







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

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION		
Common/Trade Name: Cocaine Hydrochloride  Topical Solution		
Chemical Name: 1-alpha-H,5-alpha-H-Tropane-2-beta-carboxylic acid, 3-beta-hydroxy-, methyl ester,benzoate(ester), hydrochloride		
Synonyms: None		
Molecular Formula: C ₁₇ H ₂₁ NO ₄ ClH		
Molecular Weight: 339.85		
CAS No: 53-21-4		
Chemical Family: Anesthetic, Tropane Alkaloid		
Product Use: Local topical anesthetic		
Manufacturer's Name: Boehringer Ingelheim Roxane Inc.		
Address: 1809 Wilson Road Columbus, Ohio 43228		
2. COMPOSITION / INFORMATION ON INGREDIENTS		
Composition	CAS#	Exposure Limit
Cocaine Hydrochloride (active ingredient)	53-21-4	None established
<i>REFER to PHYSICIAN'S DESK REFERENCE for common components present as <1%</i>		
3. HAZARDS IDENTIFICATION		
Emergency Overview	Physical State: Liquid solution administered topically. Blue-green, aqueous solution as 4% and 10% concentrations. Odor: No data available WARNING! Causes eye irritation. May be harmful if inhaled, swallowed or absorbed through the skin. Accidental ingestion of large amounts may be fatal.	
Primary Route(s) of Entry	Ingestion	
Potential Health Effects:	Inhalation: May be harmful if inhaled. Inhalation may cause numbness to the mucous membranes/nasal cavities, nervousness, confusion, and restlessness. Eye Contact: Causes eye irritation. Contact with eye may cause irritation, burning and redness. Skin Contact: May be harmful if absorbed through the skin. Skin absorption may cause numbness at sight of contact, restlessness, confusion and increased blood pressure. Can cause hypersensitive reactions resulting in rash, redness, itching and inflammation. Ingestion: May be harmful if ingested. Ingestion may cause numbness, nausea, nervousness and increased blood pressure.	
Toxicity Data:	See Section 11	

Effects of Overexposure:	The potential for exposure is reduced in finished pharmaceutical form. Overexposure to this product may cause changes in blood pressure, irregular heartbeat, convulsions and decreased response. Severe overdoses can cause weakened cardiac/respiratory function, loss of consciousness and even death.				
Target Organs:	Central Nervous System, Skin				
4. FIRST AID MEASURES					
Eye Exposure	Immediately flush with plenty of water for at least 15 minutes. If easy to do, remove contact lenses. Get medical attention.				
Skin Exposure	Wash with soap and water. Get medical attention if symptoms occur.				
Ingestion	Call a physician or poison control center immediately.				
Inhalation	Move to fresh air and treat symptomatically. 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, carbon dioxide, dry chemical, foam 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 LIQUID IS SPILLED: 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. PRECAUTIONS FOR SAFE HANDLING AND USE					
Precautions Handling Significant Quantities of Liquid:	Avoid breathing mist or vapors. Avoid contact with eyes, skin and clothing. Do not taste or swallow. Use only with adequate ventilation. Wash thoroughly after handling.				
Storage	Store at 20° to 25°C (68° to 77°F). Keep container closed tightly. Protect from light and moisture. Store away from foodstuffs. Keep from freezing.				
8. CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT					
Exposure Limits	None				
Engineering Controls	Not required when handling containers. If containers are compromised or exposure is likely: Good ventilation should be used. Ventilation should be matched to conditions.				
Respiratory Protection	Not required when handling containers. If containers are compromised or exposure is likely wear: NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary. Ventilation should be matched to conditions.				
Personal Protection	If containers are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves				
Recommended Facilities	Eye wash, washing facilities				
9. PHYSICAL / CHEMICAL CHARACTERISTICS					
Appearance	Blue-green aqueous solution	Melting point	Not available	Solubility in water	Soluble
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	Calomel, mercuric acid, silver nitrate, alkaloid precipitants
Hazardous Decomposition	Oxides of carbon, oxides of nitrogen, hydrogen chloride
Conditions to Avoid	Excessive heat and light
Hazardous Polymerization	Will not occur.
11. TOXICOLOGICAL INFORMATION	
Acute Toxicity:	
Active Ingredient: LD50 Oral (mouse): 96 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: Cocaine Hydrochloride  is a DEA Schedule II controlled substance.	
FDA: Cocaine 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. Cocaine Hydrochloride  Topical Solution, Package Insert, Boehringer Ingelheim Roxane Inc., Columbus, Ohio 2. RTECS No. YM3050000 for 1-alpha-H,5-alpha-H-Tropane-2-beta-carboxylic acid, 3-beta-hydroxy-, methyl ester,benzoate(ester), 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

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.