# Safety data sheet
**according to 1907/2006/EC, Article 31**

Printing date 06.08.2021 Version number 2.00 Revision: 06.08.2021

## * 1 Identification of the substance/mixture and of the company/undertaking

· **Product identifier**

· **Trade name:** **Methadone hydrochloride, API**

· **Article number:** 2415
· **CAS Number:**
1095-90-5
· **EC number:**
214-140-7
· **Registration number** The substance is exempt from REACH-registration.
· **Relevant identified uses of the substance or mixture and uses advised against**
· **Application of the substance / the mixture**
Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.
· **Uses advised against** No relevant information available.

· **Details of the supplier of the safety data sheet**
· **Manufacturer/Supplier:**
CAELO
Caesar & Loretz GmbH
Herderstr. 31
D-40721 Hilden
GERMANY

· **Further information obtainable from:**
E-mail: info@caelo.de
Tel.: +49210349940 (during regular opening hours)
· **Emergency telephone number:**
Poison Information Center Bonn
Venusberg-Campus 1, 53127 Bonn
Tel: +49 (0) 228-192400

## 2 Hazards identification

· **Classification of the substance or mixture**
· **Classification according to Regulation (EC) No 1272/2008**
Acute Tox. 2 H300 Fatal if swallowed.

· **Label elements**
· **Labelling according to Regulation (EC) No 1272/2008**
The substance is classified and labelled according to the CLP regulation.
· **Hazard pictograms**

GHS06

· **Signal word** Danger

(Contd. on page 2)

# Safety data sheet
**according to 1907/2006/EC, Article 31**

Printing date 06.08.2021 Version number 2.00 Revision: 06.08.2021

**Trade name: Methadone hydrochloride, API**

(Contd. of page 1)

· **Hazard statements**
H300 Fatal if swallowed.
· **Precautionary statements**

| | |
|---|---|
| P264 | Wash thoroughly after handling. |
| P301+P310 | IF SWALLOWED: Immediately call a POISON CENTER/ doctor. |
| 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 regulations. |

· **Other hazards**
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.

## 3 Composition/information on ingredients

· **Chemical characterisation: Substances**
· **CAS No. Description**
1095-90-5 methadone hydrochloride
· **Identification number(s)**
· **EC number:** 214-140-7

## 4 First aid measures

· **Description of first aid measures**
· **General information:**
Immediately remove any clothing soiled by the product.
In case of irregular breathing or respiratory arrest provide artificial respiration.
· **After inhalation:**
Supply fresh air or oxygen; call for doctor.
In case of unconsciousness place patient stably in side position for transportation.
· **After skin contact:** Generally the product does not irritate the skin.
· **After eye contact:** Rinse opened eye for several minutes under running water. Then consult a doctor.
· **After swallowing:** Do not induce vomiting; call for medical help immediately.
· **Information for doctor:**
· **Most important symptoms and effects, both acute and delayed**
No further relevant information available.
· **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

## 5 Firefighting measures

· **Extinguishing media**
· **Suitable extinguishing agents:**
All regular extinguishing media can be used.
Use fire extinguishing methods suitable to surrounding conditions.
· **Special hazards arising from the substance or mixture**
Combustible but not oxidising. In case of fire dangerous vapours/gases can be generated: Smoke gases.

(Contd. on page 3)

# Safety data sheet
**according to 1907/2006/EC, Article 31**

Printing date 06.08.2021 Version number 2.00 Revision: 06.08.2021

**Trade name: Methadone hydrochloride, API**

(Contd. of page 2)

· **Advice for firefighters**
· **Protective equipment:** In case of fire wear suitable protective clothes and respiratory protection.
· **Additional information**
Prevent from entering into drains. Fire residues must be disposed in accordance with official regulations.

## 6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
Avoid contact with the substance.
Avoid formation of dust.
· **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
· **Methods and material for containment and cleaning up:**
Take up dry. Clean up with water.
Dispose contaminated material as waste according to item 13.
· **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.

## 7 Handling and storage

· **Handling:**
· **Precautions for safe handling** Thorough dedusting.
· **Information about fire - and explosion protection:** No special measures required.

· **Conditions for safe storage, including any incompatibilities**
· **Storage:**
· **Requirements to be met by storerooms and receptacles:**
Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).
· **Information about storage in one common storage facility:**
TRGS 514 - "Storage of highly toxic and toxic substances in packages and nonstationary vessels" to be observed.
· **Further information about storage conditions:** No further information
· **Storage class:** TRHS 510: 6.1 A Combustible, acutely toxic substances
· **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Control parameters**
· **Ingredients with limit values that require monitoring at the workplace:** Not required.

· **Exposure controls**
· **Personal protective equipment:**
· **General protective and hygienic measures:**
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:** Dust protection mask.

(Contd. on page 4)

# Safety data sheet
**according to 1907/2006/EC, Article 31**

Printing date 06.08.2021 Version number 2.00 Revision: 06.08.2021

**Trade name: Methadone hydrochloride, API**

(Contd. of page 3)

· **Protection of hands:** Protective gloves
· **Material of gloves**
PVC gloves
Natural rubber, NR
The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.
· **Penetration time of glove material**
The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
· **Eye protection:** Tightly sealed goggles
· **Body protection:** Protective work clothing

## 9 Physical and chemical properties

· **Information on basic physical and chemical properties**
· **General Information**
· **Appearance:**

| | |
|---|---|
| **Form:** | Solid |
| **Colour:** | White |
| · **Odour:** | Odourless |
| · **Odour threshold:** | Not determined. |
| · **pH-value:** | 4.5–5.6 (1% Lösung) |
| · **Change in condition** | |
| **Melting point/freezing point:** | 233–236 °C |
| **Initial boiling point and boiling range:** | Undetermined. |
| · **Flash point:** | Not applicable. |
| · **Flammability (solid, gas):** | Product is not flammable. |
| · **Decomposition temperature:** | Not determined. |
| · **Auto-ignition temperature:** | Not determined. |
| · **Explosive properties:** | Product does not present an explosion hazard. |
| · **Explosion limits:** | |
| **Lower:** | Not determined. |
| **Upper:** | Not determined. |
| · **Vapour pressure:** | Not applicable. |
| · **Density:** | Not determined. |
| · **Relative density** | Not determined. |
| · **Vapour density** | Not applicable. |
| · **Evaporation rate** | Not applicable. |
| · **Solubility in / Miscibility with water at 20 °C:** | 120 g/l |
| · **Partition coefficient: n-octanol/water:** | Not determined. |

(Contd. on page 5)

# Safety data sheet
**according to 1907/2006/EC, Article 31**

Printing date 06.08.2021 Version number 2.00 Revision: 06.08.2021

**Trade name: Methadone hydrochloride, API**

(Contd. of page 4)

· **Viscosity:**
**Dynamic:** Not applicable.
**Kinematic:** Not applicable.

· **Other information** No further relevant information available.

## 10 Stability and reactivity

· **Reactivity** No further relevant information available.
· **Chemical stability**
· **Thermal decomposition / conditions to be avoided:**
No decomposition if used according to specifications.
· **Possibility of hazardous reactions**
Reactions with oxidants and strong acids.
Reaction with strong bases.
· **Conditions to avoid** No further relevant information available.
· **Incompatible materials:** No further relevant information available.
· **Hazardous decomposition products:**
Carbon monoxide
Carbon dioxide
Hydrogen chloride (HCl)

## 11 Toxicological information

· **Information on toxicological effects**
· **Acute toxicity**
Fatal if swallowed.
· **LD/LC50 values relevant for classification:**

| | |
|---|---|
| Oral LD50 | 124 mg/kg (mouse) |
| | 30 mg/kg (rat) |
| TDL0 | 25,000 mg/kg /multip (rat) |
| LD50 (i.p.) | 8.3 mg/kg (mouse) |
| | 11 mg/kg (rat) |
| LDL0 (s.c.) | 34 mg/kg (mouse) |
| LD50 (i.v.) | 16 mg/kg (mouse) |
| | 9.2 mg/kg (rat) |
| TDL0 (c.s.) | 430 mg/kg (dog) |
| | 135 mg/kg /reproductiv (rat) |

· **Primary irritant effect:**
· **Skin corrosion/irritation** Irritant.
· **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.
· **Subacute to chronic toxicity:**
There are sufficient signs that the product can impair human fertility.
In animal experiments this property has been prooved. If this substance is consumed by breast feeding women, harmful effects on the health of the child are possible.

(Contd. on page 6)

# Safety data sheet
**according to 1907/2006/EC, Article 31**

Printing date 06.08.2021 Version number 2.00 Revision: 06.08.2021

**Trade name: Methadone hydrochloride, API**

(Contd. of page 5)

· **Additional toxicological information:**
· **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
· **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** Based on available data, the classification criteria are not met.
· **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.

## 12 Ecological information

· **Toxicity**
· **Aquatic toxicity:** No further relevant information available.
· **Persistence and degradability** Heavily biodegradable
· **Behaviour in environmental systems:**
· **Bioaccumulative potential** No further relevant information available.
· **Mobility in soil** No further relevant information available.
· **Additional ecological information:**
· **General notes:**
Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
· **Results of PBT and vPvB assessment**
· **PBT:** Not applicable.
· **vPvB:** Not applicable.
· **Other adverse effects** No further relevant information available.

## 13 Disposal considerations

· **Waste treatment methods**
· **Recommendation**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· **Uncleaned packaging:**
· **Recommendation:** Disposal must be made according to local regulations.

## 14 Transport information

| | |
|---|---|
| · **UN-Number** | |
| · **ADR, IMDG, IATA** | UN2811 |
| · **UN proper shipping name** | |
| · **ADR** | 3288 TOXIC SOLID, INORGANIC, N.O.S. (methadone hydrochloride) |
| · **IMDG** | TOXIC SOLID, ORGANIC, N.O.S. (methadone hydrochloride) |
| · **IATA** | Toxic solid, organic, n.o.s. (methadone hydrochloride) |
| · **Transport hazard class(es)** | |
| · **ADR, IMDG, IATA** | |
| · **Class** | 6.1 Toxic substances. |

(Contd. on page 7)

# Safety data sheet
**according to 1907/2006/EC, Article 31**

Printing date 06.08.2021 Version number 2.00 Revision: 06.08.2021

**Trade name: Methadone hydrochloride, API**

(Contd. of page 6)

| | |
|---|---|
| · **Label** | 6.1 |
| · **Packing group** | |
| · **ADR, IMDG, IATA** | III |
| · **Environmental hazards:** | Not applicable. |
| · **Special precautions for user** | Warning: Toxic substances. |
| · **Hazard identification number (Kemler code):** | 60 |
| · **EMS Number:** | F-A,S-A |
| · **Transport in bulk according to Annex II of Marpol and the IBC Code** | Not applicable. |

· **Transport/Additional information:**

| | |
|---|---|
| · **ADR** | |
| · **Limited quantities (LQ)** | 5 kg |
| · **Transport category** | 2 |
| · **Tunnel restriction code** | E |

| | |
|---|---|
| · **IMDG** | |
| · **Limited quantities (LQ)** | 5 kg |

## 15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**
· **LIST OF SUBSTANCES SUBJECT TO AUTHORISATION (ANNEX XIV)** Not listed
· **REGULATION (EC) No 1907/2006 ANNEX XVII** Not listed

· **National regulations:**
· **Storage of hazardous substances in in nonstationary vessels (TRGS 510) (Germany)**
TRHS 510: 6.1 A Combustible, acutely toxic substances
· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

The information provided is based on our current level of knowledge. This MSDS has been compiled and is exclusively for this product intended.
· **Reasons for alterations** This version replaces all old versions.
· **Abbreviations and acronyms:**
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
MAL-Code: Måleteknisk Arbejdshygiejnisk Luftbehov (Regulation for the labeling concerning inhalation hazards, Denmark)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 2: Acute toxicity – Category 2
· *** Data compared to the previous version altered.**