

Trade name: Morphini hydrochloridum trihydricum

Substance number: 055000 Version: 5 / CH Date revised: 20.08.2024

Replaces Version: 4 / CH Print date: 20.08.24

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

1.1. Product identifier

Morphini hydrochloridum trihydricum Item No. 05500000

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

Use of the substance/preparation

Narcotic, analgesic, opioid

1.3. Details of the supplier of the safety data sheet

Address/Manufacturer

Hänseler AG Industriestrasse 35 9100 Herisau

Telephone no. 0041 (0)71 353 58 58 E-mail address of sdb@haenseler.ch

person responsible

for this SDS

1.4. Emergency telephone number

Switzerland: 145 / Abroad +41 (0)44 251 51 51

SECTION 2: Hazards identification ***

2.1. Classification of the substance or mixture

Classification (Regulation (EC) No. 1272/2008)

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4 H302 Acute Tox. 3 H331 Resp. Sens. 1 H334 Skin Sens. 1 H317 Repr. 2 H361fd Lact. H362

The product is classified and labelled in accordance with Regulation (EC) No 1272/2008 For explanation of abbreviations see section 16.

2.2. Label elements

Labelling according to regulation (EC) No 1272/2008

Hazard pictograms





Signal word

Danger

Hazard statements ***

H302 Harmful if swallowed. H331 Toxic if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.



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H317 May cause an allergic skin reaction.

H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

H362 May cause harm to breast-fed children.

Precautionary statements ***

P201 Obtain special instructions before use.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P263 Avoid contact during pregnancy and while nursing.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P284 [In case of inadequate ventilation] wear respiratory protection.

P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position

comfortable for breathing.

P308+P313 IF expsoed or concerned: Get medicinal advice/attention.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

Hazardous component(s) to be indicated on label (Regulation (EC) No. 1272/2008)

contains *** (4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-

methanobenzofuro[3,2-e]isoquinoline-7,9-diol;trihydrate;hydrochloride

2.3. Other hazards

The Substance does not meet PBT-criteria. This substance does not meet the vPvB-criteria. This substance does not have endocrine disrupting properties with respect to humans. This substance does not have endocrine disrupting properties with respect to non-target organisms.

SECTION 3: Composition/information on ingredients ***

Molecular weight

Value 375.89

Hazardous ingredients ***

(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-7,9-diol;trihydrate;hydrochloride

CAS No. 6055-06-7 EINECS no. 641-595-2 Registration no. EXCEMPT

Concentration >= 100 %

Classification (Regulation (EC) No. 1272/2008)

Acute Tox. 4 H302 Acute Tox. 3 H331 Resp. Sens. 1 H334 Skin Sens. 1 H317 Repr. 2 H361fd Lact. H362

ATE oral 335 mg/kg cATpE inhalative, Dust/Mist 0.5 mg/l

SECTION 4: First aid measures

4.1. Description of first aid measures

General information

Remove contaminated, soaked clothing immediately and dispose of safely. If you feel unwell, seek medical advice (show the label where possible).

After inhalation

Remove the casualty into fresh air and keep him calm. Keep warm and at rest. Irregular breathing/no breathing: artificial respiration. If necessary, give oxygen. Summon a doctor immediately.



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After skin contact

Wash off immediately with soap and water and rinse well. Summon a doctor immediately.

After eye contact

Separate eyelids, wash the eyes thoroughly with water (15 min.). Seek medical advice immediately.

After ingestion

Rinse mouth thoroughly with water. Let plenty of water be drunk in small gulps. Never give anything by mouth to an unconscious person. Summon a doctor immediately.

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

Nausea, Vomiting, Shortness of breath, Asthmatic complaints, amentia, Headache, Dizziness

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media

Water, Alcohol-resistant foam, Carbon dioxide, Dry chemical extinguisher

5.2. Special hazards arising from the substance or mixture

Take precautionary measures against static charges. Developpment of toxic gases; Forms esplosive mixture with air are possible. In the event of fire the following can be released: Nitrogen oxides (NOx); Hydrogen chloride (HCl); The product is combustible.

5.3. Advice for firefighters

Special protective equipment for fire-fighting

Wear full protective suit. Use self-contained breathing apparatus.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Remove persons to safety. Keep people away and stay on the upwind side. Avoid dust formation. Refer to protective measures listed in Sections 7 and 8.

6.3. Methods and material for containment and cleaning up

Suitable industrial vacuum cleaners or central exhaust ventilation equipment must be used for taking up dust (with a suitable filter to prevent particles blowing back into the atmosphere e.g. Type H(BS5415)). Send in suitable containers for recovery or disposal. Containers in which spilt substance has been collected must be adequately labelled. After cleaning, flush away traces with water. When picked up, treat material as prescribed under Section 13 "Disposal".

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Advice on safe handling

Take action to prevent static discharges. Do not inhale dust. Provide good ventilation of working area (local exhaust ventilation if necessary). Avoid the formation and deposition of dust.

Advice on protection against fire and explosion

Take action to prevent static discharges. Earthing necessary during loading operations. Avoid dust formation. The product is capable of dust explosions.

7.2. Conditions for safe storage, including any incompatibilities

Storage classes

Storage class according to TRGS 510 6.1D Non-combustible substances of acute toxicity, category 3 / hazardous

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substances that are toxic or produce

chronic effects

Storage category (Switzerland) 6.1 Toxic substances

Further information on storage conditions

Protect from light. Keep container tightly closed and dry in a cool, well-ventilated place. Protect from light. Keep under lock and key or accessible only to specialists or people who are authorized.

SECTION 8: Exposure controls/personal protection

8.2. Exposure controls

Exposure controls

See Section 7. No measures exeeding the ones mentioned necessary.

General protective and hygiene measures

Wash thoroughly after work. Store work clothing separately. At work do not eat, drink, smoke or take drugs. General industrial hygiene practice. Observe the usual precautions for handling chemicals. Wash contaminated clothing before reuse.

Respiratory protection

necessary; Self-contained breathing apparatus.

Hand protection

The glove material must be sufficient impermeable and resistant to the substance. Check the tightness before wear. Gloves should be well cleaned before being removed, then stored in a well ventilated location.

Hand protection must comply with EN 374.

Eye protection

Safety glasses with side protection shield

Body protection

Protective clothing; Clothing as usual in the chemical industry.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state solid
Colour white
Odour odourless

Physical state Crystalline powder

Melting point

Value appr. 200 °C

Boiling point or initial boiling point and boiling range

Remarks No data available

Flash point

Value °C Remarks Not applicable

pH value

Remarks Not applicable

Partition coefficient n-octanol/water (log value)

Remarks No data available

Vapour pressure

Remarks No data available



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9.2. Other information

Solubility in water

Value 42 g/l

Minimum ignition energy

Minimum ignition energy 50 to 100 MJ

SECTION 10: Stability and reactivity

10.1. Reactivity

No dangerous reactions known.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No decomposition if stored and applied as directed.

10.4. Conditions to avoid

Avoid dust formation.

10.5. Incompatible materials

Oxidising agents

10.6. Hazardous decomposition products

None under normal use.

Other information

chemical stable

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute oral toxicity

ATE 335 mg/kg
Method calculated value (Regulation (EC) No. 1272/2008)

Acute oral toxicity (Components)

(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-7,9-diol;trihydrate;hydrochloride

Species rat

LD50 335 mg/kg
Remarks Possible risk of congenital malformation in the fetus.

Acute dermal toxicity (Components)

(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-7,9-diol;trihydrate;hydrochloride

Remarks Possible risk of congenital malformation in the fetus.

Acute inhalational toxicity

ATE 0.5 mg/l

Administration/Form Dust/Mist

Method calculated value (Regulation (EC) No. 1272/2008)

Acute inhalative toxicity (Components)

(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-7,9-diol;trihydrate;hydrochloride

Remarks Irritating to respiratory system.



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(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-e]isoquinoline-7,9-diol;trihydrate;hydrochloride

Remarks Possible risk of congenital malformation in the fetus.

Skin corrosion/irritation

Remarks Irritating to skin.

Skin corrosion/irritation (Components)

(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-

e]isoquinoline-7,9-diol;trihydrate;hydrochloride

evaluation irritant

Serious eye damage/irritation

Remarks Irritates the eyes.

Serious eye damage/irritation (Components)

(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-

e]isoquinoline-7,9-diol;trihydrate;hydrochloride Remarks Irritates the eyes.

Sensitization

Remarks May cause sensitization by inhalation.
Remarks May cause sensitization by skin contact.

Sensitization (Components)

(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-

e]isoquinoline-7,9-diol;trihydrate;hydrochloride

Route of exposure dermal

evaluation May cause allergic skin reactions.

(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-

e]isoquinoline-7,9-diol;trihydrate;hydrochloride

Route of exposure inhalative

evaluation May cause allergic reactions of respiratory system.

Reproductive toxicity

Remarks May cause adverse reproductive effects.

Remarks Possible risk of congenital malformation in the fetus.

Reproduction toxicity (Components)

(4R,4aR,7S,7aR,12bS)-3-methyl-2,4,4a,7,7a,13-hexahydro-1H-4,12-methanobenzofuro[3,2-

e]isoquinoline-7,9-diol;trihydrate;hydrochloride

evaluation Suspected of damaging the unborn child.

Carcinogenicity

Remarks No evidence available on carcinogenicity.

11.2 Information on other hazards

Endocrine disrupting properties with respect to humans

This substance does not have endocrine disrupting properties with respect to humans.

Experience in practice

Possible risk of harm to the unborn child. May lead to drowsiness and unconsciousness. May cause nausea/ vomiting/ asthma. May lead to nausea, headache, drowsiness and dizziness. May cause sensitization by inhalation and skin contact. Irritation

SECTION 12: Ecological information ***

12.1. Toxicity

General information



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Not applicable

12.2. Persistence and degradability

General information

Not applicable

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log value)

Remarks No data available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment ***

The Substance does not meet PBT-criteria.

This substance does not meet the vPvB-criteria.

12.6 Endocrine disrupting properties

Endocrine disrupting properties with respect to the envrionment

This substance does not have endocrine disrupting properties with respect to non-target organisms.

12.7. Other adverse effects

General information / ecology

Ecological data are not available. Warning - substance not yet fully tested.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal recommendations for the product

EWC waste code 07 Wastes from organic chemical processes EWC waste code 07 05 wastes from the MFSU of pharmaceuticals EWC waste code 07 05 08* other still bottoms and reaction residues

Disposal in compliance with local and national regulations.

Do not allow to enter drains or water courses.

Disposal recommendations for packaging

Dispose of as unused product.

SECTION 14: Transport information ***



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	Land transport ADR/RID ***	Marine transport IMDG/GGVSee ***	Air transport ICAO/IATA ***
Tunnel restriction code	E		
14.1. UN number	1544	1544	1544
14.2. UN proper shipping name	ALKALOID SALTS, SOLID, N.O.S.	ALKALOID SALTS, SOLID, N.O.S.	ALKALOID SALTS, SOLID, N.O.S.
14.3. Transport hazard class(es)	6.1	6.1	6.1
Label	6	6	6
14.4. Packing group	III	III	III
Limited Quantity	5 kg		
Transport category	2		

SECTION 15: Regulatory information ***

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

Water Hazard Class (Germany) ***

Water Hazard Class WGK 3

(Germany)

Remarks Derivation of WGK according to Annex 1 No. 5.2 AwSV

SECTION 16: Other information

Hazard statements listed in Chapter 3

H302 Harmful if swallowed.

H317 May cause an allergic skin reaction.

H331 Toxic if inhaled.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.

H362 May cause harm to breast-fed children.

CLP categories listed in Chapter 3

Acute Tox. 3
Acute toxicity, Category 3
Acute Tox. 4
Acute toxicity, Category 4
Lact.
Reproductive toxicity, Lactation
Repr. 2
Resp. Sens. 1
Respiratory sensitization, Category 1
Skin Sens. 1
Skin sensitization, Category 1

Supplemental information

Relevant changes compared with the previous version of the safety data sheet are marked with: *** This information is based on our present state of knowledge. However, it should not constitute a guarantee for any specific product properties and shall not establish a legally valid relationship.

Safety data sheet in accordance with regula	ation (EC) No 1907/2006	HÄNSELER PHARMA		
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