

SAFETY DATA SHEET

1. Identification

Product identifier Lidocaine Hydrochloride Topical Solution USP 4%

Other means of identification None.

Recommended use Indicated for the production of topical anesthesia

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Company name Boehringer Ingelheim Roxane Inc.

Address 1809 Wilson Road
Columbus, Ohio 43228

Telephone (614) 276-4000

Emergency phone number (614) 276-4000

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word Warning

Hazard statement This is a pharmaceutical product designed to be prescribed by a licensed health care professional. Should any person while using this product observe any adverse health effects, they should seek medical treatment.

Precautionary statement

Prevention Observe good industrial hygiene practices.

Response Wash hands after handling.

Storage Store away from incompatible materials. Keep from freezing. Store at a controlled room temperature, 20° - 25° C (68°-77° F.)

Disposal Incineration of waste at an approved USEPA incinerator is recommended.

Hazard(s) not otherwise classified (HNOC) None known.

3. Composition/information on ingredients

Substances

Chemical name	Common name and synonyms	CAS number	%
2 - (diethylamino)-N-(2,6-dimethyl phenyl)-acetamide		73-78-9	4%

Composition comments Components not listed are either non-hazardous or are below reportable limits. Refer to Physician's Desk Reference for common components present at <1%

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed	Side effects may include: CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. Allergic reactions as a result of sensitivity to lidocaine are extremely rare.
Indication of immediate medical attention and special treatment needed	Supportive measures (including oxygen and vasopressors) should be employed in the management of circulatory shock and pulmonary edema accompanying overdose as indicated. Cardiac arrest or arrhythmias may require cardiac massage or defibrillation.
General information	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.
5. Fire-fighting measures	
Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Use water spray to cool unopened containers.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.
6. Accidental release measures	
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear appropriate personal protective equipment (See Section 8).
Methods and materials for containment and cleaning up	Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.
7. Handling and storage	
Precautions for safe handling	Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling.
Conditions for safe storage, including any incompatibilities	Store away from incompatible materials (see Section 10 of the SDS). Do not freeze. Store at controlled room temperature at 20–25 °C (68–77°F).
8. Exposure controls/personal protection	
Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Ventilation should be matched to conditions.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Avoid contact with eyes. In laboratory, medical or industrial settings, safety glasses with side shields are recommended. The use of goggles or full face protection may be required depending on the industrial exposure setting.
Skin protection	
Hand protection	Wear protective gloves (i.e. latex, nitrile, neoprene). Wash hands after contact.
Other	Wash promptly with soap and water if skin becomes contaminated. In laboratory, medical or industrial settings, gloves and lab coats are recommended. The use of additional personal protective equipment such as shoe coverings, gauntlets, hood or head coverings may be necessary.
Respiratory protection	None required for consumer use.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Solution.
Color	Clear and colorless.
Odor	Not available.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Keep from freezing.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Not expected to be hazardous in final pharmaceutical form.
Skin contact	Contact will cause localized anesthesia.
Eye contact	Contact will cause localized anesthesia. Direct contact with eyes may cause temporary irritation.
Ingestion	Do not ingest.

Symptoms related to the physical, chemical and toxicological characteristics	Side effects may include: CNS manifestations are excitatory and/or depressant and may be characterized by lightheadedness, nervousness, apprehension, euphoria, confusion, dizziness, drowsiness, tinnitus, blurred or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression and arrest. Allergic reactions as a result of sensitivity to lidocaine are extremely rare.
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Information on toxicological effects

Acute toxicity		May be harmful if swallowed in large quantities.
Components	Species	Test Results
2 - (diethylamino)-N-(2,6-dimethylphenyl)-acetamide (CAS 73-78-9)		
Acute		
Oral	Mouse	220 mg/kg
Skin corrosion/irritation	Contact will cause localized anesthesia.	
Serious eye damage/eye irritation	Contact will cause localized anesthesia. Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Not a respiratory sensitizer.	
Skin sensitization	This product is not expected to cause skin sensitization.	
Germ cell mutagenicity	No mutagenicity studies have been conducted	
Carcinogenicity	Long-term studies in animals have not been conducted to evaluate carcinogenic potential	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		
Reproductive toxicity	Pregnancy Category B	
	There are no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.	
	It is not known whether this product is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when administering to a nursing woman	
Specific target organ toxicity - single exposure	Not classified.	
Specific target organ toxicity - repeated exposure	Not classified.	
Aspiration hazard	Not classified.	
Further information	See package insert.	
12. Ecological information		
Ecotoxicity	The product is not classified as environmentally hazardous.	
Persistence and degradability	No data is available on the degradability of this product.	
Bioaccumulative potential	No data available.	
Mobility in soil	No data available.	
Other adverse effects	None.	
13. Disposal considerations		
Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.	
Local disposal regulations	Dispose in accordance with all applicable regulations.	
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.	
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).	
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.	
14. Transport information		
DOT		
Not regulated as dangerous goods.		
IATA		
Not regulated as dangerous goods.		

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

US federal regulations

This material is not listed on the US TSCA 8(b) Inventory, therefore it may only be used for TSCA exempt purposes such as R&D or drug use. Over-the-counter drugs in their solid final form (i.e. tablets or pills) are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limits may be surpassed, they can be considered hazardous.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories

Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	20-March-2015
Revision date	-
Version #	01
References	<p>1) Lidocaine Hydrochloride Topical Solution USP 4%, Package Insert, Roxane Laboratories, Inc., Columbus, Ohio</p> <p>2) PDR – Physicians Desk Reference.</p> <p>3) Ariel Webinsight. Regulatory and ChemExpert Database.</p>

Disclaimer	Boehringer Ingelheim Roxane Inc. cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.
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