

Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05

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

1.1 Product identifier

Identification of the substance	Nalbuphine hydrochloride
Registration number (REACH)	this information is not available
CAS number	23277-43-2
Article number	A0027395

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

Relevant identified uses	General use
Uses advised against	Do not use for squirting or spraying.

1.3 Details of the supplier of the safety data sheet

Chemos GmbH & Co. KG
Sonnenring 7
84032 Altdorf
Germany

Telephone: +49 871-966346-0
Telefax: +49 871-966346-13
e-mail: chemos@chemos.de
Website: <http://www.chemos.de/>

e-mail (competent person) chemos@chemos.de

1.4 Emergency telephone number

Emergency information service +49 89 1 92 40

Poison centre				
Country	Name	Postal code/ city	Telephone	Telefax
United Kingdom	National Poison Information Centre Medical Toxicology Unit	SE14 5ER Lon- don	+44 171 635 91 91	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Category	Hazard class and category	Hazard statement
3.1O	acute toxicity (oral)	1	Acute Tox. 1	H300
3.1D	acute toxicity (dermal)	1	Acute Tox. 1	H310
3.1I	acute toxicity (inhal.)	1	Acute Tox. 1	H330

For full text of abbreviations: see SECTION 16.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

- Signal word danger

Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05

- Pictograms

GHS06

**- Hazard statements**

H300+H310+H330 Fatal if swallowed, in contact with skin or if inhaled.

- Precautionary statements

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P262 Do not get in eyes, on skin, or on clothing.
P280 Wear protective gloves/protective clothing/eye protection/face protection.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P403+P233 Store in a well-ventilated place. Keep container tightly closed.

2.3 Other hazards

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

SECTION 3: Composition/information on ingredients**3.1 Substances**

Name of substance	Nalbuphine hydrochloride
Identifiers	
CAS No	23277-43-2
Molecular formula	C ₂₁ H ₂₈ ClNO ₄
Molar mass	393.9 g/mol

SECTION 4: First aid measures**4.1 Description of first aid measures**

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

Following skin contact

Rinse skin with water/shower.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water, Foam, ABC-powder

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

Deposited combustible dust has considerable explosion potential.

Hazardous combustion products

Nitrogen oxides (NOx), Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains, Take up mechanically

Advice on how to clean up a spill

Take up mechanically.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Take precautionary measures against static discharge. Use only in well-ventilated areas. Ground/bond container and receiving equipment.

Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05

- Specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- Explosive atmospheres

Removal of dust deposits.

- Ventilation requirements

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted. Use local and general ventilation.

- Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)											
Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Ceiling-C [ppm]	Ceiling-C [mg/m ³]	Notation	Source
GB	dust		WEL		10					i	EH40/2005
GB	dust		WEL		4					r	EH40/2005

Notation

Ceiling-C ceiling value is a limit value above which exposure should not occur
i inhalable fraction
r respirable fraction
STEL short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)
TWA time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours
time-weighted average (unless otherwise specified)

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

In the case of wanting to use the gloves again, clean them before taking off and air them well.

Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

Particulate filter device (EN 143).

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state	solid
Colour	white
Odour	characteristic

Other safety parameters

pH (value)	not applicable
Melting point/freezing point	230.5 °C
Initial boiling point and boiling range	not determined
Flash point	not applicable
Evaporation rate	not determined
Flammability (solid, gas)	this material is combustible, but will not ignite readily
Explosion limits of dust clouds	not determined
Vapour pressure	not determined
Density	not determined
Vapour density	this information is not available
Relative density	information on this property is not available
Solubility(ies)	not determined

Partition coefficient

- n-octanol/water (log KOW)	this information is not available
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Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05

Auto-ignition temperature	not determined
Viscosity	not relevant (solid matter)
Explosive properties	none
Oxidising properties	none

9.2 Other information

Solid content	100 %
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SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

Hints to prevent fire or explosion

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

10.5 Incompatible materials

Oxidisers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Fatal if swallowed. Fatal in contact with skin. Fatal if inhaled.

- Acute toxicity estimate (ATE)

Oral	0.5 mg/kg
Dermal	5 mg/kg
Inhalation: dust/mist	0.005 mg/l/4h

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05

SECTION 14: Transport information

14.1 UN number	2811
14.2 UN proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.
Technical name	Nalbuphine hydrochloride
14.3 Transport hazard class(es)	
Class	6.1 (toxic substances)
14.4 Packing group	I (substance presenting high danger)
14.5 Environmental hazards	non-environmentally hazardous acc. to the dangerous goods regulations
14.6 Special precautions for user	
Provisions for dangerous goods (ADR) should be complied within the premises.	
14.7 Transport in bulk according to Annex II of MARPOL and the IBC Code	
The cargo is not intended to be carried in bulk.	

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN)

UN number	2811
Proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.
Class	6.1
Classification code	T2
Packing group	I
Danger label(s)	6.1



Special provisions (SP)	274, 614, 802(ADN)
Excepted quantities (EQ)	E5
Limited quantities (LQ)	0
Transport category (TC)	1
Tunnel restriction code (TRC)	C/E
Hazard identification No	66
Emergency Action Code	2X

International Maritime Dangerous Goods Code (IMDG)

UN number	2811
Proper shipping name	TOXIC SOLID, ORGANIC, N.O.S.
Class	6.1
Marine pollutant	-
Packing group	I
Danger label(s)	6.1

Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05



Special provisions (SP)	274
Excepted quantities (EQ)	E5
Limited quantities (LQ)	0
EmS	F-A, S-A
Stowage category	B
International Civil Aviation Organization (ICAO-IATA/DGR)	
UN number	2811
Proper shipping name	Toxic solid, organic, n.o.s.
Class	6.1
Packing group	I
Danger label(s)	6.1



Special provisions (SP)	A3, A5
Excepted quantities (EQ)	E5

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Deco-Paint Directive (2004/42/EC)

VOC content	0 %
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Directive on industrial emissions (VOCs, 2010/75/EU)

VOC content	0 %
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National inventories

Country	Inventory	Status
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
MX	INSQ	substance is listed
TW	TCSI	substance is listed

Legend

ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
INSQ	National Inventory of Chemical Substances
REACH Reg.	REACH registered substances
TCSI	Taiwan Chemical Substance Inventory

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance.

Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2015/830/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Nalbuphine hydrochloride

Version number: GHS 1.0

Date of compilation: 2020-11-05

List of relevant phrases (code and full text as stated in chapter 2 and 3)

Code	Text
H300	Fatal if swallowed.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.