



IN CASE OF EMERGENCY CALL:
National Poison Control 800-222-1222

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name: Methadone Hydrochloride Tablets for Oral Suspension, USP CII
CAS No: 1095-90-5
Chemical Name: 3-heptanone, 6-(dimethylamino)-4,4-diphenyl-, hydrochloride
Chemical Formula: $C_{21}H_{27}NO \bullet HCl$
Molecular Weight: 345.91
Product Use: Treatment of Opioid Addiction

Distributor's Name: VistaPharm, Inc.
Address: 7265 Ulmerton Road
Largo, FL 33771

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition: Methadone Hydrochloride (40mg per tablet) active ingredient

Please refer to current package insert for other components.

3. HAZARDS IDENTIFICATION

Emergency Overview Physical State: Round, biconvex, quadrisectioned, dispersible tablet.
The 40mg tablet is white, with E 132 imprinted on one side.

Odor: No data available.

WARNING:

Methadone Hydrochloride is an opioid analgesic.
May be harmful if swallowed.
Accidental ingestion of large amounts may be fatal.

Primary Route of Entry: Ingestion

Potential Health Effects: Inhalation: Not expected to be an inhalation hazard in final pharmaceutical form.

Eye Contact: Not expected to be a hazard to the eye. Contact with eye may cause irritation, burning and redness.

Skin Contact: Not expected to be a hazard to the skin. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation.

Ingestion: May be harmful if ingested. Can cause respiratory depression, nausea, vomiting, sedation and dizziness.

Toxicity Data: See Section 11.

Effects of Overexposure: The potential for exposure is reduced in finished pharmaceutical form. Overexposure may cause respiratory depression, extreme somnolence progressing toward stupor or coma, skeletal muscle flaccidity, cold and clammy skin, and constricted pupils. Severe overexposure can cause apnea, circulatory collapse, cardiac arrest and death.

Target Organs: Central nervous system.

4. FIRST AID MEASURES

Eye Exposure: Any material that contacts the eye should be washed out immediately with water. Obtain medical attention if symptoms persist.

Skin Exposure: Wash affected area with soap and water. Remove contaminated clothing and shoes immediately. Obtain medical attention if symptoms occur.

Inhalation: Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Obtain medical attention immediately.

Ingestion: Call a physician or poison control center immediately.

5. FIRE AND EXPLOSION HAZARD

Flash Point: Not determined.

Extinguishing Media: Use water spray, dry chemical, carbon dioxide, foam or material appropriate for fire in surrounding area.

Fire Fighting Procedures: Wear full protective clothing and self-contained breathing apparatus.

Hazardous Combustion Products: Carbon dioxide, carbon monoxide, oxides of nitrogen, hydrogen chloride.

6. ACCIDENTAL RELEASE MEASURES

If Material is Spilled or Released: Use appropriate personal protective equipment (see Section 8). Wipe up and containerize spill material in a compatible container. Dispose according to applicable regulations. Incineration of the waste at an approved facility is recommended.

7. HANDLING AND STORAGE

Handling: Observe good industrial hygiene practices.

Storage: Store at 20° and 25°C (68° to 77°F). Keep container closed tightly and protect from moisture. Store away from foods. Store according to DEA regulations.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

OSHA Exposure Limits: None

Engineering Controls: Not required when handling tablets or containers. Good ventilation should be use. Ventilation should be matched to conditions.

Respiratory Protection: Not required when handling tablets or containers. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.

Personal Protection: Not required when handling final product. If containers are compromised or exposure is likely, wear goggles, lab coat, and gloves.

Recommended Facilities: Eye wash, washing facilities

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: White, round, bioconvex dispersible tablet

Melting Point (deg. C): Not determined.

Boiling Point (deg. C): Not determined.

Solubility: Soluble

pH: Not determined.

10. STABILITY AND REACTIVITY

Chemical Stability: Yes

Conditions to Avoid: Excessive heat or cold, moisture

Incompatibility: Oxidizing agents, alkalis

Hazardous Decomposition: Oxides of carbon, oxides of nitrogen, hydrogen chloride

Hazardous Polymerization: No

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Active Ingredient:

Oral LD50 (rat): 30 mg/kg

Oral LD50 (mouse): 124 mg/kg

Carcinogenicity: Not listed as a carcinogen by NTP, IARC Monographs or OSHA

12. ECOLOGICAL INFORMATION

Environmental Effects : Not determined.

13. WASTE DISPOSAL INFORMATION

Waste Disposal Considerations: Drug Enforcement Administration controlled substances must be destroyed following DEA Guidelines for witness destruction of the product beyond reclamation. Disposal by incineration is recommended.

At Home: Discard away from children’s reach.

14. TRANSPORTATION INFORMATION

This product is authorized as exempt, therefore is not subject to regulations for the safe transport of hazardous chemicals.

15. REGULATORY INFORMATION

DEA: Methadone Hydrochloride CII is a DEA Schedule II controlled substance.

FDA: Methadone Hydrochloride CII is an approved prescription medication.

Inventory Status: The material is not listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.
This material is not listed on the DSL Inventory but is exempt.

16. DISCLAIMER

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user’s responsibility to evaluate the information and use it in a prudent manner for its particular purpose. VistaPharm, Inc. assumes no responsibility for the use of this information.

Date: October, 2008

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION