SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

Product Name: Malathion Lotion USP, 0.5% **Product No.:** 51672-5294

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

Recommended Use: Malathion lotion is indicated for patients infected with *Pediculus humanus capitis* (head lice and their ova) of the scalp hair.

Restrictions on Use: Malathion lotion is contraindicated for neonates and infants because their scalps are more permeable and may have increased absorption of malathion. Malathion lotion should also not be used on individuals known to be sensitive to malathion or any of the ingredients in the vehicle.

Substance Class: Pesticide

Formula: $C_{10}H_{19}O_6PS_2$

M.W.: 330.36

SECTION 2: HAZARD(S) IDENTIFICATION

Physical Hazards: Not classified.

Health Hazards:		
	Acute toxicity, oral	Category 3
	Serious eye damage/eye irritation	Category 2B
	Sensitization, skin	Category 1
	Carcinogenicity	Category 1B

Environmental Hazards: Not classified.

OSHA Defined Hazards: Not classified.

Label Elements

Signal Word: Danger

Hazard Statement: Toxic if swallowed. May cause an allergic skin reaction. Causes eye irritation. May cause cancer.

Precautionary Statement

Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid breathing mist or vapor. Wash thoroughly after handling. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.

Response: If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. 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. If exposed or concerned: Get medical advice/attention.

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

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient:	Malathion	CAS#: 121-75-5
Inactive Ingredients:	Isopropyl alcohol, terpineol, dipentene, and pine needle oil.	

SECTION 4: FIRST-AID MEASURES

Inhalation: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.

Skin Contact: Remove contaminated clothing immediately and wash skin with soap and water. In case of eczema or other skin disorders: Seek medical attention and take along these instructions.

Eye Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion: Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if victim ingested the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most Important Symptoms/Effects, Acute and Delayed: Irritation of eyes. May cause an allergic skin reaction. Gastrointestinal disturbances. Nervous system effects.

Indication of Immediate Medical Attention and Special Treatment Needed: Treatment of organophosphate overdose should be symptomatic and supportive and may include the following: 1. If material was ingested, do not induce vomiting. Consider gastric lavage with protected airway and administer activated charcoal. 2. Suction oral secretions. 3. Administer atropine to treat symptomatic organophosphate poisoning. Severe organophosphate poisoning, characterized by profound weakness and respiratory depression, may also be treated with pralidoxime (2-PAM). 4. For pulmonary edema (noncardiogenic), maintain ventilation and oxygenation and evaluate with frequent arterial blood gas or pulse oximetry monitoring. Early use of PEEP and mechanical ventilation may be needed. 5. For hypotension, infuse patient with isotonic fluid and place in Trendelenburg position. If hypotension persists, administer dopamine or norepinephrine. 6. Monitor for hypotension, dysrhythmias, respiratory

depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. 7. Succinylcholine and other cholinergic agents are contraindicated.

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.

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. Clean surface thoroughly to remove residual contamination.

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.

Stored at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Material	Type	Value	Form
Malathion (CAS 121-75-5)	PEL	15 mg/m^3	Total dust.

US. NIOSH: Pocket Guide to Chemical Hazards

Material	Type	Value
Malathion (CAS 121-75-5)	TWA	10 mg/m^3

US. ACGIH Threshold Limit Values

Material	Type	Value	Form
Malathion (CAS 121-75-5)	TWA	1 mg/m^3	Inhalable fraction and vapor.

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. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

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).

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

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point: N/A

Physical State (Liquid/Solid/Gas): Liquid

Specific Gravity (H_2O = 1): N/A

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

Solubility: N/A

Appearance: Clear, colourless to pale yellow, mobile oily liquid with terpene-like odour, essentially free of haze or opalescence

Odor Description: Terpene-like odour

SECTION 10: STABILITY AND REACTIVITY

Reactivity: None known.

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. Magnesium. Amines. Strong alkalis. Iron. This material is corrosive to metals and will attack some forms of plastic, rubber, and coatings.

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

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure

Ingestion: Toxic if swallowed.

Inhalation: Not classified.

Skin Contact: May cause an allergic skin reaction.

Eye Contact: Causes eye irritation.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics: Gastrointestinal disturbances. Behavior, mood, or mental changes. Headache. Dizziness. Drowsiness. Seizures. Muscle twitching. Increased sweating. Increased watering of mouth or eyes. Loss of bladder control. Runny nose. Blurred vision. Pinpoint pupils. Difficulty breathing. Bluish skin. Slow or fast heartbeat. Unusual weakness.

Medical Conditions Aggravated by Exposure: Asthma. Bradycardia. Hypotension. Recent heart attack. Peptic ulcer. Recent brain surgery. Neuromuscular disorders. Seizure disorders. Exposure to neurotoxic insecticides. Liver disease. Malnutrition. Dehydration. Anemia.

Acute Toxicity: Toxic if swallowed.

Product	**Species**	**Test Results**
Malathion (CAS 121-75-5)		
Acute		
Dermal		
LD50	Mouse	2330 mg/kg
	Rabbit	4100 mg/kg
Inhalation		
LC50	Rat	> 5.2 mg/l, 4 hours
Oral		
LD50	Mouse	190 mg/kg
	Rat	290 mg/kg

Skin Corrosion/Irritation: Not classified.

Serious Eye Damage/Eye Irritation: Causes eye irritation.

Respiratory or Skin Sensitization

Respiratory Sensitization: Classification not possible.

Skin Sensitization: May cause an allergic skin reaction. Contact dermatitis has been reported in the literature.

Skin Sensitization:

Guinea pig sensitization tests
Result: Mixed results.

Germ Cell Mutagenicity: Classification not possible. Results of genotoxicity tests are mixed.

Carcinogenicity: May cause cancer. IARC: Group 2A; Probably carcinogenic to humans.
Case-control studies of occupational exposures
Result: Increased risk of prostate cancer. Positive association with non-Hodgkin lymphoma.
Species: Human

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: This material is toxic to fish, aquatic invertebrates, and the aquatic life stage of amphibians. This material is highly toxic to bees.

Product		Species	Test Results
Malathion (CAS 121-75-5)			
Acute			
Other	IC50	Pseudokirchnerella subcapitata	4.06 mg/l, 72 hours
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	0.0007 - 0.0014 mg/l, 48 hours
Fish	LC50	Bluegill (Lepomis macrochirus)	0.04 - 0.052 mg/l, 96 hours
Chronic			
Crustacea	NOEC	Daphnia magna	0.06 µg/l, 21 days

Persistence and Degradability: Biodegradable.

Bioaccumulative Potential: Not available.

Mobility in Soil: Not available.

Other Adverse Effects: Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Instructions: Dispose in accordance with all applicable 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.

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: 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: UN3018
UN Proper Shipping Name: Organophosphorous pesticide, liquid, toxic (Malathion)
Transport Hazard Class(es)
Class: 6.1
Subsidiary Risk: -
Packing Group: III

IATA

UN Number: UN3018
UN Proper Shipping Name: Organophosphorous pesticide, liquid, toxic (Malathion)
Transport Hazard Class(es)
Class: 6.1
Subsidiary Risk: -
Packing Group: III
Other Information
Passenger and Cargo Aircraft: Allowed.
Cargo Aircraft Only: Allowed.

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

General Information: It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

SECTION 15: REGULATORY INFORMATION

US Federal Regulations: CERCLA/SARA Reportable Quantities: 45.4 kg (100 lb). This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard Categories: Immediate Hazard - Yes
Delayed Hazard - Yes
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): Yes

Chemical Name	CAS Number	% by wt.
Malathion	121-75-5	100

Other Federal Regulations

Clean Water Act (CWA) Section 112(r) (40 CFR 68.130): Hazardous substance

Safe Drinking Water Act (SDWA): Not regulated.

Food and Drug Administration (FDA): Not regulated.

US State Regulations

US. 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

D I S C L A I M E R

The above information has been obtained from a number of sources and its accuracy cannot be guaranteed. It is the user's responsibility to evaluate the information and use it in a prudent manner for its particular purpose. Taro Pharmaceuticals assumes no responsibility for the use of this information.