

MATERIAL SAFETY DATA SHEET: *NALTREXONE HYDROCHLORIDE DIHYDRATE*

According to regulation (EC) 1907/2006, regulation (EU) 830/2015 and OSHA HCS

Revision date: 17/02/2017

Version: 4

SECTION 1 - Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name	<i>Naltrexone Hydrochloride Dihydrate</i>
Product code	NT
CAS number	850808-02-5
EINECS number	240-723-0

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

Active Pharmaceutical Ingredient

1.3 Details of the supplier of the safety data sheet

S.A.L.A.R.S. S.p.A.
Via San Francesco 5
22100 COMO Italy
Phone +39 031 524095
Fax +39 031 520751
E-mail: contact@salars.it

1.4 Emergency telephone number

+39 02-6610-1029 (Centro Antiveneni Niguarda Ca' Granda - Milano)

SECTION 2 - Hazards identification

2.1 Classification of the substance or mixture

Classification according to regulation (EC) 1272/2008



GHS07

Acute Tox. 4

H302 Harmful if swallowed

2.2 Label elements

Labelling according to regulation (EC) 1272/2008

The substance is classified and labelled according to the CLP regulation.

(contd. on page 2)

Hazard pictograms GHS07

Signal word Warning

Hazard statements

H302 Harmful if swallowed

Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapors/spray

P264 Wash thoroughly after handling

P270 Do not eat, drink or smoke when using this product

P280 Wear protective gloves

P301+P312 IF SWALLOWED: call a POISON CENTER or doctor/physician if you feel unwell

P321 Specific treatment (see on this label)

P330 Rinse mouth

P405 Store locked up

P501 Dispose of contents/container in accordance with local/regional/national/international regulation

Classification system

NFPA ratings (scale 0-4)

HMIS ratings (scale 0-4)

2.3 Other hazards

None.

SECTION 3 - Composition/information on ingredients

3.1 Substances

Formula: $C_{20}H_{23}NO_4 \cdot HCl \cdot 2H_2O$

Molecular Weight: 413,89 g/mol

Chemical name: (5 α)-17-(Cyclopropylmethyl)-4,5-epoxy-3,14-dihydroxymorphinan-6-one hydrochloride
dihydrate

CAS# 850808-02-5

EINECS# 240-723-0

SECTION 4 - First aid measures

4.1 Description of first aid measures

General information

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

(contd. on page 3)

After inhalation

Supply fresh air and to be sure call for a doctor. In case of unconsciousness place patient stably in side position for transportation.

After skin contact

Immediately wash with water and soap and rinse thoroughly.

After eye contact

Rinse opened eye for several minutes under running water.

After swallowing

Immediately call a doctor.

4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5 - Firefighting measures

5.1 Extinguishing media

Carbon dioxide, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products are formed under fire conditions: carbon oxides, nitrogen oxides (NO_x), hydrogen chloride gas.

5.3 Advice for firefighters

Wear self-contained respiratory protective device and fully protective suit.

SECTION 6 - Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective equipment. Keep unprotected persons away.

6.2 Environmental precautions

Do not allow product to reach sewage system or any water course.
Inform respective authorities in case of seepage into water course or sewage system.
Do not allow to enter sewers/ surface or ground water.

6.3 Methods and material for containment and cleaning up

Dispose contaminated material as waste according to item 13. Ensure adequate ventilation.

6.4 Reference to other sections

See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7 - Handling and storage

7.1 Precautions for safe handling

Keep receptacles tightly sealed.
Thorough dedusting.
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of dust.
Information about fire and explosion protection: no special measures required.

7.2 Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles: no special requirements.
Information about storage in one common storage facility: not required.
Protect from exposure to the light. Store in cool (below 27°C), dry conditions in well-sealed receptacles.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8 - Exposure controls/personal protection

8.1 Control parameters

Components with limit values that require monitoring at the workplace: not required.
The lists valid during the making were used as basis.

8.2 Exposure controls

General protective and hygienic measures
Be sure to clean skin thoroughly after work and before breaks.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.

Respiratory protection

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device dust mask type N95 (US) or type P1 (EN 143). Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hands protection

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it. Handle with gloves.

Eye protection

Safety glasses with side-shields conforming to EN 166.

Skin and body protection

Protective work clothing.

SECTION 9 - Physical and chemical properties

9.1 Information on basic physical and chemical properties

General Information

Appearance

Form Crystalline powder
 Colour White or almost white

Odour odourless

pH	No data available
Melting point	(274-276)°C (crystals from methanol)
Boiling point	No data available
Flash point	Not applicable
Flammability (solid, gaseous)	Product is not flammable
Ignition temperature	No data available
Decomposition temperature	No data available
Danger of explosion	Product does not present an explosion hazard
Lower explosion limit	Not determined
Upper explosion limit	Not determined
Vapour pressure	Not applicable
Density	No data available
Relative density	No data available
Vapour density	Not applicable
Evaporation rate	Not applicable
Water solubility	About 50 g/l
Viscosity	Not applicable
Partition coefficient (n-octanol/water)	No data available

9.2 Other information

No further relevant information available.

SECTION 10 - Stability and reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.
To avoid thermal decomposition do not overheat.

10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

Moisture. Light.

10.5 Incompatible materials

Bases.

10.6 Hazardous decomposition products

Hazardous decomposition products formed under fire conditions: carbon oxides, nitrogen oxides (NO_x), hydrogen chloride gas.

SECTION 11 - Toxicological information

11.1 Information on toxicological effects

Acute toxicity

LD₅₀ Oral-rat 1450 mg/kg.

Skin corrosion/irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory or skin sensitization

No data available.

Germ cell mutagenicity

No data available.

Carcinogenicity

IARC (International Agency for Research on Cancer): substance is not listed.

NTP (National Toxicology Program): substance is not listed.

OSHA-Ca (Occupational Safety & Health Administration): substance is not listed.

(contd. on page 7)

Reproductive toxicity
No data available.

Specific target organ toxicity (STOT) - single exposure
No data available.

Specific target organ toxicity (STOT) - repeated exposure
No data available.

Aspiration hazard
No data available.

Potential health effects

Inhalation May be harmful if inhaled. May cause respiratory tract irritation.

Ingestion Harmful if swallowed.

Skin May be harmful if absorbed through skin. May cause skin irritation.

Eyes May cause eye irritation.

Signs and Symptoms of Exposure
Nausea, Headache, Vomiting.

Additional Information
RTECS#: QD2160000

SECTION 12 - Ecological information

12.1 Toxicity

No data available.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

Not applicable.

12.6 Other adverse effects

No data available.

SECTION 13 - Disposal considerations

13.1 Waste treatment methods

Product

Must be specially treated adhering to official regulations.
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

Contaminated packaging

Disposal must be made according to official regulations.

SECTION 14 - Transport information

14.1 UN-Number

Not applicable (Not dangerous goods).

14.2 UN proper shipping name

Not applicable (Not dangerous goods).

14.3 Transport hazard class(es)

Not applicable (Not dangerous goods).

14.4 Packing group

Not applicable (Not dangerous goods).

14.5 Environmental hazards

None.

14.6 Special precautions for user

Not applicable.

14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15 - Regulatory information

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

Directive 2012/18/EU Named dangerous substances - ANNEX I
Substance is not listed.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16 - Other information

This MSDS is intended to provide a brief summary of our knowledge and guidance regarding the use of this material. The information contained here has been compiled from sources considered to be dependable and is accurate to the best of the Company's knowledge. However, the information is provided without any representation or warranty, expressed or implied regarding its accuracy or correctness. The Company cannot assume responsibility for adverse events which may occur in the use and/or misuse of this product and expressly disclaims liability for loss, damage and/or expense arising out of or in any way connected with the handling, storage, use and/or disposal of this product.

Department issuing MSDS

S.A.L.A.R.S. S.p.A.

Regulatory Affairs

Contact: contact@salars.it

Abbreviations and acronyms

CAS: Chemical Abstracts Service (division of the American Chemical Society)

EINECS: European Inventory of Existing Commercial Chemical Substances

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

Acute Tox. 4: Acute toxicity, Hazard Category 4

CLP: Classification, Labelling and Packaging

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

NIOSH: National Institute for Occupational Safety and Health

CEN: European Committee for Standardization

LD₅₀: Lethal dose, 50 percent

RTECS: Registry of Toxic Effects of Chemical Substances
