



# SAFETY DATA SHEET

## Methadone Hydrochloride Injection, USP

### 1. IDENTIFICATION

<b>Product Identifier:</b>	Methadone Hydrochloride Injection, USP 
<b>Synonyms:</b>	6-(dimethylamino)-4,4-diphenyl-3-heptanone hydrochloride
<b>National Drug Code (NDC):</b>	17478-380-20
<b>Recommended Use:</b>	Pharmaceutical. Methadone Hydrochloride Injection, USP is indicated for the treatment of moderate to severe pain not responsive to non-narcotic analgesic and for use in temporary treatment of opioid dependence in patients unable to take oral medication.
<b>Company:</b>	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
<b>Contact Telephone:</b>	1-800-932-5676
<b>E mail:</b>	customer.service@akorn.com
<b>Emergency Phone Number:</b>	CHEMTREC 1-800-424-9300 (U.S. and Canada)

### 2. HAZARD(S) IDENTIFICATION

<b>Physical Hazards:</b>	Not classifiable.	
<b>Health Hazards:</b>	Acute Toxicity, Oral	Category 4
	Reproductive Toxicity	Category 2
<b>Symbol(s):</b>		
<b>Signal Word:</b>	Warning.	
<b>Hazard Statement(s):</b>	H302 Harmful if swallowed.  H361 Suspected of damaging fertility or the unborn child.	
<b>Precautionary Statement(s):</b>	P201 Obtain special instructions before use.  P202 Do not handle until all safety precautions have been read and understood.  P264 Wash hands thoroughly after handling.  P270 Do not eat, drink or smoke when using this product.	

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- P301 + P312 IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell.
- P330 Rinse mouth.
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- P501 Dispose of contents/container in accordance with all local and national regulations.

**Hazards Not Otherwise Classified:** Not classifiable.  
**Supplementary Information:** None.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient	Synonyms	CAS Number	Chemical Formula	Molecular Weight	Percentage
Methadone Hydrochloride	6-(dimethylamino)-4,4-diphenyl-3-heptanone hydrochloride	1095-90-5	$C_{21}H_{27}NO \cdot HCl$	345.91	1%

The formula also contains Chlorobutanol, 0.5%, as a preservative, Sodium Chloride and Water for Injection. Sodium Hydroxide and/or Hydrochloric Acid may have been used to adjust the pH (4.5 to 6.5).

### 4. FIRST AID MEASURES

- Ingestion:** If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
- Eye Contact:** Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
- Skin Contact:** Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

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<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Serious overdosage of Methadone is characterized by respiratory depression (a decrease in respiratory rate and/or tidal volume, Cheyne-Stokes respiration, cyanosis), extreme somnolence progressing to stupor or coma, maximally constricted pupils, skeletal-muscle flaccidity, cold and clammy skin, and sometimes, bradycardia and hypotension. In severe overdosage, particularly by the intravenous route, apnea, circulatory collapse, cardiac arrest, and death may occur.
<b>Medical Conditions Aggravated by Exposure:</b>	Opioid analgesics: Liver impairment. Kidney impairment. Hypothyroidism. Seizure disorders. Asthma. Respiratory disorders. Heart arrhythmia. Alcoholism. History of drug abuse or dependence. Gallbladder disorders. Inflammatory bowel disease. Urinary disorders. Low blood pressure. Gastrointestinal obstruction. Adrenal gland problems. Sickle cell disease. Addison's disease. Concurrent use of monoamine oxidase inhibitors.
<b>Notes to Physician:</b>	Treat supportively and symptomatically. Methadone Hydrochloride Injection is a Schedule II controlled substance and can be abused in a manner similar to other opioid agonists, legal or illicit. This should be considered when prescribing or dispensing Methadone Hydrochloride Injection in situations where the physician or pharmacist is concerned about an increased risk of misuse, abuse, or diversion.

### 5. FIREFIGHTING MEASURES

<b>Suitable Extinguishing Media:</b>	Use water, carbon dioxide, dry chemical or alcohol-resistant foam as necessary.
<b>Unsuitable Extinguishing Media:</b>	Not determined.
<b><u>Specific Hazards Arising from the Chemical</u></b>	
<b>Hazardous Combustion Products:</b>	Not determined.
<b>Other Specific Hazards:</b>	Closed containers may explode from the heat of fire.
<b>Special Protective Equipment and Precautions for Firefighters:</b>	Wear self-contained breathing apparatus and full and protective gear.

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### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions:** Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** Absorb with inert material. Recover product and place in an appropriate container for disposal in accordance with local, state and federal regulations.

**Environmental Precautions:** Contain material and prevent release to basements, confined spaces, waterways or soil.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

### 7. HANDLING AND STORAGE

**Precautions for Safe Handling:** In the US, Methadone Hydrochloride is a Schedule CII controlled substance. Appropriate training and procedures may be required during the routine handling of this product. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage, Including Any Incompatibilities:** Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from light. Store in carton until contents have been used.

**Specific End Use:** Pharmaceuticals.

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Occupational Exposure Guidelines:**

Ingredient	Type	Value
Methadone Hydrochloride	Note established	Not established

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Respiratory Protection:** Respiratory protection is normally not needed during intended product use. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

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<b>Eyes Protection:</b>	Not required for the normal use of this product. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
<b>Hand Protection:</b>	Chemically compatible gloves should be worn. For handling solutions ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
<b>Skin Protection:</b>	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.
<b>General Hygiene Considerations:</b>	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State/Color:</b>	Clear, colorless solution.
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	4.5 to 6.5
<b>Melting Point:</b>	235°C.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

### 10. STABILITY AND REACTIVITY

<b>Reactivity:</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.

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<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	Protect from light.
<b>Incompatible Materials:</b>	No data available.
<b>Hazardous Decomposition Products:</b>	Toxic gases and vapors may be released if involved in a fire.

### 11. TOXICOLOGICAL INFORMATION

#### Information on the Likely Routes of Exposure

<b>Inhalation:</b>	May cause irritation to the respiratory system.
<b>Ingestion:</b>	May cause nausea, constipation, dizziness.
<b>Skin Contact:</b>	May cause skin irritation.
<b>Eye Contact:</b>	May cause eye irritation.

#### **Symptoms Related to the Physical, Chemical and Toxicological Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

#### **Delayed and Immediate Effects of Exposure:**

No data available.

#### Acute Toxicity

Not fully established. This product is a mixture that has not been fully tested as a whole. Information provided herein is derived from the approved product insert and/or supplier SDS for active ingredients.

Ingredient	Species	Route	Test Type	Dosage
Methadone Hydrochloride	Rat	Oral	LD <sub>50</sub>	30 mg/kg; 86 mg/kg
	Mouse	Oral	LD <sub>50</sub>	70 mg/kg; 124 mg/kg

#### Irritation / Sensitization

Ingredient	Study Type	Species	Severity
No data available	No data available	No data available	No data available

#### Repeated Doses Toxicity

Ingredient	Duration	Species	Route	Dosage	Test Type	Target Organ
No data available	No data available	No data available	No data available	No data available	No data available	No data available

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### Reproduction and Developmental Toxicity

Ingredient	Study Type	Species	Route	Dosage	Test Type	Effect(s)
No data available	No data available	No data available	No data available	No data available	No data available	No data available

### Genetic Toxicity

Ingredient	Study Type	Cell Type / Organism	Result
No data available	No data available	No data available	No data available

**Aspiration Hazard:** No data available.  
**Toxicokinetics/Metabolism:** No data available.

**Target Organ Effects:** Based on clinical use, possible target organs include the nervous system, respiratory system, and cardiovascular system. May cause increased sensitivity, tolerance, habituation and addiction.

**Systemic Effects:** No data available.

**Reproductive Effects:** Pregnancy Category C. There are no controlled studies of methadone use in pregnant women that can be used to establish safety.

**Carcinogenicity:** Data from published reports of carcinogenicity studies indicate that there was a significant increase in pituitary adenomas in female B6C2F1 mice consuming 15 mg/kg/day methadone for two years. This dose was approximately 0.6 times a human daily oral dose of 120 mg/day, on a body surface area basis. However, this finding was not seen in mice consuming 60 mg/kg/day (approximately 2.5 times the human daily oral dose of 120 mg/day).

**National Toxicology Program (NTP):** Not considered to be a carcinogen.

**International Agency for Research on Cancer (IARC):** Not considered to be a carcinogen.

**Occupational Safety and Health Administration (OSHA):** Not considered to be a carcinogen.

## 12. ECOLOGICAL INFORMATION

### Aquatic Toxicity

Ingredient	Species	Test Type	Dosage	Duration
No data available	No data available	No data available	No data available	No data available

**Terrestrial Toxicity:** No data available.  
**Persistence and Degradability:** No data available.  
**Bioaccumulative Potential:** No data available.  
**Mobility in Soil:** No data available.

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**Mobility in Environment:** No data available.  
**Other Adverse Effects:** No data available.

### 13. DISPOSAL CONSIDERATIONS

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. TRANSPORT INFORMATION

**Department of Transportation (DOT):** Not regulated as hazardous material.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

UN Proper Shipping Name	UN Number	Transport Hazard Class	Packing Group
Not applicable	Not applicable	Not Applicable	Not applicable

### 15. REGULATORY INFORMATION

#### US FEDERAL REGULATIONS

**Toxic Substance Control Act (TSCA):**

Ingredient	Inventory
Methadone Hydrochloride	No

**CERCLA Hazardous Substance:**

Ingredient	Reportable Quantity
Not applicable	Not applicable

**EPCRA Extremely Hazardous Substances and Toxic Chemicals:**

Ingredient	Section 302	Section 313
Not applicable	Not applicable	Not applicable

#### .U.S. STATE RIGHT-TO-KNOW REGULATIONS

Ingredient	New Jersey	Pennsylvania	Massachusetts
Methadone Hydrochloride	Not Listed	Not Listed	Not Listed

**California Proposition 65:** This product does not contain any chemicals known to State of California to cause cancer and birth defects or other reproductive harm.



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## 16. OTHER INFORMATION

The vial stopper is not made with natural rubber latex.

See footer of this document for Revision Date and Revision Number.

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