




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

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Morphine Sulfate Tablets 		
Chemical Name: 7,8-didehydro-4,5 alpha-epoxy-17 methyl-morphinan-3,6 alpha-diol sulfate (2:1) (salt) pentahydrate		
Synonyms: None		
Molecular Formula: C ₃₄ H ₃₈ N ₂ O ₆ · H ₂ O ₄ S · 5H ₂ O		
Molecular Weight: 758		
CAS No: 6211-15-0		
Chemical Family: Opioid analgesic		
Product Use: Relief of moderate to severe acute and chronic pain		
Manufacturer's Name: Boehringer Ingelheim Roxane Inc.		
Address: 1809 Wilson Road Columbus, Ohio 43228		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Morphine Sulfate (active ingredient)	6211-15-0	None established
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: Biconvex tablet The 15 mg tablets are white, scored on one side and with "54 733" debossed on the other. The 30 mg tablets are white, scored on one side and with "54 262" debossed on the other. Odor: No data available WARNING! Morphine sulfate 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, severe hypotension, and nausea. Can produce effects on papillary response and consciousness.	
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 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, oxides of sulfur				
6. ACCIDENTAL RELEASE INFORMATION					
STEPS TO BE TAKEN IF SIGNIFICANT QUANTITIES OF TABLETS ARE BROKEN: Use appropriate personal protective equipment (see Section 8). Sweep up and containerize spill material in a compatible container. Follow DEA procedures. 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 Broken Tablets:	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 tablets or containers. Good ventilation (typically 10 air changes per hour) should be used. 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	White, biconvex tablets	Melting point	Not available	Solubility in water	Not available
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, oxides of sulfur
Conditions to Avoid	Excessive heat, light, moisture
Hazardous Polymerization	Will not occur.
11. TOXICOLOGICAL INFORMATION	
<p>Acute Toxicity:</p> <p>Active Ingredient: LD50 Oral (rat): 973 mg/kg LD50 Oral (mouse): 1,125 mg/kg</p> <p>Carcinogenicity: Not listed as a carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.</p>	
12. ENVIRONMENTAL IMPACT INFORMATION	
No information is currently available on the environmental impact of this product.	
13. DISPOSAL INFORMATION	
<p>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.</p> <p>At home: Discard away from children's reach.</p>	
14. TRANSPORTATION INFORMATION	
<p>This product is not subject to the regulations for the safe transport of hazardous chemicals.</p> <p>DOT: Not regulated TDG: Not regulated IATA: Not regulated IMDG: Not regulated</p>	
15. REGULATORY INFORMATION	
<p>DEA: Morphine Sulfate is a DEA Schedule II controlled substance.</p> <p>FDA: Morphine Sulfate is an approved prescription medication.</p> <p>Canadian Controlled Products Regulations: This product has been classified in according to the hazard criteria of the Canadian Controlled Products Regulations, Section 33, and the MSDS contains all the required information.</p> <p>WHMIS Classification for Product: Not controlled, exempt</p> <p>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.</p>	
16. OTHER DATA	
<p>ABBREVIATIONS: N/A – not applicable</p> <p>Prepared by: Boehringer Ingelheim Roxane, Inc.</p> <p>References:</p> <ol style="list-style-type: none"> 1. Morphine Sulfate Oral Solution and Tablets, Package Insert, Roxane Laboratories, Inc., Columbus, Ohio 2. RTECS No. 200608 for 7,8-didehydro-4,5 alpha-epoxy-17 methyl-morphinan-3,6 alpha-diol sulfate (2:1) (salt) pentahydrate 3. Ariel Webinsight. Regulatory and ChemExpert Database. 4. PDR – Physicians Desk Reference 	

Date: 07/16/2008 - 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.