

# Material Safety Data Sheet

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

## HYOSCINI HYDROBROMIDUM

EN

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Version: 01



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

#### 1.1 Product identifier

Product name: Hyoscine hydrobromide  
Hyoscini hydrobromidum  
Hyoscine hydrobromide  
Hyoscine (bromhydrate de)  
Scopolaminhydrobromid

N° CAS: 6533-68-2

N° EC: 204-050-6

#### 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

Acute Tox. 2	H300
Acute Tox. 4	H302
Acute Tox. 1	H310
Acute Tox. 2	H330
Repr. 2	H361

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



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Signal word(s):	Danger
Hazard statements:	
H300	Fatal if swallowed.
H302	Harmful if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H361	Suspected of damaging fertility or the unborn child.
Precautionary statements:	
P201	Obtain special instructions before use.
P202	Do not handle until all safety precautions have been read and understood.
P203	Obtain, read and follow all safety instructions before use.
P260	Do not breathe dust/fumes/gas/mist/vapours/spray.
P262	Do not get in eyes, on skin, or on clothing
P264	Wash hands thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P281	Use personal protective equipment as required.
P284	In case of inadequate ventilation wear respiratory protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.
P301+P316	IF SWALLOWED: Get emergency medical help immediately.
P301+P317	IF SWALLOWED: Get emergency medical help.
P302+P350	IF ON SKIN: Gently wash with plenty of soap and water.
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.
P308+P313	If exposed: Call a POISON CENTER or doctor/physician.
P310	Immediately call a POISON CENTER/doctor.
P316	Get emergency medical help immediately.
P318	If exposed or concerned, get medical advice.
P320	Specific treatment is urgent (see on this label).
P321	Specific treatment (see on this label).
P322	Specific measures (see on this label).
P330	Rinse mouth.
P361	Take off immediately all contaminated clothing.
P361+P364	Take off immediately all contaminated clothing and wash it before reuse.
P363	Wash contaminated clothing before reuse.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container in accordance with all local and national legislation.

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Additional applicable label elements:



### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Hyoscine hydrobromide
IUPAC name:	(1R,2R,4S,5S,7s)-9-Methyl-3-oxa-9-azatricyclo[3.3.1.0 <sup>2,4</sup> ]non-7-yl (2S)-3-hydroxy-2-phenylpropanoate hydrobromide trihydrate
Synonyms:	Scopolamine hydrobromide trihydrate Isopto hyoscine
N° CAS:	6533-68-2
N° EC:	204-050-6
Molecular Formula:	C <sub>17</sub> H <sub>22</sub> BrNO <sub>4</sub> ·3H <sub>2</sub> O
Content:	99.0 per cent to 101.0 per cent (anhydrous 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 well ventilated area; seek medical advice.
After skin contact:	Rinse immediately with plenty of water; seek medical advice.
After eye contact:	Rinse immediately with plenty of water; seek medical advice.
After ingestion:	Rinse immediately with plenty of water; seek medical advice.

### 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:	In case of fire, use water, dry chemical, foam, or alcohol resistant foam.
Unsuitable extinguishing media:	Not available.

### 5.2 Special hazards arising from the substance/mixture

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Disintegrates above 193 °C forming hardly combustible substances.

### 5.3 Advice for firefighters

Surrounding fires:	No special measures required.
Protection against fire:	In the event of fire, wear a self-contained breathing apparatus and a chemical 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

Wear protective clothing. Particular danger of slipping on leaked/spilled product. Avoid substance contact. Avoid generation of dusts. Avoid inhalation of dusts. Ensure supply of fresh air in enclosed rooms. Personal precautions and collective precautions: filtering gas masks containing K mark cartridge, as well as personal protection measures as specified in section 8.

#### For emergency responders

Wear protective clothing. Particular danger of slipping on leaked/spilled product. Avoid substance contact. Avoid generation of dusts. Avoid inhalation of dusts. Ensure supply of fresh air in enclosed rooms. Personal precautions and collective precautions: filtering gas masks containing K mark cartridge, as well as personal protection measures as specified in section 8.

### 6.2 Environmental precautions

Collect the spread product in special containers (bags).

### 6.3 Methods and material for containment and cleaning up

Collect mechanically.  
Dispose of the material collected according to regulations.  
Depending on the degree of contamination dispose of by use on farm or to an authorized waste facility (e.g. producer).  
Wash up residues with plenty of water.

### 6.4 Reference to other sections

See section 8 for personal protective equipment and section 13 for waste disposal.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Not available.
Personal protection:	While using, use gloves, wash hands well after work. Wear protective glasses.
Technical protective measures:	Prevent formation of dust.
Handling:	Not available.

### 7.2 Conditions for safe storage, including any incompatibilities

Storage:	In a well-filled, airtight container of small capacity.
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Conditions for safe storage, including any incompatibilities:

The product may also be stored in closed, dry and ventilated storing premises. Bulk product must be stored in closed, dry and ventilated storing premises. Product packed in large bags should be kept in vertical position, on pallets without protruding nails and/or sharp wood splinters, which could damage the bag.

Storage – away from:

Store protected from direct sunlight, precipitation, humidity (rain or snow, do not let water be collected on the package or package lay in water).

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Regulated occupational exposure limit values:

Maximum allowable value for long-term exposure: 500 micron/m<sup>3</sup>

### 8.2 Exposure controls

#### Appropriate engineering control

Air supply-extraction ventilation. Hygiene measures: After finishing work, take a shower, change clothing.

#### Individual protection measures

Eye/face protection: Wear glasses.

Skin protection: Working clothes, special boots.

Hand protection: Working gloves.

Respiratory protection: Respiratory mask.

Thermal hazards: Not determined.

#### Environmental exposure control

Dispose of rinse water in accordance with local and national regulations.

## 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, efflorescent.

Odour: Odourless.

Odour threshold: Not available.

pH: 4.0 to 5.5 (1% soln/water)

Melting/freezing point: 194 – 197 °C

Initial boiling point: Not available.

Boiling range: Not available.

Flash point: Not available.

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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:	Soluble in ethanol (96 per cent).
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

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

### 10.2 Chemical stability

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

### 10.3 Possibility of hazardous reactions

None.

### 10.4 Conditions to avoid

High ambient temperature.

### 10.5 Incompatible materials

Contact with other (unpacked) chemical substances is not allowed.

### 10.6 Hazardous decomposition products

None without changing the physical state of the substance.

## SECTION 11: TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

Acute toxicity: Oral LD50 (rat): 1 270 mg/kg

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Skin corrosion/irritation:	Not irritating.
Serious eye damage/irritation:	No irritant effect.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Ames test – Negative.
Carcinogenicity:	Experiments references show no carcinogenic effects on laboratory animals.
Reproductive toxicity:	Experiments references show no reproductive toxicity effects on laboratory animals.
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:	Fatal in contact with skin.
Inhalation:	Fatal if inhaled.
Ingestion:	Fatal if swallowed. Harmful if swallowed.
Aspiration:	Not available.

## SECTION 12: ECOLOGICAL INFORMATION

### 12.1 Toxicity

Not available.

### 12.2 Persistence and degradability

Products of biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the products of biodegradation: The products of degradation are less toxic than the product itself.

### 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

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

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Dispose of or mix material with a suitable combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Material should be disposed of in accordance with all local and national legislation. Packaging should be disposed of in accordance with all local and national legislation. Treat contaminated containers as 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) : 1544

##### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : ALKALOID SALTS, SOLID, N.O.S.

##### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : 6.1 Toxic substances

##### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : II

##### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Marine pollutant: No.

##### 14.6 Special precautions for user

Warning: Toxic substances.  
Danger code (Kemler): 60  
EMS Number: F-A,S-A  
Stowage category: A

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

Not applicable.

##### 14.8 Additional transport information

Not classified as dangerous in the meaning of transport regulation.

### SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Very toxic  
Irritant  
Harmful



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### Risk phrases:

R22 Harmful if swallowed.  
R26/27/28 Very toxic by inhalation, in contact with skin and if swallowed.  
R62 Possible risk of impaired fertility.  
R63 Possible risk of harm to the unborn child.

### Safety phrases:

S1 Keep locked up.  
S7/9 Keep container tightly closed and in a well-ventilated place.  
S20/21 When using do not eat, drink or smoke.  
S23 Do not breathe dust/fumes/gas/mist/vapours/spray.  
S24/25 Avoid contact with skin and eyes.  
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.  
S38 In case of insufficient ventilation wear suitable respiratory equipment.  
S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).  
S46 If swallowed, seek medical advice immediately and show this container or label.  
S51 Use only in well-ventilated areas.  
S53 Avoid exposure – obtain special precautions before use.  
S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.  
S64 If swallowed, rinse mouth with water (only if the person is conscious).

### 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

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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 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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