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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-(diethylamino)-N-(2,6-dimethyl phenyl)-acetamide</td>
<td></td>
<td>73-78-9</td>
<td>4%</td>
</tr>
</tbody>
</table>

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, blunted 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 (CO2).

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 ºC (68-77ºF).

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.
Acute toxicity
May be harmful if swallowed in large quantities.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 - (diethylamino)-N-(2,6-dimethylphenyl)-acetamide (CAS 73-78-9)</td>
<td>Mouse</td>
<td>220 mg/kg</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th>Hazard categories</th>
<th>Immediate Hazard - No</th>
<th>Delayed Hazard - No</th>
<th>Fire Hazard - No</th>
<th>Pressure Hazard - No</th>
<th>Reactivity Hazard - No</th>
</tr>
</thead>
</table>

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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>Yes</td>
</tr>
<tr>
<td>Country(s) or region</td>
<td>Inventory name</td>
<td>On inventory (yes/no)*</td>
</tr>
<tr>
<td>---------------------------</td>
<td>------------------------------------------------------------</td>
<td>------------------------</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>Yes</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>Yes</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td>(PICCS)</td>
<td></td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>Yes</td>
</tr>
</tbody>
</table>

*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

<table>
<thead>
<tr>
<th>Issue date</th>
<th>20-March-2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision date</td>
<td>-</td>
</tr>
<tr>
<td>Version #</td>
<td>01</td>
</tr>
</tbody>
</table>
| References        | 1) Lidocaine Hydrochloride Topical Solution USP 4%, Package Insert, Roxane Laboratories, Inc., Columbus, Ohio
|                   | 2) PDR – Physicians Desk Reference. |

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.