



Boehringer Ingelheim
Roxane Laboratories

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

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: DISKETTS® Dispersible Tablets (Methadone Hydrochloride Tablets for Oral Suspension USP)		
Chemical Name: 3-Heptanone, 6-(dimethylamino)-4,4-diphenyl-, hydrochloride		
Synonyms: None		
Molecular Formula: C ₂₁ H ₂₇ NO • 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
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: Rectangular, cross-scored tablets The 40 mg tablets are peach, cross-scored on one side and "54 883" engraved on the other. 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(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 in final pharmaceutical form. 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	Not available
Extinguishing Media	Use water spray, dry chemical, carbon dioxide or material appropriate for fire in surrounding area
Special Fire Fighting Procedures	Wear full protective clothing and self-contained breathing apparatus.
Unusual Fire/Explosion Hazards	Not Applicable
Hazardous Combustion Products	Carbon dioxide, carbon monoxide, oxides of nitrogen, hydrogen chloride

6. ACCIDENTAL RELEASE INFORMATION

STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF PRODUCT IS SPILLED:

Use appropriate personal protective equipment (see Section 8). Sweep 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 Product:	Observe good industrial hygiene practices.
Storage	Store at 15° to 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 tablets or containers. 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, Gloves
Recommended Facilities	Eye wash, washing facilities

9. PHYSICAL / CHEMICAL CHARACTERISTICS

Appearance	Peach, rectangular cross-scored tablets	Melting point	Not available	Solubility in water	Dispersible
Odor	Not available	Boiling point	Not available	Specific Gravity	Not available
Taste	Not available	Vapor Pressure	Not available	Flashpoint	Not available
pH	Not available	Density	Not available	Flammability Limits	Not available

10. STABILITY AND REACTIVITY DATA

Stability	Stable
Incompatibility	None known
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 not subject to the regulations for the safe transport of hazardous chemicals.	
DOT: Not regulated	
TDG: Not regulated	
IATA: Not regulated	
IMDG: Not regulated	
15. REGULATORY INFORMATION	
DEA: Methadone Hydrochloride  is a DEA Schedule II controlled substance.	
FDA: Methadone Hydrochloride  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	
ABBREVIATIONS:	
N/A – not applicable	
Prepared by: Boehringer Ingelheim Roxane, Inc.	
References:	
<ol style="list-style-type: none"> 1. DISKETTS® Dispersible Tablets  (Methadone Hydrochloride  Tablets for Oral Suspension, 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: 05/04/2009 - New MSDS	

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION

The information provided is believed to be complete and accurate. If this product is combined with other materials, deteriorates or becomes contaminated, it may pose hazards not mentioned in this MSDS. It is the users' responsibility to use the information according to the application. Boehringer Ingelheim Roxane Inc. assumes no responsibility or liability resulting from the use of this information.