

Material Safety Data Sheet

(in accordance with Regulation 878/2020/EC)

Product name: **NALTREXONE HYDROCHLORIDE**

Date: -
Revision date: 30.01.2023 ver. 3.0. EN

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Synonyms: Morphinan-6-one, 17-(cyclopropylmethyl)-4,5- α -oxy-3,14- dihydroxy-
hydrochloride, Embeda , Depade , ReVia , NIH 8503
Trade name: NALTREXONE HYDROCHLORIDE
CAS: 16676-29-2
EINECS/ ELINCS: 240-723-0
Registration nr. : -

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

Not recommended use: -

1.3 Details of the supplier of the safety data sheet

Street: Nitrianska 100
ZIP: 920 27
City: HLOHOVEC
State: Slovensko
Phone: +421 33 7362301
Fax: +421 33 7300890
E-mail: reach@saneca.com

1.4 Emergency telephone number :

+421254774166
National Toxicological Information Centre (NTIC): FNsP
Bratislava Limbová 5, 833 05 Bratislava 37, Slovak Republic
mobile phone: +421 911 166066; fax: +421 (02)
54774605 e-mail: ntic@ntic.sk ; web: www.ntic.sk

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture : CLP/GHS Classification (REGULATION (EC) No 1272/2008)

GHS07
Acute toxicity, Category 4 H302



2.2 Label elements: Signal word

WARNING

Hazard statement

H302 Harmfull if swallowed.

Precautionary Statement - Prevention

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P264 Wash hands thoroughly after handling.
P270 Do no eat, drink or smoke when using this product.
P280 Wear protective gloves/protective clothing/eye protection.

Material Safety Data Sheet

(in accordance with Regulation 878/2020/EC)

Product name: **NALTREXONE HYDROCHLORIDE**

P330 Rinse mouth

P301+312 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician if you feel unwell

P501 Dispose of contents/container to an approved waste disposal plant.

2.3 Other hazards

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3.COMPOSITION/INFORMATION ON INGREDIENTS

Name	NALTREXONE HYDROCHLORIDE
Concentration	100%
CAS	16676-29-2
EC	240-723-0
Registration nr.	-
Classification	GHS 07 Acute toxicity, Category 4 H302
H statements	H302
Signal word	Warning
Workplace limits	-
PBT/vPvB	-
Other data	-

4. FIRST AID MEASURES

4.1 Description of first aid measures

If inhaled

Remove the affected person from exposure site and provide him/her with enough of fresh air. Apply artificial respiration and get the medical attention, if needed.

In case of eye contact

Rinse eyes with large amounts of water lifting upper and lower lids. Get the medical attention.

In case of skin contact

Remove contaminated clothing and/or shoes. Wash the affected skin with a soap and large amounts of water. Get the medical attention, if needed.

If swallowed

Contact a physician or the local Toxicology Information Centre. Put the affected person to the stabilized position. Get the medical attention.

4.2 Most important symptoms and effects, both acute and delayed

No data

4.3 Indication of any immediate medical attention and special treatment needed

In case of accidental ingestion, or any of the difficulties described above, contact a doctor.

5.FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media

Regular water spray, dry chemical powder, carbon dioxide or foam extinguishers

Extinguishing media that must not

High-pressure water streams bringing a scatter of the spilled

Material Safety Data Sheet

(in accordance with Regulation 878/2020/EC)

Product name: **NALTREXONE HYDROCHLORIDE**

be used for material should be avoided
 safety reasons

5.2 Special hazards arising from the substance or mixture:

When heated to decomposition the material emits toxic fumes (nitrogen, carbon oxides)

5.3 Advice for firefighters:

Use self-contained breathing apparatus. Wear full protective suit. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Avoid rejection of extinguishing water in the environment

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

Personal precautions, protective equipment and emergency procedures:

Isolate in case of greater releases a contaminated area with no entry of unnecessary persons. Keep away ignition sources.
 Service staff performing the contaminated area sanitation has to be provided with respirators, gloves, and protective clothing.

6.2 Environmental precautions:

Avoid an escape of a release to sewers. Using protective clothing, respirator, and gloves, confine a spilled material and collect it in an emergency container.

6.3 Methods and materials for containment and cleaning up:

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

6.4 Reference to other sections:

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7. HANDLING AND STORAGE

7.1 Precautions for safe handling:

Avoid a direct contact with the substance. Prevent from a dust inhalation, skin direct contact, and direct eye affection.

Remove contaminated clothing.

7.2 Conditions for safe storage, including any incompatibilities:

Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Store in a cool (15 – 25°C) , dry place

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7.3 Specific end uses:

8.EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters	Name	CAS	NPEL (mg/m ³)		note
			average	short term	
	-	-	-	-	-
	-	-	-	-	-

Concentration limits in air : OEL : 125 µg/m³
 OEB 2

DNEL (workers) No data
 DNEL (consumers) No data

8.2 Exposure controls:

Face protection

Wear appropriate safety washable goggles.

Material Safety Data Sheet

(in accordance with Regulation 878/2020/EC)

Product name: **NALTREXONE HYDROCHLORIDE**

Body protection

Wear appropriate chemical-resistant gloves.

Respiratory protection

Provide exhaust ventilation; apply a respirator. At higher exposure the use of an approved dust mask is recommended

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 . Information on basic physical and chemical properties:

State of aggregation	Solid
Colour	white to off-white crystalline powder
Odour	Odourless
Form	Crystalline powder
pH	-
Boiling temperature [°C]	275°C
Flash temperature [°C]	-
Solubility	water – 50mg/l
Octanol/water partition coefficient	0,534
9.2 Other data:	-

10. STABILITY AND REACTIVITY

10.1 Reactivity	No data
10.2 Chemical stability	The substance is stable under the normal atmospheric conditions
10.3 Possibility of hazardous reactions	No data
10.4 Conditions to avoid	No data
10.5 Incompatible materials	Bases
10.6 Hazardous decomposition products	No data

11. TOXICOLOGICAL INFORMATION

11.1 Acute toxicity

Acute toxicity	LD50 (oral rat)- 1450gm/kg
LD ₅₀ /LC ₅₀	No data
Dermal	No data
Inhalation	No data
Irritant effect on skin	No irritant effect.
Irritant effect on eyes	No data
Mutagenicity	No data

Material Safety Data Sheet

(in accordance with Regulation 878/2020/EC)

Product name: **NALTREXONE HYDROCHLORIDE**

Reproductive toxicity	Reproductive toxicity - rat - Intraperitoneal Effects on Newborn: Growth statistics (e.g., reduced weight gain).
Carcinogenicity evaluation	No data
STOT SE	No data
STOT RE	No data
Aspiration toxicity	No data

12. ECOLOGICAL INFORMATION

12.1 Toxicity	No data
12.2 Persistence and degradability:	No data
12.3 Bioaccumulative potential:	No data
12.4 Mobility in soil:	No data
12.5 Results of PBT and vPvB assessment:	No data
12.6 Endocrine disrupting properties:	No data
12.7 Other adverse effects:	No data

13. DISPOSAL CONSIDERATIONS

13.1 . Waste treatment methods:	Deliver to the Environmental service of the factory or to any specialized and approved disposal service. Make the container unusable.
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14. TRANSPORT INFORMATION

14.1 UN number or ID number	-
14.2 UN proper shipping name	-
14.3 Transport hazard class (es)	-
14.4 Packing group	-
14.5 Environmental hazards	-
14.6 Special precautions for user	-
14.7 Maritime transport in bulk according to IMO instruments	-

15. REGULATORY INFORMATION

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

Regulation (EC) No 1907/2006 of the European Parliament and of the Council on registration, evaluation, authorization and restriction Chemicals (REACH) and establishing a European Chemicals Agency, amending certain directives Commission Regulation No 2015/830 amending Regulation (EC) No 882/2004 of the European Parliament and of the Council no. 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) Regulation of the European Parliament and of the Council no. 1272/2008 on classification, labeling and packaging of substances and mixtures Act of the National Council of the Slovak Republic no. 67/2010

Material Safety Data Sheet

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Product name: NALTREXONE HYDROCHLORIDE

Coll. on the placing on the market of chemical substances and mixtures Regulation of the Government of the Slovak Republic No. 355/2006 on the protection of employees against risks related to exposure to chemical factors at work, as amended by Government Regulation No. 471/2011 and as amended by Government Regulation No. 82/2015 Act no. 313/2016 Coll., Amending and supplementing Act no. 79/2015 Coll. on waste and on the amendment of certain acts as amended by Act no. 91/2016 Coll.

Restrictions under Regulation 552/2009 (Annex XVII of REACH Regulation 1907/2006): none

Substances on the Candidate List (SVHC) according to REACH Regulation 1907/2006: none

Annex XIV substances: none

15.2 Chemical safety assessment: not performed

16. OTHER INFORMATION

Reason for revision: -

Text of H-statements from section 3:

H302 Acute toxicity, Category 4

Hazard classes:

Acute toxicity, Category 4 H302

Precautions for packaging when placed on the retail network: none