IN CASE OF EMERGENCY
Emergency Phone: (614) 276-4000

Boehringer Ingelheim
Roxane Laboratories

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Common/Trade Name: Methadone Hydrochloride CII Oral Solution USP
Chemical Name: 3-Heptanone, 6-(dimethylamino)-4,4-diphenyl-, hydrochloride
Synonyms: None
Molecular Formula: $C_{21}H_{27}NO \cdot HCl$
Molecular Weight: 345.91
CAS No: 1095-90-5
Chemical Family: Opioid analgesic
Product Use: Management of moderate to severe pain

Manufacturer's Name: **Boehringer Ingelheim Roxane Inc.**
Address: **1809 Wilson Road**
Columbus, Ohio 43228

2. COMPOSITION / INFORMATION ON INGREDIENTS

Composition	CAS#	Exposure Limit
Methadone Hydrochloride (active ingredient)	1095-90-5	None established
Alcohol, ethyl	64-17-5	ACGIH TLV-TWA: 1000ppm OSHA Z-1 PEL: 1000ppm

REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%

3. HAZARDS IDENTIFICATION

Emergency Overview	**Physical State: Liquid solution administered orally.** **Clear, orange, citrus-flavored solution with 5 mg/5 mL or 10 mg/5 mL active ingredient.** **Odor: No data available** **WARNING!** **Methadone Hydrochloride is an opioid analgesic.** **Contains flammable liquid.** **May be harmful if swallowed.** **Accidental ingestion of large amounts may be fatal.**
Primary Route(s) 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, skeletal muscle flaccidity and pupil dilation. 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. If easy to do, remove contact lenses if worn. Get medical attention if symptoms persist.**
Skin Exposure	**Wash with soap and water. Get medical attention if symptoms occur.**
Ingestion	**Call a physician or poison control center immediately.**
Inhalation	**Should not pose a hazard in the final form. If breathing is difficult, move to fresh air. Get medical attention immediately.**

5. FIRE AND EXPLOSION HAZARDS

Flammability	**Lower: N/A Upper: N/A**
Flash Point	**49°C (estimated for ethanol)**
Extinguishing Media	**Use water spray, dry chemical, carbon dioxide, foam or material appropriate for fire in surrounding area**
Special Fire Fighting Procedures	**Wear full protective clothing and self-contained breathing apparatus. Use water spray to keep fire-exposed containers cool.**
Unusual Fire/Explosion Hazards	**For significant quantities of product: Combustible. Prevent build-up of vapors or gases to explosive concentrations.**
Hazardous Combustion Products	**Carbon dioxide, carbon monoxide, oxides of nitrogen, hydrogen chloride**

6. ACCIDENTAL RELEASE INFORMATION

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF LIQUID IS SPILLED:
Use appropriate personal protective equipment (see Section 8). Eliminate ignition sources. 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. PRECAUTIONS FOR SAFE HANDLING AND USE

Precautions Handling Significant Quantities of Liquid:	**Observe good industrial hygiene practices.**
Storage	**Store at 15° and 30°C (59° to 86°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs.**

8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

Exposure Limits	**None**
Engineering Controls	**Not required when handling liquid or containers. Good ventilation should be used. Ventilation should be matched to conditions.**
Respiratory Protection	**Not required when handling liquid 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, Gloves**
Recommended Facilities	**Eye wash, washing facilities**

9. PHYSICAL / CHEMICAL CHARACTERISTICS

Appearance	**Clear, orange liquid solution**	**Melting point**	**Not available**	**Solubility in water**	**Soluble**
Odor	**Not available**	**Boiling point**	**Not available**	**Specific Gravity**	**Not available**
Taste	**Citrus-flavored**	**Vapor Pressure**	**Not available**	**Flashpoint**	**49°C (estimated for ethanol)**
pH	**Not available**	**Density**	**Not available**	**Flammability Limits**	**Not available**

10. STABILITY AND REACTIVITY DATA

Stability	**Stable**
Incompatibility	**Oxidizing agents, alkalis, chlorocresal, iodides, mercury salts, saccharin sodium**
Hazardous Decomposition	**Oxides of carbon, oxides of nitrogen, hydrogen chloride**
Conditions to Avoid	**Excessive heat, light**
Hazardous Polymerization	**Will not occur.**

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. ENVIRONMENTAL IMPACT INFORMATION

No information is currently available on the environmental impact of this product.

13. DISPOSAL INFORMATION

Waste Disposal Considerations: Drug Enforcement Administration controlled substances must be destroyed following DEA Guidelines for witnessed 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. For more information, please contact a Boehringer-Ingelheim Roxane, Inc. representative.
DOT: Not Regulated
TDG: Not Regulated
IATA: Not Regulated
IMDG: Not Regulated

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: This 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. OTHER DATA

ABBEVIATIONS:
N/A – not applicable

Prepared by: Boehringer Ingelheim Roxane, Inc.

References:

1. **Methadone Hydrochloride Oral Solution USP, Package Insert, Boehringer Ingelheim Roxane, Inc., Columbus, Ohio**
2. **RTECS No. NJ6300000 - 3-Heptanone, 6-(dimethylamino)-4,4-diphenyl-, hydrochloride**
3. **Ariel Webinsight. Regulatory and ChemExpert Database.**
4. **PDR – Physicians Desk Reference**

Date: 09/13/2008 - New MSDS

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION