

PILOCARPINI HYDROCHLORIDUM

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

1.1 PRODUCT IDENTIFIER

Product name:	EN: Pilocarpine hydrochloride
	LAT: Pilocarpini hydrochloridum
	NL: Pilocarpine hydrochloride
	FR: Pilocarpine (chlorhydrate de)
	DE: Pilocarpinhydrochlorid
N° CAS:	54-71-7
N° EC:	200-212-5

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE/MIXTURE AND USES ADVISED AGAINST

Identified uses:	Active Pharmaceutical Ingredient.
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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., oral 3	H301
Acute Tox. 2	H330

2.2 LABEL ELEMENTS

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H300+H330 Fatal if swallowed or if inhaled.

H301 Toxic if swallowed.

Precautionary statements:

P260 Do not breathe dust/fume/gas/mist/vapors/spray.

P264 Wash hands [and ...] thoroughly after handling.

MAGIS-PHARMA NV

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P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P284	[In case of inadequate ventilation] Wear respiratory protection.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P301+P316	IF SWALLOWED: Get emergency medical help immediately.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P316	Get emergency medical help immediately.
P320	Specific treatment is urgent (see ... on this label).
P321	Specific treatment (see ... on this label).
P330	Rinse mouth.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P405	Store locked up.
P501	Dispose of contents/container to local/regional/national/international regulations.

Additional applicable label elements:



2.3 OTHER HAZARDS

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

Product name:	Pilocarpine hydrochloride
IUPAC name:	(3S,4R)-3-Ethyl-4-[(1-methyl-1H-imidazol-5-yl)methyl]-dihydrofuran-2(3H)-one hydrochloride
Synonyms:	Pilocarpine HCl Almocarpine Salagen Pilocarpal
N° CAS:	54-71-7
N° EC:	200-212-5
Molecular Formula:	C ₁₁ H ₁₇ ClN ₂ O ₂
Content:	99.0 per cent to 101.0 per cent (dried substance)

3.2 MIXTURES

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General notes:	First aider: Pay attention to self-protection! Remove affected person from the danger area and lay down.
After inhalation:	Provide fresh air. No mouth-to-mouth or mouth-to-nose resuscitation. Use Ambu bag or ventilator. Call a physician immediately.

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After contact with skin:	Wash with plenty of water. Immediately remove any contaminated clothing, shoes or stockings. Medical treatment necessary.
After contact with eyes:	After eye contact: Rinse immediately carefully and thoroughly with eye-bath or water. Consult an ophthalmologist.
After ingestion:	Never give anything by mouth to an unconscious person or a person with cramps. Rinse mouth immediately and drink 1 glass of water. Induce vomiting when the affected person is not unconscious. Call a physician immediately. Do NOT induce vomiting.

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

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media:	Co-ordinate fire-fighting measures to the fire surroundings.
Unsuitable extinguishing media:	Full water jet.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE/MIXTURE

Non-flammable.

5.3 ADVICE FOR FIREFIGHTERS

Surrounding fires:	Use water spray jet to protect personnel and to cool endangered containers. Suppress gases/vapours/mists with water spray jet. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.
Protection against fire:	In case of fire: Wear 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

General advice: Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

FOR EMERGENCY RESPONDERS

General advice: Avoid dust formation. Do not breathe dust. Avoid contact with skin, eyes and clothes. Use personal protection equipment.

6.2 ENVIRONMENTAL PRECAUTIONS

Do not allow to enter into surface water or drains.

6.3 METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

Take up mechanically. Treat the recovered material as prescribed in the section on waste disposal.

6.4 REFERENCE TO OTHER SECTIONS

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Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: HANDLING AND STORAGE

7.1 PRECAUTIONS FOR SAFE HANDLING

Precautions for safe handling:	If handled uncovered, arrangements with local exhaust ventilation have to be used. Avoid dust formation. Do not breathe dust.
Personal protection:	Not available.
Technical protective measures:	No special fire protection measures are necessary.
Handling:	Remove contaminated, saturated clothing immediately. Draw up and observe skin protection programme. Wash hands and face before breaks and after work and take a shower if necessary. When using do not eat, drink, smoke, sniff.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Keep container tightly closed. Keep locked up. Store in a place accessible by authorized persons only. Provide adequate ventilation as well as local exhaustion at critical locations.
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

To date, no national critical limit values exist.

8.2 EXPOSURE CONTROLS

APPROPRIATE ENGINEERING CONTROL

If handled uncovered, arrangements with local exhaust ventilation have to be used. Do not breathe dust.

INDIVIDUAL PROTECTION MEASURES

Eye/face protection:	Wear eye/face protection.
Skin protection:	Use of protective clothing.
Hand protection:	When handling with chemical substances, protective gloves must be worn with the CE-label including the four control digits. 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.
Respiratory protection:	In case of inadequate ventilation wear respiratory protection.
Thermal hazards:	Not determined.

ENVIRONMENTAL EXPOSURE CONTROL

Not available.

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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, hygroscopic.
Odour:	Characteristic.
Odour threshold:	Not available.
pH:	3.5 to 4.5
Melting/freezing point:	201 - 205 °C
Initial boiling point:	Not determined.
Boiling range:	Not determined.
Flash point:	Not applicable.
Evaporation rate:	Not determined.
Flammability (solid/gas):	Solid/liquid: Not determined. Gas: Not applicable.
Upper/lower flammability or explosive limits:	Not determined.
Vapour pressure:	Not determined.
Vapour density:	Not determined.
Relative density:	Not determined.
Solubility:	Freely soluble in ethanol (96 per cent).
Solubility in water:	Very soluble in water.
Partition coefficient (n-octanol/water):	Not determined.
Auto-ignition temperature:	Not determined.
Decomposition temperature:	Not determined.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	The product is not oxidising.

9.2 OTHER INFORMATION

Molecular weight: 244.7

SECTION 10: STABILITY AND REACTIVITY

10.1 REACTIVITY

No hazardous reaction when handled and stored according to provisions.

10.2 CHEMICAL STABILITY

The product is stable under storage at normal ambient temperatures.

10.3 POSSIBILITY OF HAZARDOUS REACTIONS

Not available.

10.4 CONDITIONS TO AVOID

None.

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10.5 INCOMPATIBLE MATERIALS

Not available.

10.6 HAZARDOUS DECOMPOSITION PRODUCTS

No known hazardous decomposition products.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity:	Inhalation ATE (vapour): 0,5 mg/l Inhalation ATE (dust/mist): 0,05 mg/l Dermal: Data lacking. Oral LD ₅₀ (mouse): 200 mg/kg Fatal if swallowed. Fatal if inhaled.
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Based on available data, the classification criteria are not met.
Respiratory/skin sensitisation:	Based on available data, the classification criteria are not met.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met.
Carcinogenicity:	Based on available data, the classification criteria are not met.
Reproductive toxicity:	Based on available data, the classification criteria are not met.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Based on available data, the classification criteria are not met.
STOT-repeated exposure:	Based on available data, the classification criteria are not met.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	This substance is classified as hazardous according to Regulation (EC) No 1272 (2008). Special hazards arising from the substance or mixture.

11.2 ADDITIONAL INFORMATION ON POTENTIAL ADVERSE HUMAN HEALTH EFFECTS AND SYMPTOMS

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

SECTION 12: ECOLOGICAL INFORMATION

12.1 TOXICITY

The product is not: Ecotoxic.
Acute crustacea toxicity, EC₅₀: 13,1 mg/l (48h) (*Daphnia magna* (Big water flea))

12.2 PERSISTENCE AND DEGRADABILITY

The product has not been tested.

12.3 BIOACCUMULATIVE POTENTIAL

The product has not been tested.

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12.4 MOBILITY IN SOIL

The product has not been tested.

12.5 RESULTS OF PBT AND VPVB ASSESSMENT

This substance does not have endocrine disrupting properties with respect to non-target organisms.

12.6 OTHER ADVERSE EFFECTS

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

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

Disposal recommendations

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil. Dispose of waste according to applicable legislation.

List of Wastes Code - residues/unused products

070513	WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of pharmaceuticals; solid wastes containing hazardous substances; hazardous waste
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List of Wastes Code - used product

070513	WASTES FROM ORGANIC CHEMICAL PROCESSES; wastes from the MFSU of pharmaceuticals; solid wastes containing hazardous substances; hazardous waste
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List of Wastes Code - contaminated packaging

150110	WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED; packaging (including separately collected municipal packaging waste); packaging containing residues of or contaminated by hazardous substances; hazardous waste
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Contaminated packaging

Hazardous waste according to Directive 2008/98/EC (waste framework directive). 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), 1544
IATA/ICAO (Air) :

14.2 UN PROPER SHIPPING NAME

ADR/ RID(Land),IMDG(Sea), ALKALOIDS, SOLID, N.O.S. (PILOCARPIN HYDROCHLORID)
IATA/ICAO (Air) :

14.3 TRANSPORT HAZARD CLASS(ES)

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

14.4 PACKING GROUP

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

14.5 ENVIRONMENTAL HAZARDS

ADR/ RID(Land),IMDG(Sea), Environmentally hazardous: No.
IATA/ICAO (Air) :

14.6 SPECIAL PRECAUTIONS FOR USER

Land transport (ADR/RID)

Classification code: T2
Special provisions: 43 274
Limited quantity: 500 g
Excepted quantity: E4
Transport category: 2
Hazard No: 60
Tunnel restriction code: D/E

Marine transport (IMDG)

Special provisions: 43 274
Limited quantity: 500 g
Excepted quantity: E4
EmS: F-A, S-A

Air transport (ICAO-TI/IATA-DGR)

Special provisions: A3 A5 A6 A801
Limited quantity passenger: 1 kg
Passenger LQ: Y644
Excepted quantity: E4
IATA-packing instructions - Passenger: 669
IATA-max. quantity - Passenger: 25 kg
IATA-packing instructions - Cargo: 676
IATA-max. quantity - Cargo: 100 kg

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

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Hazard symbol:



Risk phrases:

Acute toxicity

R28 Very toxic if swallowed.

R23; R26 Toxic by inhalation; Very toxic by inhalation.

Safety phrases:

S7/9 Keep container tightly closed and in a well-ventilated place.

S23 Do not breathe gas/fumes/vapour/spray.

S38 In case of insufficient ventilation wear suitable respiratory equipment.

S46 If swallowed, seek medical advice immediately and show this container or label.

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

For this substance 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 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

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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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