

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

Material Safety Data Sheet

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Common/Trade Name: Lidocaine Hydrochloride Topical Solution USP 4%

Chemical Name: 2-Diethylamino-2',6'-acetoxylidide hydrochloride

Synonyms: None

Molecular Formula: C₁₄H₂₂N₂O • HCl

Molecular Weight: 270.84

CAS No: 73-78-9

Chemical Family: Anesthetic

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
Lidocaine Hydrochloride (active ingredient)	73-78-9	None established

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

3. HAZARDS IDENTIFICATION

Emergency Overview	Physical State: Liquid solution administered topically. Colorless liquid with 4% concentration of active ingredient.			
	Odor: No data available			
	WARNING!			
	May be harmful if inhaled or swallowed. 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: 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 eye. 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	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.
Central Nervous System, Mucous Membranes, Gastrointestinal tract

4. FIRST AID MEASURES

Overexposure:

Target Organs:

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	Wash with soap and water. Get medical attention if symptoms occur.					
Ingestion	Call a phys	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.			fresh air. Get		
5. FIRE AND EXP	PLOSION HA	ZARDS					
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 IN	IFORMATION					
Use appropriate pe	rsonal protec	CANT QUANTITIES OF LIQUI tive equipment (see Section 8 ccording to applicable regula	3). Wipe up and cor				
7. PRECAUTION	S FOR SAFE	HANDLING AND USE					
	ecautions Handling Avoid breathing mist or vapors. Avoid contact with eyes, skin and clothing. Do not taste of swallow. Use only with adequate ventilation. Wash thoroughly after handling.						
Storage		15° to 30°C (59° to 86°F). Keep container closed tightly. Protect from light and . Store away from foodstuffs.					
8. CONTROL MEA	SURES AND F	PERSONAL PROTECTIVE EQ	JIPMENT				
Exposure Limits None							
Engineering Contro		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	wear: NI	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.					
		ners are compromised or exposure is likely wear: Goggles, Lab Coat, Gloves					
Recommended Facilities	Eye was	h, washing facilities					
9. PHYSICAL/C	HEMICAL CH	HARACTERISTICS					
Appearance Cold solu	rless liquid tion	Melting point	Not available	Solubility in water	Soluble		
Odor Not	available	Boiling point	Not available	Specific Gravity	Not available		
	available	Vapor Pressure	Not available	Flashpoint	Not available		
	oveileble.	Density	Not available	Flammability	Not seed to be		
pH Not	available	Density	Trot available	Limits	Not available		

Stability	Stable
Incompatibility	None known
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): 220 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: Dispose of material according to federal, state and local disposal regulations or company operating procedures. 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: Lidocaine Hydrochloride is a not a controlled substance.

FDA: Lidocaine 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

ABBEVIATIONS:

N/A - not applicable

Prepared by: Boehringer Ingelheim Roxane Inc.

References:

- 1. Lidocaine Hydrochloride Topical Solution USP, Package Insert, Boehringer Ingelheim Roxane Inc., Columbus, Ohio
- 2. RTECS No. AN7600000 2',6'-Acetoxylidide, 2-(diethylamino)-, hydrochloride
- 3. Ariel Webinsight. Regulatory and ChemExpert Database.
- 4. PDR Physicians Desk Reference

Date: 10/24/2012 - Revised MSDS

SEE CURRENT PACKAGE INSERT FOR FURTHER INFORMATION

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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.