

Trade name: Methadoni HCl solutio oralis 1%

Substance number: 054050

Version: 3 / CH

Date revised: 09.09.2020

Replaces Version: 2 / CH

Print date: 09.09.20

**SECTION 1: Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Methadoni HCl solutio oralis 1%

Item No. 05405000

**Registration no.**

Registration no. EXCEMPT

**1.2. Relevant identified uses of the substance or mixture and uses advised against****Use of the substance/preparation**

Medicinal product

**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**

This product is not classified hazardous in accordance with Regulation (EC) No 1272/2008.

**2.2. Label elements****Labelling according to regulation (EC) No 1272/2008**

Voluntary product information following the Safety Data Sheet format

**Supplemental information**

EUH210

Safety data sheet available on request.

**SECTION 3: Composition/information on ingredients \*\*\*****Hazardous ingredients \*\*\*****methadone hydrochloride**

CAS No. 1095-90-5

EINECS no. 214-140-7

Concentration &gt;= 1 &lt; 4.7 %

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

Acute Tox. 3 H301

Aquatic Chronic 2 H411

**Further ingredients \*\*\*****Water**

CAS No. 7732-18-5

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EINECS no. 231-791-2  
 Concentration >= 95 %  
 Advice: [4]

**Propane-1,2-diol**

CAS No. 57-55-6  
 EINECS no. 200-338-0  
 Concentration >= 1 < 10 %  
 Advice: [4]

**methyl 4-hydroxybenzoate**

CAS No. 99-76-3  
 EINECS no. 202-785-7  
 Registration no. 01-2119463264-40  
 Concentration < 1 %  
 Advice: [4]  
 Classification (Regulation (EC) No. 1272/2008)  
 Aquatic Chronic 3 H412

**4-hydroxybenzoic acid propyl ester**

CAS No. 94-13-3  
 EINECS no. 202-307-7  
 Registration no. 01-2119969462-29  
 Concentration < 1 %  
 Advice: [4]

**Note**

[4] Voluntary information

**SECTION 4: First aid measures****4.1. Description of first aid measures****General information**

Remove contaminated, soaked clothing immediately and dispose of safely.

**After inhalation**

Ensure supply of fresh air.

**After skin contact**

After contact with skin, wash immediately with plenty of water.

**After eye contact**

Separate eyelids, wash the eyes thoroughly with water (15 min.).

**After ingestion**

Rinse mouth thoroughly with water. Do NOT induce vomiting. Summon a doctor immediately.

**SECTION 5: Firefighting measures****5.1. Extinguishing media****Suitable extinguishing media**

Extinguishing measures to suit surroundings

**5.3. Advice for firefighters****Special protective equipment for fire-fighting**

Use self-contained breathing apparatus.

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## **SECTION 6: Accidental release measures**

### **6.1. Personal precautions, protective equipment and emergency procedures**

Avoid contact with eyes and skin.

### **6.2. Environmental precautions**

No special measures required.

### **6.3. Methods and material for containment and cleaning up**

Pick up with absorbent material. Send in suitable containers for recovery or disposal. 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**

Avoid contact with skin, eyes and clothing.

### **7.2. Conditions for safe storage, including any incompatibilities**

#### **Hints on storage assembly**

Not required.

#### **Storage classes**

Storage class according to TRGS 510 12

Non-combustible liquids

#### **Further information on storage conditions**

Keep container tightly closed.

## **SECTION 8: Exposure controls/personal protection**

### **8.2. Exposure controls**

#### **General protective and hygiene measures**

Observe the usual precautions for handling chemicals.

#### **Respiratory protection**

necessary

#### **Hand protection**

necessary

#### **Eye protection**

Safety glasses

#### **Body protection**

necessary

## **SECTION 9: Physical and chemical properties**

### **9.1. Information on basic physical and chemical properties**

**Form** liquid, clear**Colour** colourless

#### **pH value**

Value 4.5 to 5.5

#### **Melting point**

Remarks No data available

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**Initial boiling point and boiling range**

Remarks No data available

**Flash point**

Value °C

Remarks Not applicable

**Upper/lower flammability or explosive limits**

Remarks No data available

**Vapour pressure**

Remarks No data available

**Vapour density**

Remarks No data available

**Density**

Remarks No data available

**Solubility in water**

Remarks No data available

**Partition coefficient: n-octanol/water**

Remarks No data available

**Ignition temperature**

Remarks No data available

**Viscosity**

Remarks No data available

**SECTION 10: Stability and reactivity****10.6. Hazardous decomposition products**

No data available.

**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute oral toxicity**

ATE 9'500 mg/kg  
 Method calculated value (Regulation (EC) No. 1272/2008)

**Acute oral toxicity (Components)****methadone hydrochloride**

Species mouse  
 LD50 124 mg/kg

**methadone hydrochloride**

Species rat  
 LD50 95 mg/kg

**Propane-1,2-diol**

Species rat  
 LD50 20000 mg/kg

**Propane-1,2-diol**

Species rat  
 LD50 6660 mg/kg  
 Remarks intraperitoneal

**Propane-1,2-diol**

Species mouse

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LD50 9718 mg/kg  
Remarks intraperitoneal

**Acute dermal toxicity (Components)****Propane-1,2-diol**

Species rabbit  
20800 mg/kg

**Skin corrosion/irritation**

Remarks No data available.

**Serious eye damage/irritation**

Remarks No data available.

**Sensitization**

Remarks No data available.

**SECTION 12: Ecological information****12.1. Toxicity****Fish toxicity**

Remarks No data available.

**Fish toxicity (Components)****methadone hydrochloride**

LC50 7.49 mg/l

**Propane-1,2-diol**

Species Fathead minnow (Pimephales promelas)  
NOEC 52930 mg/l  
Duration of exposure 96 h

**Daphnia toxicity**

Remarks No data available.

**Daphnia toxicity (Components)****methadone hydrochloride**

Species Daphnia  
EC50 0.68 mg/l

**Propane-1,2-diol**

Species Daphnia  
NOEC 13020 mg/l

**Propane-1,2-diol**

Species Daphnia magna  
EC50 > 10000 mg/l  
Duration of exposure 48 h

**Algae toxicity (Components)****methadone hydrochloride**

EC50 2.28 mg/l

**12.2. Persistence and degradability****Biodegradability (Components)****methadone hydrochloride**

evaluation sparingly degradable

**12.3. Bioaccumulative potential**

Partition coefficient: n-octanol/water

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Remarks

No data available

**SECTION 13: Disposal considerations****13.1. Waste treatment methods****Disposal recommendations for the product**

Disposal in compliance with local and national regulations.

**Disposal recommendations for packaging**

Dispose of as unused product.

**SECTION 14: Transport information**

	Land transport ADR/RID	Marine transport IMDG/GGVSee	Air transport ICAO/IATA
<b>14.1. UN number</b>	The product does not constitute a hazardous substance in land transport.	The product does not constitute a hazardous substance in sea transport.	The product does not constitute a hazardous substance in air transport.

**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 (Germany)      WGK 2

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

**SECTION 16: Other information****Hazard statements listed in Chapter 3**

H301      Toxic if swallowed.  
H411      Toxic to aquatic life with long lasting effects.

**CLP categories listed in Chapter 3**

Acute Tox. 3      Acute toxicity, Category 3  
Aquatic Chronic 2      Hazardous to the aquatic environment, chronic, Category 2

**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.