

SAFETY DATA SHEET

1. Identification

Product Identifier:	Lidocaine Ointment, USP 5%
Synonyms:	Lignocaine
National Drug Code (NDC):	50383-933-35 50383-933-55
Recommended Use:	Pharmaceutical.
Company:	Akorn, Inc. 1925 West Field Court, Suite 300 Lake Forest, Illinois 60045
Contact Telephone:	1-800-932-5676
E mail:	customer.service@akorn.com
Emergency Phone Number:	CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards:	Combustible liquid	Category 4
Health Hazards:	Not classifiable.	
Symbol(s):	None.	
Signal Word:	Warning.	
Hazard Statement(s):	H227 Combustible liquid.	
Precautionary Statement(s):	P210 Keep away from flames and hot surfaces. No smoking.	
	P280 Wear protective gloves/eye protection/ face protection.	
	P370 + P378 In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary to extinguish.	
	P403 + P235 Store in a well-ventilated place. Keep cool.	
	P501 Dispose of contents/container in accordance with local/regional/national/ international regulations.	
Hazards Not Otherwise Classified:	Not classifiable.	
Supplementary Information:	None.	

3. **Composition/Information on Ingredients**

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Acetamide, 2-(diethylamino)-N-(2,6-dimethylphenyl)-	137-58-6	Lignocaine	C ₁₄ H ₂₂ N ₂ O	234.34	5%

*The formula also contains Polyethylene Glycols and Peppermint Oil.

4. **First Aid Measures**

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

Eye Contact:

Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Skin Contact:

Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Inhalation:

Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.

Protection of First-Aiders:

Use personal protective equipment (see section 8).

Signs and Symptoms:

See package insert for more information.

Medical Conditions Aggravated by Exposure:

No data available.

Notes to Physician:

Treat supportively and symptomatically.

5. **Firefighting Measures**

Suitable Extinguishing Media: Water Spray, Carbon Dioxide, Foam, Dry Chemical, Halon.

Unsuitable Extinguishing Media: Not determined.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products: This product is combustible. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon oxides and nitrogen oxides). The Lidocaine component of this product is a skin sensitizer, and so it poses a contact hazard to firefighters.

Other Specific Hazards: Closed containers may explode from the heat of fire.

Special Protective Equipment/Precautions for Firefighters: Wear self-contained breathing apparatus and full and protective gear.

6. **Accidental Release Measures**

Personal Precautions: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate personal protective equipment and clothing.

Personal Protective Equipment: For personal protection see section 8.

Methods for Cleaning Up:

Small Spills: Wear goggles and gloves while wiping up small spills of this product with polypad or sponge.

Large Spills: Trained personnel following pre-planned procedures should handle non-incident releases. Access to the spill area should be restricted. Protective apparel should be used with a respirator when there is any danger of mists or sprays being generated. Minimum Personal Protective Equipment should be rubber gloves, rubber boots, face shield, and Tyvek suit. The dispersal of mists or sprays into surrounding air and the possibility of inhalation is serious matter and should be treated as such. Absorb spilled liquid using polypads or other suitable absorbent material.

Decontaminate the area of the spill thoroughly using detergent and water. Place all spill residue in an appropriate container and seal. Dispose of in accordance with applicable Federal, State, and local procedures.

Environmental Precautions: Prevent material from entering sewer or confined spaces, waterways, soil or public waters.

SDS: Lidocaine Ointment, USP 5%

Reference to Other Sections: Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities: Store according to label and/or product insert information. Store this product away from incompatible materials. Store this product in original container.

Specific End Use: Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Lidocaine	5 mg/m ³ STEL 1 mg/m ³ TWA

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Respiratory Protection: A respirator is not required for routine conditions of use of this product. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

Eyes Protection: Not normally needed during normal use. Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Hand Protection: Not normally needed during normal use. Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Skin Protection: Not normally needed during normal use. Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	White ointment.
Odor:	Peppermint odor.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	No data available.
Freezing Point:	40°C (104°F).
Boiling Point:	225°C (437°F).
Flash Point:	No data available.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	No data available.
Flammability Limit - Upper:	No data available.
Vapor Pressure:	No data available.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	No data available.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.
Specific Gravity:	1.053.

10. Stability and Reactivity

Reactivity:	No data available.
Chemical Stability:	Stable under recommended storage conditions.
Possibility of Hazardous Reactions:	No data available.
Conditions to Avoid (e.g., static discharge, shock, or vibration):	Acids, caustics, and other chemicals that could affect its performance should be avoided. Avoid heat, light, and contact with materials listed to avoid.
Incompatible Materials:	Oxidizers, acids, bases.
Hazardous Decomposition Products:	None if used for intended purpose.
Hazardous Polymerization:	Will not occur.

11. Toxicological Information**Information on the Likely Routes of Exposure:**

Inhalation:	Unlikely due to form of product. May cause irritation.
Ingestion:	May be harmful if swallowed.
Skin Contact:	May cause skin irritation.
Eye Contact:	May cause eye irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure:

No data available.

Acute Toxicity – Oral:

No data available.

Acute Toxicity – Dermal:

No data available.

Acute Toxicity – Inhalation:

No data available.

Corrosivity:

No data available.

Dermal Irritation:

No data available.

Eye Irritation:

No data available.

Sensitization:

No data available.

Toxicokinetics/Metabolism:

No data available.

Target Organ Effects:

No data available.

Reproductive Effects:

No data available.

Carcinogenicity:

No data available.

National Toxicology Program (NTP):

Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC):

Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA):

Not considered to be a carcinogen.

Mutagenicity:

No data available.

Aspiration Hazard:

No data available.

12. Ecological Information**Ecotoxicity****Aquatic:**

No data available.

Terrestrial:

No data available.

Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Soil:

No data available.

Mobility in Environment:

No data available.

Other Adverse Effects:

No data available.

13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information**UN Number:**

Not applicable.

UN Proper Shipping Name:

Not applicable.

Transport Hazard Class(es):

Not applicable.

Packing Group:

Not applicable.

Department of Transportation:

Not regulated as a hazardous material.

International Air Transport Association (IATA): Not regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Not regulated as a dangerous good.

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA): This product is a drug regulated by the Food and Drug Administration (FDA), and is not regulated by TSCA.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

Massachusetts: Not listed.
New Jersey: Not listed.
Pennsylvania: Not listed.
California Proposition 65: Not listed.

16. Other Information

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