

SAFETY DATA SHEET

NFPA Rating: Health: 2 Flammability: 0 Reactivity: 0 Special: 0

TELEPHONE CONTACTS:

Product Technical and Medical Information: (800) 433-8871
Transportation Emergency 24-Hour Response (CHEMTREC): (800) 424-9300

SECTION 1: PRODUCT IDENTIFICATION

Compound Name: **ZORAC® (Tazarotene Cream) 0.05% and 0.10% and TAZORAC® (Tazarotene Topical Cream) 0.05% and 0.10%**

Chemical Class: Polyaromatic Retinoid

Manufacturer's Name: Allergan, Inc.

Address: 2525 Dupont Drive
Irvine, CA 92612

Preparation Date: October 2, 2007 (Supersedes June 20, 2001)

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW: May cause skin irritation with redness and skin peeling on repeated or prolonged contact. When administered at therapeutic doses, certain retinoid compounds have been shown to cause adverse reproductive effects when administered during pregnancy. Women of child bearing age should handle this compound with extreme care. Observe all precautions for safe handling and protective equipment use.

Hazard Classification (GHS): Reproductive Toxicity – Category 2

Signal Word and Hazard Statements (GHS): Warning – Retinoid compounds are suspected of causing fetal developmental abnormalities.



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 **ZORAC® (Tazarotene Cream) 0.05% and 0.10% and TAZORAC® (Tazarotene Topical Cream) 0.05% and 0.10%** may result in skin dryness, itching, redness, peeling or burning. Other potential health effects listed in this MSDS are based on known effects caused by other retinoid compounds

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 (equivalent to 250 mg/kg/day of 0.1 % gel formulation) 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/HAZARDOUS INGREDIENTS

Chemical Name	CAS Number	Percent (by weight)	Exposure Limits in Air (8 hr. TWA)		
			OSHA PEL	ACGIH – TLV	ALLERGAN OEL
Tazarotene	118292-40-3	0.05%, 0.10%	N/E	N/E	25ug/m ³
Mineral Oil	8012-95-1	<25%	5 mg/m ³	5 mg/m ³	N/A

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: Not determined

Fire-Extinguishing Materials:	Material is non-flammable. Use extinguishing media suitable for materials supporting combustion such as water fog, CO ₂ , 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 or take up with absorbent material and flush area with water. Do not allow contact with skin.

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.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

Engineering Controls:	None required during normal handling of ZORAC[®] (Tazarotene Cream) 0.05% and 0.10% and TAZORAC[®] (Tazarotene Topical Cream) 0.05% and 0.10% . In large quantities, this material should be handled in a laboratory fume hood or in other areas equipped with suitable local exhaust ventilation.
Respiratory Protection:	None required during normal clinical administration of ZORAC[®] (Tazarotene Cream) 0.05% and 0.10% and TAZORAC[®] (Tazarotene Topical Cream) 0.05% and 0.10% . Gram quantities of the cream should be handled in well ventilated areas. For kilogram quantities, wear a powered air-purifying respirator or a positive pressure air-supplied respirator whenever local exhaust ventilation is not adequate.
Eye and Face Protection:	None required during normal administration or use of ZORAC[®] (Tazarotene Cream) 0.05% and 0.10% and TAZORAC[®] (Tazarotene Topical Cream) 0.05% and 0.10% . When handling gram quantities of the material, wear safety glasses with side shields (or goggles) or a full face shield.
Protective Clothing:	During clinical administration of multiple applications of ZORAC[®] (Tazarotene Cream) 0.05% and 0.10% and TAZORAC[®] (Tazarotene Topical Cream) 0.05% and 0.10% , rubber (latex) or other chemical-resistant gloves are recommended to avoid excessive skin contact. In clinical or laboratory settings, wear lab coat or other protective outer clothing.
Hygienic Work Practices:	Wash hands thoroughly after handling. If working with large quantities of the cream (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

Specific Gravity (Water = 1.0 @ 20° C):	Approximately 1.0
Appearance and Odor:	White cream. Slight odor.
pH:	Not Determined
Melting Point/ Freezing Point:	Data Not Available
Boiling Point:	Not determined
Vapor Pressure (mm Hg at 20° C):	No data for this product
Vapor Density (Air = 1):	No data for this product
Solubility in Water:	Soluble
Partitian coefficient: n-octanol/ water:	Data Not Available

SECTION 10: STABILITY AND REACTIVITY

General:	This product is stable and hazardous polymerization will not occur.
Incompatible Materials and Conditions to Avoid:	Store away from oxidizers and heat. Store below 25°C
Hazardous Decomposition:	None known.

SECTION 11: TOXICOLOGICAL INFORMATION

The dosages listed refer to quantities of the active ingredient Tazarotene administered.

SKIN: Daily dermal application of up to 0.5 mg/kg/day for 3 months and 0.25 mg/kg/day for 12 months to the skin of Hanford miniswine produced no evidence of systemic toxicity. Skin response was dose dependent with minimal to moderate to marked irritation occurring as the dose increase from 0.05 to 0.5 mg/kg/day. Black scabs formed after four weeks of the study with dosages higher than 0.05 mg/kg. Twice daily dermal application (0.05 mL/application) of concentrations 0.01% to 0.1% to rats for six months produced treatment-related irritation which increased in intensity and frequency with concentration and duration of treatment. All skin reactions were observed to be reversible.

ORAL: A single oral dose of 2 g/kg to rats produced no lethality.

Doses in female rats of 2 mg/kg/day and in monkeys of 1.0-1.6 mg/kg/day for three months produced debilitation and/or death. Decreased hematological parameters, increased alkaline phosphates, AST and BUN and decreased total protein, calcium, cholesterol and albumin were observed. Many of the changes observed during the treatment period (fatty changes in the liver, decreased hemoglobin, increased AST) are similar to those seen during hypervitaminosis A. During the recovery period, these changes reversed to normal. At higher doses, a reduction of body weight gain, hepatic impairment and bone effects were observed. These effects are similar to those observed for other retinoid compounds, and were reversible after cessation of treatment.

In a three month study in monkeys, doses of 0.25 mg/kg produced no significant adverse effects. A dose level of 1.6 mg/kg produced renal failure and mineralization of various soft tissues. No blood cell or blood chemistry abnormalities were observed at any dose level. At dose levels of 0.125 mg/kg/day administered for six months or longer, skeletal abnormalities similar to those observed with other retinoid compounds, including the disruption and closure of the growth plate, ankylosis of the vertebrae, and deformity of the joints were observed.

REPRODUCTION: Dermal administration of this compound to rats and rabbits produced no evidence of teratogenicity, impaired fertility or reproductive capabilities in the test animals or of adverse effects in their offspring. Developmental toxicity was observed in male offspring of treated female rats, characterized by decreased lactation pup weights (0.05 to 0.125 mg/kg/day dosage).

Oral administration of this material to rats and rabbits at doses of 0.20 mg/kg/day (rabbits) and 0.25 mg/kg/day (rats) resulted in developmental toxicity. A no effect level of 0.05 mg/kg/day was established. Similar teratogenic effects have been reported for other retinoid compounds.

MUTAGENICITY: This compound was found to be non-mutagenic in the Ames Salmonella assay (with and without metabolic activation), did not produce structural chromosomal aberrations in a human lymphocyte assay, and was non-mutagenic in the CHO/HPRT mammalian cell forward gene mutation assay.

CARCINOGENICITY: No increased tumorigenicity was observed in mice following dermal application of this compound at dosages of up to 1.0 mg/kg/day for 21 months. Dietary administration of this material to rats at dosages of up to 0.125 mg/kg/day for two years resulted in no increased tumorigenicity.

PHOTOSENSITIVITY AND PHOTOCARCINOGENICITY: This compound was determined to be non-photosensitizing and non-phototoxic in guinea pigs. In hairless mice, enhancement of photocarcinogenicity was observed in all treatment groups. Similar photocarcinogenic enhancement has been previously demonstrated for other topical retinoids (e.g. all-trans-retinoic acid).

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 Allergan for information on return, recycle or disposal options.

SECTION 14: TRANSPORT INFORMATION

This product is not a hazardous material for DOT, IATA, IMO or TDG shipment.

SECTION 15: REGULATORY INFORMATION

TSCA (Toxic Substances Control Act):

As defined by U.S. Code Title 15, Chapter 53 (TSCA), Section 2602 and TSCA Regulations at 40CFR, Subchapter R, Part 710, this drug product is exempt from regulations under TSCA.

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

Revision Summary: SDS revised October 2, 2007

The preceding information is based on available data and is believed to be correct. However, no warranty is expressed or to be implied regarding the accuracy of this information, the results to be obtained from the use thereof or the hazards connected with the use of the material. Since the information contained herein may be applied under conditions beyond our control and with which we may be unfamiliar, Allergan does not assume any responsibility for the results of its use. This information is furnished upon the condition that the persons receiving it shall make their own determinations of the effects, properties, and protections which pertain to their particular conditions.