

Material Safety Data Sheet

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

PHOLCODINUM MONOHYDRICUM

EN

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

1.1 Product identifier

Product name:	Pholcodine monohydrate Pholcodinum monohydricum Folcodine monohydraat Pholcodine monohydratée Pholcodin-Monohydrat
N° CAS:	6254-99-5
N° EC:	823-357-1

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

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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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

Acute Tox. 4	H302
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2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention; Warning

Hazard statements:

H302 Harmful if swallowed.

Precautionary statements:

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P260	Do not breathe dust.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P280	Wear protective gloves/protective clothing/eye protection.
P309+P311	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P301+P312	IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
P330	Rinse mouth.
P405	Store Locked up
P501	Dispose of contents/container to an approved waste disposal plant.

Additional applicable label elements:



2.3 Other hazards

Physical-, chemical and toxicological hazards: May be harmful by inhalation and in contact with skin. May be sensitizing. May cause some adverse effects to the unborn child. May cause some adverse effects on breastfeed babies. Risk of dust explosion.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Pholcodine monohydrate
IUPAC name:	(4 <i>R</i> ,4 <i>aR</i> ,7 <i>S</i> ,7 <i>aR</i> ,12 <i>bS</i>)-3-methyl-9-(2-morpholin-4-ylethoxy)-2,4,4 <i>a</i> ,7,7 <i>a</i> ,13-hexahydro-1 <i>H</i> -4,12-methanobenzofuro[3,2- <i>e</i>]isoquinolin-7-ol;hydrate
Synonyms:	3-(2-Morpholinoethyl)morphine monohydrate 17-Methyl-3-[2-(morpholin-4-yl)ethoxy]-7,8-didehydro-4,5 <i>α</i> -epoxymorphinan-6 <i>α</i> -ol monohydrate.
N° CAS:	6254-99-5
N° EC:	823-357-1
Molecular Formula:	C ₂₃ H ₃₀ N ₂ O ₄ , H ₂ O
Content:	98.5 per cent to 101.5 per cent (dried substance)

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

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General notes:	Move out of dangerous area. Remove contaminated clothing immediately and dispose of safely. When in doubt or if symptoms are observed, get medical advice.
After inhalation:	Make the victim breathe fresh air. Make the victim blow his nose. Seek medical advice immediately.
After skin contact:	Rinse immediately with plenty of soap and water for at least 15 minutes. Change contaminated, saturated clothing. Wash contaminated clothing prior to re-use. Seek medical advice immediately.
After eye contact:	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Seek medical advice immediately.
After ingestion:	Do not induce vomiting. Call emergency medical care. In case of acute poisoning, lie the victim in half upright position. Put the victim under medical supervision. Keep the victim warm. If major quantity of dust is swallowed or inhaled, immediately drink water.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms: Nausea, vomiting. Drowsiness. Dizziness. Irritations. Respiratory depression.

4.3 Indication of any immediate medical attention and special treatment needed

None.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	All means (e.g. water, carbon dioxide, dry chemical extinguisher).
Unsuitable extinguishing media:	Strong water jet.

5.2 Special hazards arising from the substance/mixture

In case of fire, the product may emit toxic and/or irritating fumes.
Supposed thermal decomposition/oxidation: Carbon monoxide, carbon dioxide and nitrogen oxides (NOx)

5.3 Advice for firefighters

Surrounding fires:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Collect contaminated fire extinguishing water separately and avoid rejection in the environment. Do not allow entering drains or surface water.
Protection against fire:	Use self-contained breathing apparatus. Wear full protective suit.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid contact with skin, eyes and clothes.
Use personal protection equipment. Insulating breathing apparatus and chemical suit.

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For emergency responders

Avoid contact with skin, eyes and clothes.

Use personal protection equipment. Insulating breathing apparatus and chemical suit.

6.2 Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Make sure spills can be contained, e.g. in sump pallets or kerbed areas.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

6.3 Methods and material for containment and cleaning up

General advice: Sweep and shovel the solid product in a container adapted for its recovery or destroying (avoiding dust formation). Close and label rigorously.

Cleaning of contaminated zone: After taking up the product, rinse the polluted area with water.

Elimination of recovered materials: Deliver to Environmental service of the factory or to any specialized and approved disposal service.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Not available.

Personal protection: Not available.

Technical protective measures: Local ventilation and emission point dust extraction. Enclosed transfer strongly recommended. Work in a defined area with restricted access recommended. Take precautionary measures against electrostatic loading. Earth vessels and equipment well. Handle milled or in bulk only after a detailed safety study.

Handling: Handling in a fume cupboard. Work in a defined area with restricted access recommended.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Keep/Store only in original container.

Conditions for safe storage, including any incompatibilities: Keep containers tightly closed in a cool, well-ventilated place. Store in a dark place. Keep at room temperature (below 25°C).

Packaging material advised: Glass, plastic, stainless steel.

Light-resistant container.

Storage class (TRGS 510) : 13

Storage – away from: Keep away from chemicals as it is a pharmaceutical substance. Keep away from moisture and light. The product is sensitive to light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

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8.1 Control parameters

Concentration limits in air: OEL-8h (Internal): : 12.5 µg/m³

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Special recommendations: Pregnant women, seek medical advice before handling. Specific dermal hazard: avoid any contact with skin. Warning drivers of machines on risks of drowsiness.

Eye/face protection: Eye glasses with side protection.

Skin protection: The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. DIN-/EN-Norms EN ISO 374 DIN EN 420 Suitable material NBR (Nitrile rubber) PVA (Polyvinyl alcohol) PVC (polyvinyl chloride).

General health and safety measures: Immediately remove any contaminated clothing, shoes or stockings. Wash contaminated clothing prior to re-use.

Hand protection: Doubled gloves recommended.

Glove material: Nitrile rubber.

Breakthrough time (maximum wearing time): > 60 m.

Thickness of the glove material: > 0.5 mm

Respiratory protection: If technical exhaust or ventilation measures are not possible or insufficient, respiratory protection must be worn.

Suitable respiratory protection apparatus: Full-/half-/quarter-face masks (DIN EN 136/140), filtering device (full mask or mouthpiece) with filter: ABEK-P3.

Thermal hazards: Not determined.

Environmental exposure control

See section 7. No additional measures necessary.

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: Not available.

Melting/freezing point: Ca. 91 °C

Initial boiling point: Not available.

Boiling range: Not available.

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Flash point:	Not applicable.
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 acetone and in ethanol (96 per cent). It dissolves in dilute mineral acids.
Solubility in water:	Sparingly soluble in water.
Partition coefficient (n-octanol/water):	Log(Pow): 0.56 Method: Computed value
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Molar mass: 416.5 g/mol

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not applicable.

10.2 Chemical stability

Stable under normal conditions of use.

Safety remarks: Risk of dust explosion.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Not available.

10.5 Incompatible materials

Strong acids and oxidizing agents

10.6 Hazardous decomposition products

Supposed thermal decomposition/oxidation: Carbon monoxide and carbon dioxide. Nitrogen oxides (NO_x).

SECTION 11: TOXICOLOGICAL INFORMATION

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11.1 Information on toxicological effects

Acute toxicity:	Oral LD ₅₀ (mouse): 1000 mg/kg
Skin corrosion/irritation:	Irritant.
Serious eye damage/irritation:	Irritant.
Respiratory/skin sensitisation:	Not sensitizing.
Germ cell mutagenicity:	No indications of human germ cell mutagenicity exist.
Carcinogenicity:	This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.
Reproductive toxicity:	This substance does not meet the criteria for classification as CMR category 1A or 1B according to CLP.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not applicable.
STOT-repeated exposure:	Prolonged or repeated contact with skin or mucous membrane result in irritation symptoms such as redness, blistering, dermatitis, etc.
Aspiration Hazard:	Not available.
Other:	Pharmacological activity: Substance pharmacologically active. Opioid analgesic. Other toxicity data: Nausea, vomiting. Constipation. Drowsiness. Dizziness. Risk of dependence.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Harmless to aquatic organisms up to the tested concentration.

12.2 Persistence and degradability

Biodegradable.

12.3 Bioaccumulative potential

No indication of bioaccumulation potential.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

This substance does not meet the PBT/vPvB criteria of REACH, Annex XIII.

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12.6 Other adverse effects

Note: Ecological data insufficient for a precise risk assessment. Do not release material and cleaning waters into the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Delivery to an approved waste disposal company. Contaminated packages must be completely emptied and can be re-used following proper cleaning. Handle contaminated packages in the same way as the substance itself.

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) : Not a dangerous good within the meaning of these transport regulations.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not a dangerous good within the meaning of these transport regulations.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not a dangerous good within the meaning of these transport regulations.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not a dangerous good within the meaning of these transport regulations.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not a dangerous good within the meaning of these transport regulations.

14.6 Special precautions for user

None.

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

Not applicable.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Irritant

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Risk phrases: R22 Harmful if swallowed.
Safety phrases: S20/21 When using do not eat, drink or smoke.
S56 Dispose of this material and its container to hazardous or special waste collection point.
S64 If swallowed, rinse mouth with water (only if the person is conscious).

15.2 Chemical safety assessment

Chemical safety assessments for substances in this preparation were not 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 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)

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

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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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