

MATERIAL SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: Imiquimod Cream, 5% **PRODUCT No.:** 51672-4145

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

Recommended Use: Imiquimod Cream is indicated for the topical treatment of:

- Clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratoses (AK) on the face or scalp in immunocompetent adults.
- External genital and perianal warts/condyloma acuminata in patients 12 years old or older.

Restrictions on Use: Limitations of Use: Efficacy was not demonstrated for molluscum contagiosum in children aged 2-12.

Imiquimod Cream has been evaluated in children ages 2 to 12 years with molluscum contagiosum and these studies failed to demonstrate efficacy.

SUBSTANCE CLASS: Immune Response Modifier

FORMULA: $C_{14}H_{16}N_4$

M.W.: 240.30

SECTION 2: HAZARD(S) IDENTIFICATION

EMERGENCY OVERVIEW

POTENTIAL HEALTH HAZARDS

Eye: Mild eye irritation: signs/symptoms may include redness, pain, and tearing.

Skin: Delayed dermal irritation: Signs/symptoms may include localized redness, swelling, itching, and pain. These effects may not appear immediately following exposure.

Ingestion: Ingestion is not a likely route of exposure to this product.

Inhalation: No health effects are expected.

NFPA Hazard Classification

Health: 1 **Flammability:** 0 **Reactivity:** 0 **Special Hazards:** None

National Fire Protection Association (NFPA) hazard ratings are designed for use by emergency response personnel to address the hazards that are presented by short-term, acute exposure to a material under conditions of fire, spill, or similar emergencies. Hazard ratings are primarily based on the inherent

physical and toxic properties of the material but also include the toxic properties of combustion or decomposition products that are known to be generated in significant quantities.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient:	Imiquimod	CAS#: 99011-02-6
Inactive Ingredients:	Benzyl alcohol, cetyl alcohol, glycerin, isostearic acid, methylparaben, polysorbate 60, propylparaben, purified water, sorbitan monostearate, stearyl alcohol, white petrolatum, and xanthan gum.	

SECTION 4: FIRST-AID MEASURES

Eye Contact:	Flush eyes with large amounts of water. If signs/symptoms persist, get medical attention.
Skin Contact:	Wash affected area with soap and water. If signs/symptoms develop, get medical attention.
Ingestion:	Do not induce vomiting unless instructed to do so by medical personnel. If signs/symptoms develop, get medical attention.
Inhalation:	No need for first aid is anticipated.

SECTION 5: FIRE-FIGHTING MEASURES

FLASH POINT:	N/A
EXTINGUISHING MEDIA:	Non-combustible. Choose material suitable for surrounding fire.
SPECIAL FIRE FIGHTING PROCEDURES:	Wear full protective equipment (Bunker Gear) and a self-contained breathing apparatus (SCBA).
UNUSUAL FIRE AND EXPLOSION HAZARDS:	No unusual fire or explosion hazards are anticipated.

SECTION 6: ACCIDENTAL RELEASE MEASURES

STEPS TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:

Observe precautions from other sections. Evacuate unprotected and untrained personnel from hazard area. The spill should be cleaned up by qualified personnel. Ventilate the area with fresh air. Clean up residue with detergent and water. Place in a closed container approved for transportation by appropriate authorities. Dispose of collected material as soon as possible.

SECTION 7: HANDLING AND STORAGE

HANDLING: Avoid eye contact. Do not eat, drink or smoke when using this product.
Wash exposed areas thoroughly with soap and water. Avoid skin contact.

STORAGE: Store at 4 - 25°C (39 - 77°F). Avoid freezing.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: Use in a well-ventilated area.

PERSONAL PROTECTION:

Respiratory: Under normal use conditions, airborne exposures are not expected to be significant enough to require respiratory protection.

Eye: Safety glasses with side shields.

Skin: Avoid skin contact.

Clothing: Select and use gloves and/or protective clothing to prevent skin contact based on the results of an exposure assessment.

Gloves: Butyl Rubber, Neoprene, Nitrile Rubber.

Prevention of swallowing: Do not ingest. Wash hands after handling and before eating.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

MELTING RANGE: No data available.

BOILING POINT: No data available.

PHYSICAL STATE (liquid/solid/gas): Liquid

SPECIFIC GRAVITY (H₂O=1): 0.94-0.96

EVAPORATION RATE (Butyl Acetate=1): No data available.

SOLUBILITY: Moderately soluble in water.

APPEARANCE: White to slightly yellow smooth cream

ODOR DESCRIPTION: N/A

SECTION 10: STABILITY AND REACTIVITY

CHEMICAL STABILITY: Stable.

MATERIALS AND CONDITIONS TO AVOID: Strong bases; Strong oxidizing agents.

HAZARDOUS DECOMPOSITION
PRODUCTS:

During combustion following decomposition
products: Hydrocarbons, Carbon monoxide,
Carbon dioxide, Irritant Vapours or Gases

HAZARDOUS POLYMERIZATION:

Will not occur

SECTION 11: TOXICOLOGICAL INFORMATION

Acute toxicity: No data available

Irritation and corrosion: No data available

SECTION 12: ECOLOGICAL INFORMATION

Characteristic

Toxicity

Details

LC50 and EC50 values have not been established
for this product

Degradability

No data on formulation.

Persistence

No applicable information available

Bioaccumulation

No applicable information available

Mobility in Soil

No applicable information available

SECTION 13: DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHOD:

Incinerate in an industrial or commercial facility in the presence of a combustible material. As a disposal alternative, dispose of waste product in a facility permitted to accept chemical waste.

SECTION 14: TRANSPORT INFORMATION

Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labeling for air, maritime, US or European ground transport purposes

SECTION 15: REGULATORY INFORMATION

US FEDERAL REGULATIONS

311/312 Hazard Categories:

Fire Hazard - No Pressure Hazard - No

Reactivity Hazard - No

Immediate Hazard - Yes

Delayed Hazard - Yes

SECTION 16: OTHER INFORMATION

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

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