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

- Informations to product No. 2415
- Product name:

Methadonhydrochlorid, API Methadoni hydrochloridum

- Supplier of the Product / responsible Company:

Caesar & Loretz GmbH
Herderstr. 31
40721 Hilden
Tel.: 02103/4994-0
Fax: 02103/32360
e-mail: info@caelo.de

- Emergency telephone:

Giftinformationszentrum Mainz
Langenbeckstr. 1, 55131 Mainz
Tel.: 06131/19240

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

No further relevant information available.

- Application of the substance / mixture:

Ingredient for pharmaceutical drugs or active pharmaceutical ingredient.

2 Hazards identification

- GHS-Labeling Elements:



- Signal word: Danger

- H-Phrases:

H300 Fatal if swallowed

- P-Phrases:


P264 Wash thoroughly after handling

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

P301 IF SWALLOWED:

P310 Immediately call a POISON CENTER or doctor/physician

Acute Tox. 2

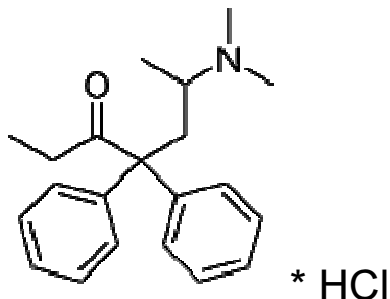
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3 Composition / information on ingredients

CAS-No. Substance name

1095-90-5 Methadone hydrochloride (Racemat)

- **EINECS-No.:** 214-140-7
- **REACH Reg. No.:** (pre-registered)
- **INCI-Name:** -
- **Chemical characterization:**



4 First aid measures


- **after inhalation:** Fresh air. Seek medical advice immediately.
- **after skin contact:** Take off contaminated clothes and shoes, wash immediately with plenty of water and soap. bei anhaltender Irritation seek medical advice immediately.
- **after eye contact:** Rinse out with plenty of water with the eyelid wide open. AugenSeek medical advice.
- **after swallowing:** Drink water. Induce vomiting. Seek medical advice immediately.
- **The following symptoms might occur:** After contact wits skin and eyes: Irritations. After inhalation or swallowing: Illness, dizziness, Headache, fatigue. In case of serious intoxication: respiratory insufficiency and coma.

5 Fire-fighting measures

- **Suitable extinguishing media:** All regular extinguishing media can be used. Select fire fighting measures suitable to surrounding environment.
- **Specific hazards during fire fighting:** Combustible but not flammable. In case of fire dangerous gases / vapours can be released: Smoke gases.
- **Special protective equipment for fire-fighters:** Suitable protective clothes and respiratory protection.

6 Accidental release measures

- **Personal protective measures:** Avoid dust formation and contact with substance.
- **Environmental protective measures:** Prevent from entering into drains.
- **Methods for cleaning:** Take up dry. Disposal according to Chapter 13 of this MSDS. Clean up with water.

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7 Handling and storage

- **Informations to fire or explosion protection:** No special requirements.
- **Storage:**
- **Requirements for storage areas and containers:** Tightly closed. Store at a dry place. At room temperature (+15°C to +25°C).
- **Advices on common storage:** TRGS 514 "Storage of toxic and very toxic substances ..."
- **Additional informations to storage conditions:** Keep container tightly closed.

8 Exposure controls / personal protective equipment

- **Personal protective equipment:**
- **General protective and hygiene measures:** Wash hands before breaks and after work. Avoid inhalation of dust. Avoid contact with eyes and skin.
- **Respiratory protection:** Dust protection mask
- **Hand protection:** Gloves of Latex or PVC
- **Eye protection:** Safety glasses.

9 Physical and chemical properties


- **Form:** solid
- **Colour:** white
- **Odour:** odourless
- **Melting point / melting range:** 233 - 236 °C (Pharm. Eur.)
- **Boiling point / boiling range:** not determined
- **Explosion hazard:** The product is not explosive, but explosive dust-air-mixtures can be formed.
- **Density:** not determined
- **Solubility in / Miscibility with**
- **Water:** (20 °C) 120 g/l
- **pH-range:** 4,5 - 5,6 1% solution

10 Stability and reactivity

- **Thermal decomposition / conditions to avoid:** No decomposition during appropriate use.
- **Hazardous reactions:** Reactions with oxidants and strong acids and bases.
- **Hazardous decomposition products:** In case of fire: Carbon monoxide und Carbon dioxide, Hydrogen chloride.

11 Toxicological information

- **Acute toxicity:**
- LD/LD50-data relevant for hazard classification:**
- LD50 (oral, rat): 30 mg/kg
- LD50 (i.p., rat): 11 mg/kg
- LD50 (oral, mouse): 124 mg/kg
- LD50 (i.v., mouse): 16 mg/kg
- LDL0 (s.c., mouse): 34 mg/kg

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LD50 (i.p., mouse): 8,3 mg/kg
TDL0 (s.c., dog): 430 mg/kg
LD50 (i.v., rat): 9,2 mg/kg
TDL0 (oral, rat): 25000 mg/kg (14W-C) multiple dose
TDL0 (oral, rat): 130 mg/kg 8-22 days after conception
TDL0 (reproductive, i.p., rat): 135 mg/kg (female 5 days pre mating, female 1-22 days after conception)
TDL0 (reproductive, s.c., rat): 50 mg/kg (female 6-15 days after conception)

- **Primary irritant effect:** Irritant effect on skin and eyes.
- **Sub-acute / chronic toxicity:** There are sufficient signs that the product can impair human fertility. In animal experiments this property has been proved. If this substance is consumed by breast feeding women, harmful effects on the health of the child are possible.

12 Ecological information

- **Information about elimination (persistence and degradability):** Not readily biodegradable.
- **Ecotoxicological effects:** Quantitative ecotoxicological data are not available.
- **General advices:** Prevent from entering into environmental waters, waste water or soil! Danger for drinking water if even small quantities leak into the ground.
- **Water hazard class:** 2 (self classification): hazardous for water.

13 Disposal considerations


- **Product:**
- **Recommendation:** Disposal according to local regulations as pharmaceutical waste.
- **Empty contaminated packaging:**
- **Recommendation:** Disposal according to the local regulations.

14 Transport informations

- **Land transport according to ADR:**
- **Proper shipping name:** Toxic solids, organic, n.o.s., Methadonhydrochlorid
- **Class:** 6.1
- **UN-number:** 2811
- **Packing group:** III
- **Classification code:** T2
- **Limited quantities (Table 3.4.6. ADR):** 5 kg
- **Hazard classification number:** 60
- **Special provisions (Chapter 3.3 ADR):** 274, 614
- **Additional informations for sea transport IMDG:**
- **EMS-No.:** F-A, S-A
- **Properties:** -

15 Regulatory information

- **Labelling according to actual legislation (GHS, Globally Harmonized System of Classification and Labelling of Chemicals):**

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The product is classified and labelled according to GHS-regulations.

· **Hazard symbols:** GHS06

· **Signal word:** Danger

· **H-Phrases:**

H300 Fatal if swallowed

· **P-Phrases:**

P264 Wash thoroughly after handling

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

P301 IF SWALLOWED:

P310 Immediately call a POISON CENTER or doctor/physician

· **National regulations (Germany):**

· **Water hazard class:** see chapter 12

· **Storage class TRGS 510:** 6.1A

16 Other Information

The information provided in this MSDS is correct to the best of our knowledge at the date of edition.

· **Reason for last revision:** Adjustment to regulation (EC) 1907/2006 (REACH) and GHS-labelling system.