

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Product Name: Ammonium Lactate Lotion, 12% **Product No.:** 51672-1300

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

Recommended Use: Ammonium lactate lotion is indicated for the treatment of dry, scaly skin (xerosis) and ichthyosis vulgaris and for temporary relief of itching associated with these conditions.

Restrictions on Use: Ammonium Lactate Lotion is contraindicated in those patients with a history of hypersensitivity to any of the label ingredients.

Substance Class: Organic acid

Formula: Lactic Acid C₃H₆O₃

SECTION 2: HAZARD(S) IDENTIFICATION

Physical Hazards: Corrosive to metals Category 1

Health Hazards: Skin corrosion/irritation Category 1

Serious Eye Damage/Eye Irritation: Category 1

Environmental Hazards: Not classified.

OSHA Defined Hazards: Not classified.

Label Elements

Hazard Statement: May be corrosive to metals. Causes severe skin burns and eye damage. Causes serious eye damage.

Precautionary Statement

Prevention: Keep only in original container. Do not breathe mist or vapor. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

Response: If swallowed: Rinse mouth. Do NOT induce vomiting. If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. If inhaled: Remove person to fresh air and keep comfortable for breathing. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to

do. Continue rinsing. Immediately call a poison center/doctor. Wash contaminated clothing before reuse. Absorb spillage to prevent material damage.

Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) Not Otherwise Classified (HNOC): None known.

Supplemental Information: None.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient:	Ammonium lactate equivalent to 12% lactic acid	CAS#: 79-33-4
Inactive Ingredients:	Cetyl alcohol, glycerin, glyceryl monostearate, laureth-4, light mineral oil, magnesium aluminum silicate, methylcellulose, methylparaben, polyoxyethylene 100 stearate, polyoxyl 40 stearate, propylene glycol, propylparaben, purified water, and for pH adjustment: lactic acid.	

SECTION 4: FIRST-AID MEASURES

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing. 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: Call a physician or poison control center immediately.

Most Important Symptoms/Effects, Acute and Delayed: Corrosive effects.

Indication of Immediate Medical Attention and Special Treatment Needed: Provide general supportive measures and treat symptomatically. Chemical burns: Flush with water immediately. While flushing, remove clothes which do not adhere to affected area. Call an ambulance. Continue flushing during transport to hospital. Do not induce vomiting. Administer water for dilution if patient can swallow. Neutralization, activated charcoal, ipecac, and gastric lavage are all contradicted. For eye exposure, irrigate each eye continuously with normal saline during transport. (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 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: No unusual fire or explosion hazards noted.

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

Firefighting Equipment/Instructions: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Move containers from fire area if you can do so without risk.

General Fire Hazards: No unusual fire or explosion hazards noted.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of vapors. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and Materials for Containment and Cleaning Up: Absorb spillage with suitable absorbent material. For waste disposal, see section 13 of the SDS.

Environmental Precautions: Avoid discharge into drains, water courses or onto the ground.

SECTION 7: HANDLING AND STORAGE

Precautions for Safe Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. 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 controlled room temperature 20°-25°C (68°-77°F).

SECTION 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: 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. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other: For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties 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: Wear appropriate thermal protective clothing, when necessary.

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point: Approximately 212°F.

Physical State (Liquid/Solid/Gas): Lotion.

Specific Gravity (H₂O = 1): Greater than 1.

Evaporation Rate (Butyl Acetate = 1): N/A.

Solubility: Soluble.

Appearance: A clear liquid free from any particulate matter

Odor Description: Perfume.

SECTION 10: STABILITY AND REACTIVITY

Reactivity: May be corrosive to metals.

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.

Incompatible Materials: Strong oxidizing agents. Metals.

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

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure

Inhalation: May cause irritation to the respiratory system.

Skin Contact: Causes severe skin burns.

Eye Contact: Causes severe eye burns. Causes serious eye damage.

Ingestion: Causes digestive tract burns.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics: Burning pain and severe corrosive skin damage. Permanent eye damage including blindness could result. Red eyes. Blurred vision. Burning in mouth, throat, and/or stomach. Gastrointestinal disturbances. Sweating. Shortness of breath.

Acute Toxicity

<u>Product</u>	<u>Species</u>	<u>Test Results</u>
Lactic Acid (CAS 79-33-4)		
<u>Acute</u>		

Dermal		
LD50	Rabbit	> 2000 mg/kg > 2000 mg/kg, 24 hours
Inhalation		
LC50	Rat	> 7.94 mg/l, 4 Hours
Oral		
LD50	Guinea pig	1810 mg/kg
	Mouse	4875 mg/kg
	Rat	3543 mg/kg

Skin Corrosion/Irritation: Causes severe skin burns and eye damage.

Serious Eye Damage/Eye Irritation: Causes severe eye burns. Causes serious eye damage.

Respiratory or Skin Sensitization

Respiratory Sensitization: Knowledge about health hazard is incomplete.

Skin Sensitization: Knowledge about health hazard is incomplete.

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

Mutagenicity:

Chromosomal aberration assay in Chinese hamster ovary cells

Result: Negative (with and without activation).

S. typhimurium Ames assay

Result: Negative.

Carcinogenicity: Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity: Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050): Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens: Not listed.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Product	Species		Test Results
Lactic Acid (CAS 79-33-4)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	180 - 320 mg/l, 48 hours

Persistence and Degradability: Expected to be readily biodegradable.

Bioaccumulative Potential

Bioaccumulative Potential

Octanol/Water Partition Coefficient Log Kow: 0.72

Mobility in Soil: No data available.

Other Adverse Effects: No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Instructions: Dispose of contents/container in accordance with local/regional/national/international regulations. 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.

Local Disposal Regulations: Dispose in accordance with all applicable regulations.

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.

Contaminated Packaging: Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: TRANSPORT INFORMATION

DOT:

UN Number: UN3265

UN Proper Shipping Name: Corrosive liquid, acidic, organic, n.o.s. (Lactic Acid)

Transport Hazard Class(es):

Class: 8

Subsidiary Risk: -

Packing Group: II

IATA

UN Number: UN3265

UN Proper Shipping Name: Corrosive liquid, acidic, organic, n.o.s. (Lactic Acid)

Transport Hazard Class(es):

Class: 8

Subsidiary Risk: -

Packing Group: II

Other Information

Passenger and Cargo Aircraft: Allowed with restrictions.

Cargo Aircraft Only: Allowed with restrictions

Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not established.

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. This product is a “Hazardous Chemical” as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D): Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4): Not listed.

SARA 304 Emergency Release Notification: Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050): Not regulated.

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: Not listed.

SARA 311/312 Hazardous Chemical: Yes

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.

Food and Drug Administration (FDA):

- Total food additive
- Direct food additive
- GRAS food additive

U.S. State Regulations

U.S. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100): Not listed.

U.S. Massachusetts RTK - Substance List: Not regulated.

U.S. New Jersey Worker and Community Right-to-Know Act: Not listed.

U.S. Pennsylvania RTK - Hazardous Substances: Not regulated.

U.S. Pennsylvania Worker and Community Right-to-Know Law: Not listed.

U.S. Rhode Island RTK: Not regulated.

U.S. California Proposition 65: 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: August 2016

DISCLAIMER

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