Material Safety Data Sheet

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

POVIDONUM

Publication: 26/04/2022
Revision: XX/XX/XXXX
Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Povidone Povidonum Povidone Povidone Povidon
N° CAS:	9003-39-8
N° EC:	658-049-4

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

The substance is not classified according to Regulation (EC) 1272/2008 (CLP).

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.

2.3 Other hazards

None.

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POVIDONUM

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Povidone
IUPAC name:	1-ethenylpyrrolidin-2-one
Synonyms:	Polyvinylpyrrolidone (PVP) N-vinylpyrrolidone
N° CAS:	9003-39-8
N° EC:	658-049-4
Molecular Formula:	$C_{6n}H_{9n+2}N_nO_n$
Content:	11.5 per cent to 12.8 per cent of nitrogen (N; Ar 14.01) (anhydrous substance). The different types of povidone are characterised by their viscosity in solution expressed as a nominal K-value. The nominal K-value is 10 to 120. It consists of linear polymers of 1-ethenylpyrrolidin-2-one.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	Consult a doctor. 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.
After skin contact:	Wash immediately with plenty of soap and water for at least 15 minutes. Remove all 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 the eyelids, for at least 15 minutes. Get medical attention.
After ingestion:	If conscious, give the victim plenty of water to drink. Never give anything by mouth to an unconscious person. Call a doctor immediately.

4.2 Most important symptoms and effects, both acute and delayed

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:	Foam, dry powder, carbon dioxide, sand, water fog. Neighbouring fires (containers exposed to fire): Water spray or fog.
Unsuitable extinguishing media:	Direct water jet.

5.2 Special hazards arising from the substance/mixture

Avoid breathing combustion products (carbon dioxide, nitrous gases, cyanides).

5.3 Advice for firefighters

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

If vapours or dust are released when breathing, wear respiratory protection.

For emergency responders

If vapours or dust are released when breathing, wear respiratory protection.

6.2 Environmental precautions

Do not allow product to enter sewers, surface and/or ground water.

6.3 Methods and material for containment and cleaning up

Contain spillage with soil or inert material.

Collect most of the material and remove the residue with water jets.

Disposal of contaminated material must be carried out in accordance with section 13.

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:	Do not inhale dust. Avoid contact with eyes, skin and clothing.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Keep tightly closed. Store in a cool, dry place. Store in a dry and ventilated place.
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

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 viscoelastic 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:	Not required.
Skin protection:	Not required.
Hand protection:	Not required.
Respiratory protection:	Where risk assessment shows that air-purifying respirators are appropriate, use dust mask type N95 (USA) or type P1 (EN 143). Use respirators and components tested and approved under appropriate governmental standards such as NIOSH (US) or CEN (EU).
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 yellowish-white, hygroscopic powder or flakes.
Odour:	Weak (characteristic)
Odour threshold:	Not available.
pH:	3.0 – 7.0 (100 g/l, 20 °C)
Melting/freezing point:	> 130 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	990 °C
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.

Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in ethanol (96 per cent) and in methanol, very slightly soluble in acetone.
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	460 °C
Decomposition temperature:	Not available.
Viscosity:	K = 30
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Density: 0.449 g/ml

Dry residue: 100.00 % VOC (Directive 1999/13/EC)

VOC (Directive 1999/13/EC): 0

VOC (Volatile Carbon): 0

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable if used properly. No special conditions.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Extremely high temperatures.

10.5 Incompatible materials

Strong oxidizing agents.

10.6 Hazardous decomposition products

Carbon oxides (CO_x).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute toxicity (LD_{50}, rat): > 2 000 mg/kg Acute Toxicity (LC_{50}, rat): 5.2 mg/l - 4 h (OCSE)
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.

Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	No component of this product is identified as a probable, possible or confirmed human carcinogen at levels greater than or equal to 0.1%.
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
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:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Acute toxicity (LC_{50}, fish): > 10 000 mg/l - 96 h (*Leuciscus idus*)

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

PBT/vPvB assessment is not available as chemical safety assessment is not required/not performed.

12.6 Other adverse effects

Not available.

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 container: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) : It is not dangerous in transport.

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

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).

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 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/

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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