SAFETY DATA SHEETS

This SDS packet was issued with item:

078944636

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078934593

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Product Name: Lidocaine Ointment USP, 5% (Spearmint flavored) **Product No.:** 51672-3008

Distributor: Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive, Hawthorne, New York 10532
Telephone: 1-888-TARO-USA

Recommended Use: Lidocaine Ointment USP, 5% is indicated for production of anesthesia of accessible mucous membranes of the oropharynx.

It is also useful as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites.

Restrictions on Use: Lidocaine is contraindicated in patients with a known history of hypersensitivity to local anesthetics of the amide type or to other components of Lidocaine Ointment USP, 5%.

Substance Class: Anesthetic (local)

Formula: $C_{14}H_{22}N_2O$

M.W.: 234.34

SECTION 2: HAZARD(S) IDENTIFICATION

Physical Hazards: Not classified.

Health Hazards:

Acute toxicity, oral	Category 4
Serious eye damage/eye irritation	Category 2A

OSHA Hazard(s): Not classified.

Label Elements

Signal Word: Warning

Hazard Statement: Harmful if swallowed. Causes serious eye irritation.

Precautionary Statement

Prevention: Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Wear eye/face protection.

Response: If swallowed: Call a poison center/doctor/medical professional/ if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Disposal: Dispose of contents/container to an approved disposal site.

Hazard(s) Not Otherwise Classified (HNOC): Not classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient:	Lidocaine USP	CAS#: 137-58-6
Inactive Ingredients:	Polyethylene glycol 400, polyethylene glycol 3350, propylene glycol, and spearmint flavor.	

SECTION 4: FIRST-AID MEASURES

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

Skin Contact: Rinse skin with water/shower. Get medical attention if irritation develops and persists.

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

Ingestion: Rinse mouth. If swallowed: Call a Poison Center or doctor/physician if you feel unwell.

Most Important Symptoms/Effects, Acute and Delayed: Not available.

Indication of Immediate Medical Attention and Special Treatment Needed: Treatment of local anesthetic overdose should be symptomatic and supportive and may include the following: Do not induce vomiting. Administer activated charcoal as a slurry. For circulatory depression, administer a vasopressor or intravenous fluids. For seizures, administer an intravenous benzodiazepine, followed by phenobarbital or propofol if seizures recur. Avoid the use of phenytoin which may worsen or precipitate cardiac arrhythmias. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. Lipid infusion may be useful for reversing severe cardiac toxicity. For coma and respiratory depression, protect airway with an endotracheal tube and assist ventilation as necessary. For bradycardia and bradyarrhythmias with heart rates less than 60, administer intravenous, intramuscular, or subcutaneous atropine. For hypotension, infuse isotonic fluid. If persistent, administer dopamine. For severe metabolic acidosis, correct with intravenous sodium bicarbonate. For respiratory acidosis, treat with assisted

ventilation. For methemoglobinemia in symptomatic patients, administer intravenous methylene blue. Enhanced elimination with hemodialysis, exchange transfusion, AV hemofiltration, and forced diuresis has not been shown to increase clearance substantially. Urinary acidification is not recommended. Cardiac bypass support should be considered for cardiovascular collapse. (Poisindex)

General Information: Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.

Unsuitable Extinguishing Media: None known.

Specific Hazards Arising From the Chemical: No unusual fire or explosion hazards noted.

Special Protective Equipment and Precautions for Firefighters: Wear suitable protective equipment.

Fire-Fighting Equipment/Instructions: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific Methods: Cool containers exposed to flames with water until well after the fire is out.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

Methods and Materials for Containment and Cleaning Up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Wash spill site.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling: Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

Conditions for Safe Storage, Including Any Incompatibilities: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. Protect from freezing. Keep tightly closed.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit Values

Industrial Use

Material	Type	Value
Lidocaine (CAS 137-58-6)	STEL	5 mg/m^3
	TWA	1 mg/m^3

Biological Limit Values: No biological exposure limits noted for the ingredient(s).

Appropriate Engineering Controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.

Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Individual Protection Measures, Such As Personal Protective Equipment

Eye/Face Protection: Safety glasses with sideshields 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.

Skin Protection

Hand Protection: Chemically compatible gloves. 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 nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other: For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory Protection: 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).

Thermal Hazards: Not available.

General Hygiene Considerations: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point:	Not Applicable.
Physical State (Liquid/Solid/Gas):	Solid
Specific Gravity (H_2O=1):	Not Applicable.
Evaporation Rate (Butyl Acetate=1):	Slower than ether
Solubility:	Not Applicable.
Appearance:	White ointment
Odor Description:	Spearmint odor

SECTION 10: STABILITY AND REACTIVITY

Reactivity: No reactivity hazards known.

Chemical Stability: Stable at normal conditions.

Possibility of Hazardous Reactions: No dangerous reaction known under conditions of normal use.

Conditions To Avoid: None known.

Incompatible Materials: Strong oxidizing agents. Strong mineral acids. Ammonia.

Hazardous Decomposition Products: NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure

Ingestion: Harmful if swallowed.
Inhalation: Due to lack of data the classification is not possible.
Skin Contact: Due to lack of data the classification is not possible.
Eye Contact: Causes serious eye irritation.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics: For local anesthetics: Nausea. Vomiting. Headache. Numbness. Skin rash. Skin redness. Itching. Hives. Hive-like swelling in mouth or throat. Sweating. Pale or bluish skin. Neck or back pain. Chest pain. Change in vision. Slurred speech. Dizziness. Lightheadedness. Drowsiness. Tiredness. Weakness. Feeling hot or cold. Ringing in ears. Shivering. Dilation of pupils. Disorientation. Hallucinations. Anxiety. Nervousness. Excitement. Confusion. Difficulty breathing. Fainting. Muscle twitching. Tremor. Convulsion.

Delayed and Immediate Effects of Exposure: For local anesthetics: Change in blood pressure. Slow or irregular heartbeat. Cessation of breathing. Circulatory depression. Shock. Cardiac arrest. Coma. Death.

Cross Sensitivity: Persons sensitive to one amide-type anesthetics, flecainide, or tocainide may be sensitive to this material also.

Medical Conditions Aggravated by Exposure: Hearing disorders. Epilepsy. Liver impairment. Kidney impairment.

Acute Toxicity: Harmful if swallowed.

Product	Species	Test Results
Lidocaine (CAS 137-58-6)		
Acute		
Oral		
LD50	Mouse	220 mg/kg
	Rat	317 mg/kg
Other		
LD50	Mouse	19.5 mg/kg
	Rat	25 mg/kg

Skin Corrosion/Irritation: Based on available data, the classification criteria are not met.

Serious Eye Damage/Eye Irritation: Causes serious eye irritation.

Respiratory Sensitization: Due to lack of data the classification is not possible.

Skin Sensitization: Based on available data, the classification criteria are not met.

Sensitization

Modified Buehler topical closed-patch test	Result: Non-sensitizing.
Species: Guinea pig	Organ: Skin

Germ Cell Mutagenicity: Based on available data, the classification criteria are not met.

Mutagenicity

Ames S. typhimurium reverse mutation assay	Result: Negative.
In vitro chromosome aberration assay in human lymphocytes	Result: Negative.
In vivo mouse microsome assay	Result: Negative.

Carcinogenicity: Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data noted for the ingredient(s).

Persistence and Degradability: No data is available on the degradability of this product.

Bioaccumulative Potential: Not available.

Mobility in Soil: Not available.

Other Adverse Effects: Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Instructions: This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

Local Disposal Regulations: Not available.

Hazardous Waste Code: Not regulated.

Waste From Residues / Unused Products: 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.

SECTION 14: TRANSPORT INFORMATION

DOT: Not regulated as a hazardous material by DOT.

IATA: Not regulated as a dangerous good.

Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: No information available.

SECTION 15: REGULATORY INFORMATION

U.S. Federal Regulations CERCLA/SARA Hazardous Substances - Not applicable. All components are on the U.S. EPA TSCA Inventory List.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard Categories: Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely Hazardous Substance: No

SARA 311/312 Hazardous Chemical: No

Other Federal Regulations

Safe Drinking Water Act (SDWA): Not regulated.

Food and Drug Administration (FDA): Not regulated.

U.S. State Regulations: California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

SECTION 16: OTHER INFORMATION

Contact: Taro Pharmaceuticals U.S.A., Inc., Regulatory Affairs Department
3 Skyline Drive, Hawthorne, NY 10532

Preparation and/or Revision Date: December 2016

D I S C L A I M E R

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