



## METHADONE HYDROCHLORIDE INJECTION, USP

### SAFETY DATA SHEET

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

#### 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY

##### Product Identifier

**Product name:** Methadone Hydrochloride Injection, USP

##### Intended Use Of The Product

**Use of the substance/preparation:** Pharmaceutical. Opioid analgesic. Use only as directed. Refer to product insert for usage instructions and product information.

##### Name, Address, And Telephone Of The Responsible Party

##### Supplier:

Mylan Institutional LLC  
1718 Northrock Court  
Rockford, IL 61103 USA  
800.848.0462

[www.mylan.com](http://www.mylan.com)

##### Emergency Telephone Number

**Emergency number** : +1 877-446-3679

#### 2. HAZARDS IDENTIFICATION

**Patients/Consumers:** Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions. Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk.

##### Classification Of The Substance Or Mixture

**Classification (GHS-US)**

Repr. 2 H361

##### Label Elements

**GHS-US labeling**

**Hazard pictograms (GHS-US)** :



**Signal word (GHS-US)**

: Warning

**Hazard statements (GHS-US)**

: H361 - Suspected of damaging fertility or the unborn child

**Precautionary statements (GHS-US)**

: P201 - Obtain special instructions before use.  
P202 - Do not handle until all safety precautions have been read and understood.  
P280 - Wear eye protection, protective clothing, protective gloves.  
P308+P313 - IF exposed or concerned: Get medical advice/attention.  
P405 - Store locked up.  
P501 - Dispose of contents/container according to local, regional, national, territorial, provincial, and international regulations.

**Other Hazards** Not available

**Unknown acute toxicity (GHS US)** Not available

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

##### Mixture

Name	Product identifier	% (w/w)	Classification (GHS-US)
Methadone hydrochloride	(CAS No.) 1095-90-5	0.5 - 1.5	Acute Tox. 2 (Oral), H300 Repr. 2, H361

Full text of H-phrases: see section 16

**Additional information:** Sodium hydroxide and Hydrochloric acid was also added for pH adjustment.

#### 4. FIRST AID MEASURES

##### **Description Of First Aid Measures**

**General:** Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice.

**Inhalation:** The risk of inhalation exposure is negligible when product is in its final packaged form. If exposed and become symptomatic, move to fresh air and get medical attention if symptoms persist.

**Skin Contact:** Basic hygiene and appropriate precautions should prevent skin contact. If skin contact occurs, wash affected area with soap and water for at least 15 minutes. Should skin irritation, allergic reaction, or rash occur, remove contaminated clothing (if required) and seek medical advice.

**Eye Contact:** The risk of eye exposure is negligible when product is in its final packaged form. If eye contact occurs, flush immediately with water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.

**Ingestion:** Ingestion is not an anticipated route of exposure. If accidental ingestion occurs, flush mouth out with water and get medical attention.

##### **Most Important Symptoms And Effects Both Acute and Delayed**

**General:** Please refer to the package insert for more detailed information.

**Inhalation:** Inhalation is not considered a potential route of exposure.

**Skin Contact:** May cause mild skin irritation. Absorption through the skin may occur from direct contact.

**Eye Contact:** Direct contact with the eyes is likely irritating.

**Ingestion:** Ingestion is likely to be harmful or have adverse effects.

**Injection:** Exposure may cause central nervous system effects (nausea, dizziness, drowsiness, respiratory depression).

**Chronic symptoms:** Suspected of damaging the unborn child. Possible addiction.

##### **Indication Of Any Immediate Medical Attention And Special Treatment Needed**

If exposed or concerned, get medical advice and attention. In the event of accidental injection, go immediately to the nearest emergency room.

#### 5. FIREFIGHTING MEASURES

##### **Extinguishing Media**

**Suitable extinguishing media:** Use extinguishing media appropriate for surrounding fire.

**Unsuitable extinguishing media:** Do not use a heavy water stream. Use of heavy stream of water may spread fire.

##### **Special Hazards Arising From The Substance Or Mixture**

**Fire hazard:** Not considered flammable but may burn at high temperatures.

**Explosion hazard:** Product is not explosive.

**Reactivity:** Hazardous reactions will not occur under normal conditions.

##### **Advice For Firefighters**

**Precautionary measures fire:** Exercise caution when fighting any chemical fire.

**Firefighting instructions:** Use water spray or fog for cooling exposed containers.

**Protection during firefighting:** Do not enter fire area without proper protective equipment, including respiratory protection.

**Hazardous Combustion Products:** Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides.

**Other information:** Refer to Section 9 for flammability properties.

#### 6. ACCIDENTAL RELEASE MEASURES

##### **Personal Precautions, Protective Equipment And Emergency Procedures**

**General measures:** Avoid all eye and skin contact and do not breathe vapor and mist.

##### **For Non-Emergency Personnel**

**Protective equipment:** Use appropriate personal protection equipment (PPE).

**Emergency procedures:** Evacuate unnecessary personnel.

##### **For Emergency Personnel**

**Protective equipment:** Equip cleanup crew with proper protection.

##### **Environmental Precautions**

Prevent entry to sewers and public waters.

##### **Methods And Material For Containment And Cleaning Up**

**Methods for cleaning up:** For small quantities associated with normal therapeutic use, collect spillage and transfer to a closed waste container for disposal. For large or bulk quantities, after absorption with inert material, collect spillage by sweeping up spilled material and place in a labeled, sealed container for proper disposal.

##### **Reference To Other Sections**

See heading 8, Exposure Controls and Personal Protection.

**7.****HANDLING AND STORAGE****Precautions For Safe Handling**

**Patients/Consumers:** Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.

**Hygiene measures:** This SDS is a pharmaceutical agent - Handling of this product in its final form presents minimal occupational exposure risk. In an occupational setting, handle in accordance with good industrial hygiene and safety procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use appropriate personal protective equipment when handling and observe good personal hygiene measures after handling.

**Conditions For Safe Storage, Including Any Incompatibilities**

**Storage conditions:** Store in original container. Store in a dry, cool place. Protect from light.

**Storage temperature:** 15-30°C (59-86°F)

**Special rules on packaging:** Examine the vial for particulate matter and discoloration prior to administration. If the solution is discolored or contains solid particles (precipitate), do not use.

**Specific End Use(s)**

Pharmaceutical. Opioid analgesic. Use only as directed. Refer to product insert for usage instructions and product information.

**8.****EXPOSURE CONTROLS/PERSONAL PROTECTION****Control Parameters**

No Occupational Exposure Limits (OELs) have been established for this product or its chemical components.

**Exposure Controls**

**Appropriate engineering controls:** Not generally required. Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

**Personal protective equipment:** Gloves. Protective clothing. In case of splash hazard: safety glasses.

**Hand protection:** Wear protective gloves made from PVC, neoprene, nitrile, vinyl, or PVC/NBR.

**Eye protection:** In laboratory, medical or industrial settings, or operations in which airborne particulates will be generated, safety glasses with side shields are recommended.

**Skin and body protection:** In laboratory, medical or industrial settings, impervious disposable gloves and protective clothing are recommended if skin contact with drug product is possible.

**Respiratory protection:** When manufacturing or handling product in large quantities and dusts or particulates may be generated, maintain airborne concentrations below recommended limits. Workplace risk assessments should be completed before specifying and implementing respirator usage. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

**9.****PHYSICAL AND CHEMICAL PROPERTIES****Information On Basic Physical And Chemical Properties**

<b>Physical state</b>	: Liquid
<b>Appearance</b>	: Clear, colorless
<b>Odor</b>	: Not available
<b>Odor threshold</b>	: Not available
<b>pH</b>	: 4.5-6.5
<b>Relative evaporation rate (butyl acetate=1)</b>	: Not available
<b>Melting point</b>	: Not available
<b>Freezing point</b>	: Not available
<b>Boiling point</b>	: Not available
<b>Flash point</b>	: Not available
<b>Auto-ignition temperature</b>	: Not available
<b>Decomposition Temperature</b>	: Not available
<b>Flammability (solid, gas)</b>	: Not available
<b>Lower flammable limit</b>	: Not available
<b>Upper flammable limit</b>	: Not available
<b>Vapor pressure</b>	: Not available
<b>Relative vapor density at 20 °C</b>	: Not available
<b>Relative density</b>	: Not available
<b>Specific gravity density</b>	: Not available
<b>Solubility</b>	: Not available
<b>Log Pow</b>	: Not available
<b>Log Kow</b>	: Not available
<b>Viscosity, kinematic</b>	: Not available

Viscosity, dynamic : Not available  
Explosion data - sensitivity to mechanical impact : Not available  
Explosion data - sensitivity to static discharge : Not available

#### 10. STABILITY AND REACTIVITY

**Reactivity** Hazardous reactions will not occur under normal conditions.  
**Chemical Stability** Stable under normal conditions.  
**Possibility Of Hazardous Reactions** Hazardous polymerization will not occur.  
**Conditions To Avoid** Direct sunlight. Extremely high or low temperatures.  
**Incompatible Materials** Strong acids. Strong bases. Strong oxidizers.  
**Hazardous Decomposition Products** Carbon oxides (CO, CO<sub>2</sub>). Nitrogen oxides. Chlorine.

#### 11. TOXICOLOGICAL INFORMATION

##### **Information On Toxicological Effects - Product**

**Acute toxicity:** Not classified  
**LD50 and LC50 Data:** Not available  
**Skin corrosion/irritation:** Not classified (pH: 4.5 - 6.5)  
**Serious eye damage/irritation:** Not classified (pH: 4.5 - 6.5)  
**Respiratory or skin sensitization:** Not classified  
**Germ cell mutagenicity:** Not classified  
**Teratogenicity:** Animal studies have shown that methadone effects development and respiratory function of the fetus.  
**Carcinogenicity:** Not classified  
**Specific target organ toxicity (repeated exposure):** Not classified  
**Reproductive toxicity:** Suspected of damaging the unborn child.  
**Specific target organ toxicity (single exposure):** Not classified  
**Aspiration hazard:** Not classified

##### **Information On Toxicological Effects - Ingredient(s)**

###### **LD50 and LC50 Data**

<b>Methadone hydrochloride (1095-90-5)</b>	
LD50 oral rat	30 mg/kg
LD50 Intravenous Rat	9200 µg/kg

#### 12. ECOLOGICAL INFORMATION

**Toxicity** Not available  
**Persistence And Degradability** Not available  
**Bioaccumulative Potential**

<b>Methadone hydrochloride (1095-90-5)</b>	
Log Pow	2.068

#### 13. DISPOSAL CONSIDERATIONS

**Waste disposal recommendations:** Dispose of waste material in accordance with all local, regional, national, provincial, territorial and international regulations. Do not dispose of waste into sewer.  
**Additional information:** Contaminated sharps should be discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a Safe Syringe Disposal Program.

#### 14. TRANSPORT INFORMATION

**In accordance with ICAO/IATA/DOT/TDG**  
**UN Number** Not regulated for transport  
**UN Proper Shipping Name** Not regulated for transport

#### 15. REGULATORY INFORMATION

##### **US Federal regulations**

<b>Methadone Hydrochloride Injection, USP</b>	
SARA Section 311/312 Hazard Classes	Delayed (chronic) health hazard

##### **US State regulations**

Not applicable

##### **Canadian regulations**

<b>Methadone Hydrochloride Injection, USP</b>	
WHMIS Classification	Class D Division 2 Subdivision A - Very toxic material causing other toxic effects



This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by CPR.

**16. OTHER INFORMATION**

**Revision date** : 06/10/2014

**Data sources** : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

**Other information** : Outpatient maintenance and outpatient detoxification treatment may be provided only by Opioid Treatment Programs (OTPs) certified by the Federal Substance Abuse and Mental Health Services Administration (SAMHSA) and registered by the Drug Enforcement Administration (DEA). This does not preclude the maintenance treatment of a patient with concurrent opioid addiction who is hospitalized for conditions other than opioid addiction and who requires temporary maintenance during the critical period of his/her stay, or of a patient whose enrollment has been verified in a program which has been certified for maintenance treatment with methadone.  
This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warnings included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

**GHS Full Text Phrases:**

Acute Tox. 2 (Oral)	Acute toxicity (oral) Category 2
Repr. 2	Reproductive toxicity Category 2
H300	Fatal if swallowed
H361	Suspected of damaging fertility or the unborn child

**Party Responsible For The Preparation Of This Document:**

Mylan Global Environmental, Health, and Safety Department  
Phone Number: 304-599-2595

*This MSDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions.*

*To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.*

North America Mylan Pharmaceuticals