

NALTREXONI HYDROCHLORIDUM

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

1.1 Product identifier

Product name:	Naltrexone hydrochloride Naltrexoni hydrochloridum Naltrexon hydrochloride Naltrexone (Chlorhydrate de) Naltrexonhydrochlorid
N° CAS:	16676-29-2
N° EC:	240-723-0

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. 4	H302
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2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H302	Harmful if swallowed.
H312	Harmful in contact with skin.

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H332	Harmful if inhaled.
H341	Suspected of causing genetic defects.
Precautionary statements:	
P203	Obtain, read and follow all safety instructions before use.
P233	Keep container tightly closed.
P260	Do not breathe dust/fume/gas/mist/vapors/spray.
P264	Wash hands [and ...] thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...
P284	[In case of inadequate ventilation] Wear respiratory protection.
P301+P317	IF SWALLOWED: Get medical help.
P302+P352	IF ON SKIN: wash with plenty of water/...
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P318	If exposed or concerned, get medical advice.
P321	Specific treatment (see section 4 on this label).
P330	Rinse mouth.
P333+P317	If eye irritation persists: Get medical help.
P342+P316	If experiencing respiratory symptoms: Get emergency medical help immediately.
P362+P364	Take off contaminated clothing and wash it before reuse.
P403	Store in a well-ventilated place.
P405	Store locked up.
P501	Dispose of contents/container to local/regional/national/international regulations.
Additional applicable label elements:	Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Naltrexone hydrochloride
IUPAC name:	(5 α)-17-(cyclopropylmethyl)- 4,5-epoxy-3,14- dihydroxymorphinan-6-one hydrochloride
Synonyms:	Naltrexone Hcl
N° CAS:	16676-29-2
N° EC:	240-723-0

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Molecular Formula: $C_{20}H_{24}ClNO_4 \cdot HCl$
Content: 98.0 per cent to 102.0 per cent (anhydrous substance)

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, also under the 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.

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 under heading 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: Use water spray, alcohol-resistant foam, dry powder or carbon dioxide.
Unsuitable extinguishing media: There are no extinguishing agent limitations for this substance/mixture.

5.2 Special hazards arising from the substance/mixture

Carbon oxides (CO, CO₂).
Nitrogen oxides (NO_x).
Hydrogen chloride gas.

5.3 Advice for firefighters

Surrounding fires: Cool containers with water to avoid product decomposition and the development of health hazards. Always use complete fire protection. Collect water that should not enter sewage system. Dispose of contaminated water used to extinguish and the remains of the second in accordance with current regulations.

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Protection against fire:

Helmet with visor, flame retardant clothing (jacket and pants with straps around the arms, legs and waist, EN 469), gloves (fireproof and dielectric, EN 659), a mask with face mask covering the entire face of the operator or the car (self-protector) in the 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 it from entering sewers and water pipes. If product enters sewers 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.

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:

Ensure good ventilation of the processing area to avoid vapor formation.

Handling:

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

In an airtight container.

Conditions for safe storage, including any incompatibilities:

Not available.

Storage – away from:

Protected from light.

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7.3 Specific end use(s)

Active Pharmaceutical Ingredient.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

In the risk assessment process, it is recommended to take into account the ACGIH occupational exposure limit values for unclassified inert dusts (respirable PNOC: 3 mg/mc; inhalable PNOC: 10 mg/mc). If these limits are exceeded, it is recommended to use a type P filter whose class (1, 2 or 3) will be selected depending on the results of the risk assessment.

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 bear the CE marking attesting to 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 the end of the workday.

Individual protection measures

Eye/face protection: Protective face shields and safety glasses according to EN 165, EN 166, EN 167, EN 168.

Skin protection: Choose body protection according to the amount 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 (USA) 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 almost white powder, very hygroscopic.

Odour: Not available.

Odour threshold: Not available.

pH: Not available.

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Melting/freezing point:	274 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
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:	Slightly soluble in ethanol (96 per cent), practically insoluble in methylene chloride.
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

Molecular weight (g/mol): 377,90

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

There are no special risks of reaction with other substances under normal conditions of use.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Dusts are potentially explosive when mixed with air.

10.4 Conditions to avoid

Avoid accumulation of dust in the environment.

10.5 Incompatible materials

Not available.

10.6 Hazardous decomposition products

See section 5.

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SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity (LD ₅₀ , rat): 1450 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Negative.
Carcinogenicity:	Not available.
Reproductive toxicity:	May damage the fetus or fertility.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	N° RTECS: TU3980000

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

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

12.1 Toxicity

Not available.

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

Not available.

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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 to dispose 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), 1544
IATA/ICAO (Air) :

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), ALKALINE SOLID, N.A.S. or SALT OF ALKALINE SOLID, N.A.S. (NALTREXONE
IATA/ICAO (Air) : HYDROCHLORIDE)

14.3 Transport hazard class(es)

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

14.4 Packing group

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

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), It is not dangerous for the environment.
IATA/ICAO (Air) :

14.6 Special precautions for user

Transport by land (ADR)

Hazard identification number (Kemler code): 60

Limited quantities: 5 kg

Tunnel restriction code: E

Maritime transport (IMDG)

EMS (No FS (fire) and No FS (spill)): F-A and S-A

Limited quantities: 5 kg

Air transport (IATA)

Maximum net quantity for passenger and cargo aircrafts: 100 kg

Maximum net quantity for Cargo Aircraft Only: 200 kg

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Packing instructions for passenger and cargo aircraft: 670
Packing Instructions for Cargo Aircraft Only: 677
Special provisions: A3, A5, A6, A801

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

Not available.

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:



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 at hazardous or special waste collection point.

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 Bioaccumulative

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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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