

SAFETY DATA SHEET

Product name:	Buprenorphine Hydrochloride	Page:	1/8
Supersedes date:	2020-04-16	Revision:	2020-10-12
Product No.:		SDS-ID:	EU-EN/2.0

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

1.1. Product identifier

Product name: Buprenorphine Hydrochloride
CAS-No.: 53152-21-9
Container size: Varying.

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

Identified use(s): Active ingredient in the pharmaceutical industry.

1.3. Details of the supplier of the safety data sheet

Supplier: Chr. Olesen Synthesis A/S
Kanalholmen 8-12
DK-2650 Hvidovre
Denmark
Tel:+45 3679 4500
Fax:+45 3834 1572
info@COSynthesis.dk
www.cosynthesis.dk,

Responsible for safety data sheet authoring: info@COSynthesis.dk

1.4. Emergency telephone number

Emergency telephone: +45 3679 4500
Only during office hours

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SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

CLP: Acute Tox. 4;H302 - Repr. 2;H361

2.2. Label elements



Warning

Contains: [5 α ,7 α (S)]- α -tert-butyl-17-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy- α -methyl-6,14-ethenomorphinan-7-methanol hydrochloride
CAS: 53152-21-9

H302 Harmful if swallowed.
H361 Suspected of damaging fertility or the unborn child.
P261a Avoid breathing dust.
P280 Wear protective clothing, gloves, eye and face protection.
P308 + P313 IF exposed or concerned: Get medical advice/attention.

2.3. Other hazards

Dust may irritate the eyes and the respiratory system.

PBT/vPvB: This substance is not classified as PBT or vPvB.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

CLP:

<u>%:</u>	<u>CAS-No.:</u>	<u>EC No.:</u>	<u>REACH Reg. No.:</u>	<u>Chemical name:</u>	<u>Hazard classification:</u>	<u>Notes:</u>
100	53152-21-9	258-396-8	-	[5 α ,7 α (S)]- α -tert-butyl-17-(cyclopropylmethyl)-4,5-epoxy-18,19-dihydro-3-hydroxy-6-methoxy- α -methyl-6,14-ethenomorphinan-7-methanol hydrochloride	Acute Tox. 4;H302 Repr. 2;H361	

References: The full text for all hazard statements is displayed in section 16.

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SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation: Dust inhalation: In case of problems: Move into fresh air and keep at rest. In case of persistent throat irritation or coughing: Seek medical attention and bring along these instructions.

Skin contact: Remove contaminated clothes and rinse skin thoroughly with water. In case of eczema or other skin disorders: Seek medical attention and bring along these instructions.

Eye contact: Do not rub eye. Immediately flush with plenty of water for at least 15 minutes. Remove any contact lenses and open eyelids widely. If irritation persists: Seek medical attention and bring along these instructions.

Ingestion: Immediately rinse mouth and drink plenty of water. Keep person under observation. If person becomes uncomfortable seek hospital and bring these instructions.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects: See section 11 for more detailed information on health effects and symptoms.

4.3. Indication of any immediate medical attention and special treatment needed

Medical attention/treatments: Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media

Extinguishing media: Use fire-extinguishing media appropriate for surrounding materials. Follow the general fire precautions indicated by the workplace.

5.2. Special hazards arising from the substance or mixture

Specific hazards: During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Protective equipment for fire-fighters: Selection of respiratory protection for fire fighting: follow the general fire precautions indicated in the workplace.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid inhalation of dust. Use work methods which minimise dust production. Follow precautions for safe handling described in this safety data sheet.

6.2. Environmental precautions

Environmental precautions: Avoid spreading dust or contaminated materials.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Use a vacuum cleaner. If not possible, moisten dust with water before it is collected with shovel, broom or the like.

6.4. Reference to other sections

References: For personal protection, see section 8.
For waste disposal, see section 13.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Safe handling advice: Observe good chemical hygiene practices. Avoid inhalation of dust. Avoid contact with skin and eyes. Wash hands after handling. Change contaminated clothing. Pregnant women should not work with the product, if there is the least risk of exposure.

Technical measures: Use work methods which minimise dust production.

Technical precautions: During dust-raising work: Local exhaust is recommended.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures for safe storage: No special precautions.

Storage conditions: Store in tightly closed original container in a dry, cool and well-ventilated place. Protect against direct sunlight.

7.3. Specific end use(s)

Specific use(s): Not relevant.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Please note that there may be national occupational exposure limits.

8.2. Exposure controls

Engineering measures: Provide adequate ventilation. The risk of inhalation of dust must be minimized as much as possible.

Personal protection: Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Respiratory equipment: In case of inadequate ventilation or risk of inhalation of dust, use suitable respiratory equipment with particle filter (type P2).

Hand protection: Risk of contact: Wear protective gloves. Nitrile gloves are recommended. The most suitable glove must be chosen in collaboration with the supplier of gloves, who can inform about the breakthrough time of the glove material.

Eye protection: Use tight fitting goggles if dust is generated.

Skin protection: Use dust-repellant working clothes.

Hygiene measures: Wash hands after handling.

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Form: Powder, dust.
Colour: White.
Odour: None.
Odour threshold: Not available.
pH: Not available.
Melting point / freezing point: Not available.
Boiling point: Not available.
Flash point: Not available.
Evaporation rate: Not available.
Explosion limits: Not available.
Vapour pressure: Not available.
Vapour density: Not available.
Relative density: Not available.
Solubility: Not available.
Partition coefficient (n-octanol/water): Not available.
Auto-ignition temperature (°C): Not available.
Decomposition temperature (°C): Not available.
Viscosity: Not available.
Oxidising properties: Not available.

9.2. Other information

Other data: Not available.

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SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity: None known.

10.2. Chemical stability

Stability: Stable under normal temperature conditions.

10.3. Possibility of hazardous reactions

Hazardous Reactions: None known.

10.4. Conditions to avoid

Conditions/materials to avoid: Avoid exposure to high temperatures or direct sunlight.

10.5. Incompatible materials

Incompatible materials: None known.

10.6. Hazardous decomposition products

Hazardous decomposition products: None in particular.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Acute Toxicity (Oral): Harmful if swallowed.

Acute Toxicity (Dermal): Based on available data, the classification criteria are not met.

Acute Toxicity (Inhalation): Based on available data, the classification criteria are not met.

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 or 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: Suspected of damaging fertility or the unborn child.

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.

Inhalation: Dust may irritate throat and respiratory system and cause coughing.

Skin contact: Prolonged contact may cause redness and irritation.

Eye contact: May irritate and cause redness and pain.

Ingestion: Harmful if swallowed.

Specific effects: Frequent inhalation of dust over a long period of time increases the risk of developing lung diseases.

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SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity: There are no data on the ecotoxicity of this product.

12.2. Persistence and degradability

Degradability: Not known.

12.3. Bioaccumulative potential

Bioaccumulative potential: No data available on bioaccumulation.

12.4. Mobility in soil

Mobility: No data available.

12.5. Results of PBT and vPvB assessment

PBT/vPvB: This substance is not classified as PBT or vPvB.

12.6. Other adverse effects

Other adverse effects: None known.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Dispose of waste and residues in accordance with local authority requirements. Waste is classified as hazardous waste.

Waste from residues: EWC-code: 07 05 13

SECTION 14: TRANSPORT INFORMATION

The product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).

14.1. UN number

UN-No: -

14.2. UN proper shipping name

Proper Shipping Name: -

14.3. Transport hazard class(es)

Class: -

14.4. Packing group

PG: -

14.5. Environmental hazards

Marine pollutant: No.

Environmentally Hazardous substance: No.

14.6. Special precautions for user

Special precautions: None known.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk: Not relevant.

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SECTION 15: REGULATORY INFORMATION

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

National regulation: This Safety Data Sheet has been prepared according to the EU-regulation.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a 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 Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, with amendments.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 with amendments.

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work, with amendments.

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, with amendments.
2014/955/EC: Commission Decision of 18 December 2014 amending Decision 2000/532/EC as regards the list of wastes.

15.2. Chemical Safety Assessment

CSA status: No chemical safety assessment has been carried out.

SECTION 16: OTHER INFORMATION

The user must be instructed in the proper work procedure and be familiar with the contents of these instructions.

The following sections contain revisions or new statements: 7, 13.

Abbreviations and acronyms used in the safety data sheet: PBT = Persistent, Bioaccumulative and Toxic.
vPvB = very Persistent and very Bioaccumulative.
CSA = Chemical Safety Assessment.

Wording of H-statements:

H302 Harmful if swallowed.

H361 Suspected of damaging fertility or the unborn child.

The information on this data sheet represents our current data and is reliable provided that the product is used under the prescribed conditions and in accordance with the application specified on the packaging and/or in the technical guidance literature. Any other use of the product which involves using the product in combination with any other product or any other process is the responsibility of the user.