

Potential Health Effects:

Eye Contact: Contact with the eyes may result in mild to moderate irritation (burning or stinging). Avoid contact with the eyes.

Skin Contact: In sensitive individuals, repeated or prolonged skin contact With **Tazarotene** may result in skin dryness, itching, redness, peeling or burning.

Inhalation: The product is non-volatile and inhalation is not likely to occur.

Ingestion: May cause moderate to severe irritation and nausea.

Chronic Effects: Overexposure to members of this class of compounds may affect liver function causing hypertriglyceridemia. Other symptoms may include conjunctival irritation, hair loss, headache, edema, fatigue, dermatitis, nausea, and visual disturbances.

Reproductive Effects: Retinoids have been shown to produce an increased incidence of adverse reproductive outcomes, specifically spontaneous fetal abortions or malformed fetal development when orally administered to women during pregnancy. Therefore, **women of childbearing age should observe all precautions for safe handling and use of protective equipment indicated in this MSDS when handling this product.**

Teratogenicity: A study in female rats indicated that topical application of Tazarotene at doses up to 0.25 mg/kg/day was not teratogenic, though fetal abnormalities were detected at higher dose levels when administered orally.

Carcinogenicity: None of the components of this product are listed as carcinogens by the NTP, IARC or OSHA. In long-term studies, no increased rates of tumor formation were observed in mice or rats.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: Tazarotene **CAS#:** 118292-40-3

Inactive Ingredients: Benzyl alcohol 1%, carbomer copolymer type B, carbomer homopolymer type B, edetate disodium, medium-chain triglycerides, mineral oil, purified water, sodium hydroxide (to adjust pH), sodium thiosulfate, and sorbitan monooleate.

SECTION 4: FIRST-AID MEASURES

- Eye Contact:** Immediately flush eyes with water for 15 minutes. Obtain medical attention.
- Skin Contact:** Immediately flush skin with water for 15 minutes. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. Destroy or thoroughly clean contaminated shoes. Get medical attention if symptoms are present.
- Inhalation:** Inhalation is not likely to occur. If symptoms occur, move to fresh air and obtain medical attention. Treat symptomatically.
- Ingestion:** Consult a physician or poison control center immediately. Treatment of an oral overdose includes supportive and symptomatic therapy.

SECTION 5: FIRE-FIGHTING MEASURES

- Flash Point and Method:** Greater than 200°F (Seta Flash Cup)
- Flammable Limits:** Not applicable
- Autoignition Temperature:** 786° F (419° C)
- Fire-Extinguishing Materials:** Material is non-flammable. Use extinguishing media suitable for materials supporting combustion such as water fog, CO₂, foam, or dry chemical.
- Firefighting Procedures:** Use self-contained breathing apparatus in enclosed or confined spaces or as otherwise needed.
- Unusual Fire and Explosion Hazards:** None known

SECTION 6: ACCIDENTAL RELEASE MEASURES

Wipe up and flush area with water. Do not allow contact with skin.
Wear self-contained breathing apparatus, rubber boots and heavy rubber gloves. Sweep up, place in a bag and hold for waste disposal.
Avoid raising dust. Ventilate area and wash spill site after material pickup is complete. Evacuate area.

SECTION 7: HANDLING AND STORAGE

Handling: Avoid inadvertent contact with hands or face. Wash thoroughly after handling. Observe all precautions contained on product label and package insert.

Storage: Store in a cool, dry location out of direct sunlight. Keep container closed when not in use

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

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: None required during normal handling of **Tazarotene**. In large quantities, this material should be handled in a laboratory fume hood or in other areas equipped with suitable local exhaust ventilation.

Eye and Face Protection: When handling material, wear safety glasses with side shields (or goggles) or a full face shield.

Protective Clothing: Rubber (latex) or other chemical-resistant gloves are recommended when administering or handling **Tazarotene**. Wear lab coat or other protective clothing.

Hygienic Work Practices: Wash hands thoroughly after handling. If working with large quantities of liquid (such as spill clean-up), use latex or chemical resistant gloves and appropriate eye protection. No eating, drinking or smoking in area.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point: no data available

Freezing/Melting Point: no data available

Evaporation Rate (Ether = 1): no data available

Appearance: White cream

Odor Description: None

SECTION 10: STABILITY AND REACTIVITY

General: This product is stable and hazardous polymerization will not occur.

Incompatible Materials: Store away from oxidizers and heat.

Conditions to Avoid: N/A

Hazardous Decomposition: None known.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute effects

May cause skin irritation.

May be harmful if absorbed through the skin. May cause eye irritation.

May be harmful if inhaled.

Material may be irritating to mucous membranes and upper respiratory tract.

Harmful if swallowed.

May cause allergic respiratory and skin reactions.

SECTION 12: ECOLOGICAL INFORMATION

No ecological information is available for the product.

SECTION 13: DISPOSAL CONSIDERATIONS

This product is not a hazardous waste when disposed of. For small quantities, discard in a municipal landfill as ordinary trash. For large quantities, contact Taro for information on return, recycle or disposal options

SECTION 14: TRANSPORT INFORMATION

Not a hazardous material for DOT, IATA, IMO or TDG shipment.

SECTION 15: REGULATORY INFORMATION

TSCA (Toxic Substances Control Act):

Components of this product are listed on the TSCA Inventory.

CERCLA (Comprehensive Environmental Response, Compensation, and Liability Act):

This product contains no components subject to reporting or notification requirements.

SARA Title III (Superfund Amendments and Reauthorization Act):

311/312 Hazard Categories: Immediate Health, Chronic Health

313 Reportable Ingredients: None

WHMIS (Workplace Hazardous Materials Information System - Canada):

Not Regulated (Product is regulated by the Food and Drugs Act)

SECTION 16: OTHER INFORMATION

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

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DISCLAIMER

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.