consult a physician. Show the safety data sheet to the doctor on duty.

After inhalation: Take to fresh air. If breathing is irregular, call a doctor immediately. Only give artificial

respiration if breathing stops or under medical supervision.

Wash immediately with plenty of soap and water for at least 15 minutes. Remove all After skin contact:

contaminated clothing immediately. Get medical attention if irritation develops and

persists.

After eye contact: Remove contact lenses and rinse immediately with plenty of water, including under

eyelids, for at least 15 minutes. Get medical attention.

After ingestion: If conscious, give the victim water (maximum 2 glasses) to drink. Never give anything

by mouth to an unconscious person. Call a doctor immediately.



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4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The most important known symptoms and effects are described on the label (see section 2.2) and/or in section 11.

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

In cases of doubt, or when symptoms of discomfort persist, seek medical attention. Never administer anything by mouth to unconscious persons.

SECTION 5: FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media: Foam, dry powder, carbon dioxide, water.

Unsuitable extinguishing media: No extinguishing agent limitations for this substance/mixture.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE/MIXTURE

Nature of decomposition products unknown.

Flammable.

Vapours are heavier than air and may spread along the ground.

In case of strong heating, explosive mixtures with air may occur.

In case of fire possible formation of dangerous combustion gases or vapours.

5.3 ADVICE FOR FIREFIGHTERS

Surrounding fires: Cool containers with water to prevent decomposition of product and

development of health hazards. Always use full fire protection. Collect water from which must not enter sewage system. Dispose of contaminated water used for extinguishing and residues in

accordance with current regulations.

Protection against fire: Helmet with visor, flame retardant clothing (jacket and trousers with

straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the whole face of the operator or the car (self protective) in case of large amounts of

smoke, a self-contained breathing apparatus (EN 137).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

FOR NON-EMERGENCY PERSONNEL

For exposure control and personal protective measures, see section 8. Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

FOR EMERGENCY RESPONDERS

For exposure control and personal protective measures, see section 8. Equip clean-up personnel with appropriate protective equipment. Ventilate the area. Evacuate unnecessary personnel.

6.2 ENVIRONMENTAL PRECAUTIONS

Prevent release to the environment. Prevent entry into sewers and watercourses. If product enters drains or public waterways, notify authorities.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Store away from other materials. If on the ground, sweep or scoop (shovel or similar) into suitable containers. Limit dust production.



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6.4 REFERENCE TO OTHER SECTIONS

For exposure control and personal protective measures, see section 8.

For waste disposal, follow the recommendations in section 13.

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Precautions for safe handling: Wash thoroughly after handling. Do not eat, drink or smoke while

handling this product. Ask for special instructions before use.

Personal protection: Not available.

Technical protective measures: Work with good ventilation of the processing area to avoid vapour

formation.

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 in a cool, dry place.

Storage – away from: 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

Since the use of appropriate technical measures should always take precedence over personal protective equipment, ensure good ventilation at the workplace by effective local suction. When choosing personal protective equipment, ask your chemical suppliers if this is necessary. Personal protective equipment must be CE-marked for compliance with applicable regulations. Provide an emergency shower with a visco-elastic tray.

Hygiene measures: Handle with proper industrial hygiene precautions, and observe safety practices. Wash hands before breaks and after finishing work.

INDIVIDUAL PROTECTION MEASURES

Eye/face protection: Protective face shields and safety goggles according to EN 165, EN 166, EN 167, EN

168.

Skin protection: Choose body protection according to the quantity and concentration of the

hazardous substance in the workplace.

Hand protection: Handle with gloves. The selected protective gloves must comply with the

specifications of EU Directive 89/686/EEC and the derived standards EN 374-1, EN

374-2, EN 374-3, EN 420.

Respiratory protection: Where risk assessment shows that air-purifying respirators are appropriate, use dust

mask type N95 (USA) or type P1 (EN 149). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).

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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: Yellowish-brown or reddish-brown, amorphous powder.

Odour: Not available. Odour threshold: Not available. pH: 1.5 to 5.0 300 °C Melting/freezing point:

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

explosive limits:

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

Solubility: Practically insoluble in acetone.

Solubility in water: Soluble in water and in ethanol (96 per cent).

Partition coefficient Not available.

(n-octanol/water):

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

9.2 OTHER INFORMATION

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

Not available.

10.2 CHEMICAL STABILITY

Stable under recommended handling and storage conditions (see section 7).

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Not available.

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10.4 CONDITIONS TO AVOID

Not available.

10.5 INCOMPATIBLE MATERIALS

Oxidising agents.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

See section 5.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity: Acute oral toxicity (LD₅₀, rat): 8000 mg/kg

Skin corrosion/irritation: May cause mild skin irritation.

Serious eye damage/irritation: Not available. Respiratory/skin sensitisation: Not available. Germ cell mutagenicity: Negative. Not available. Carcinogenicity: Not available. Reproductive toxicity: Summary of evaluation of the Not available.

CMR properties:

STOT-single exposure: Not available. STOT-repeated exposure: Not available. Aspiration Hazard: Not available. Other: RTFCS: TR1579600

11.2 ADDITIONAL INFORMATION ON POTENTIAL ADVERSE HUMAN HEALTH EFFECTS AND SYMPTOMS

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

SECTION 12: ECOLOGICAL INFORMATION

Use in accordance with good working practices, avoiding dispersal of the product into the environment. Notify the competent authorities if the product has reached watercourses or if it has contaminated soil or vegetation.

12.1 TOXICITY

Toxicity to fish: Mortality LC₅₀ – Oncorhynchus mykiss (rainbow trout) 1050 mg/L – 1 h

12.2 PERSISTENCE AND DEGRADABILITY

Not available.

12.3 BIOACCUMULATIVE POTENTIAL

Not available.



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12.4 MOBILITY IN SOIL

Not available.

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

Not available.

12.6 OTHER ADVERSE EFFECTS

This substance/mixture does not contain components that are considered to be persistent bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative and very persistent (vPvB) at levels of 0.1% or higher.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Product: Consider all federal, state and local environmental regulations. Contact a licensed professional waste disposal service for disposal of this material. Dissolve or mix material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

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

The product is not to be considered dangerous according to the applicable regulations on the transport of dangerous goods by road (ADR), rail (RID), sea (IMDG Code) and air (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 available.

14.8 ADDITIONAL TRANSPORT INFORMATION

Carriage by sea in bulk under IMO instruments: Not applicable.



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SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:





Corrosive Irritant

Dangerous to the environment

Risk phrases: R38 Irritating to skin.

R41 Risk of serious damage to eyes.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the

aquatic environment.

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

medical advice.

S27 Take off immediately all contaminated clothing.

S28 After contact with skin, wash immediately with plenty of soap and water. S26/27/29 Wear suitable protective clothing, gloves and eye/face protection. S61 Avoid release to the environment. Refer to special instructions/safety data

sheet.

15.2 CHEMICAL SAFETY ASSESSMENT

A chemical safety assessment of the product has not been carried out.

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 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/



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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

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