1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

GHS product identifier

Product Name
ZORAC® (Tazarotene Gel) 0.05% and 0.10% and TAZORAC® (Tazarotene Topical Gel)

Other means of identification

Synonyms
None

Recommended use of the chemical and restrictions on use

Recommended Use
No information available

Uses advised against
No information available

Supplier's details

Supplier Address
Allergan, Inc.
2525 Dupont
Irvine, CA
TEL: 1-714-246-4500

Emergency telephone number

Emergency Telephone Number
Chemtrec 1-800-424-9300

2. HAZARDS IDENTIFICATION

Classification
This product is considered hazardous by the OSHA Hazard Communication Standard 2012 (29 CFR 1910.1200).

Reproductive Toxicity
Category 2

GHS Label elements, including precautionary statements

Emergency Overview

Signal Word
Warning

Hazard Statements
• Suspected of damaging fertility or the unborn child

Appearance
Colorless to light yellow
Physical State
Gel (compressed).
Odor
Slight
Prevention
- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Use personal protective equipment as required.

General Advice
- If exposed or concerned: Get medical attention/advice

Storage
- Store locked up.

Disposal
- Dispose of contents/container to an approved waste disposal plant.

Hazard Not Otherwise Classified (HNOC)
Not applicable

Other information
In sensitive individuals, repeated or prolonged skin contact may result in skin dryness, itching, redness, peeling or burning. Overexposure may affect liver function causing hypertriglyceridemia, skeletal abnormalities, and kidney effects. Other symptoms may include conjunctival irritation, hair loss, headache, edema, fatigue, dermatitis, nausea, and visual disturbances.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS-No</th>
<th>Weight %</th>
<th>Trade secret</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexylene glycol</td>
<td>107-41-5</td>
<td>2</td>
<td>*</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>1</td>
<td>*</td>
</tr>
<tr>
<td>Tazarotene</td>
<td>118292-40-3</td>
<td>0.1</td>
<td>*</td>
</tr>
</tbody>
</table>

* Where range is displayed, the exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of necessary first-aid measures
Eye Contact
Immediately flush with plenty of water. After initial flushing, remove any contact lenses and continue flushing for at least 15 minutes. Get medical attention.

Skin Contact
Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes. Get medical attention if symptoms occur.

Inhalation
Not an expected route of exposure. IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention.

Ingestion
Clean mouth with water and afterwards drink plenty of water. Do NOT induce vomiting. Get medical attention.

Most important symptoms/effects, acute and delayed
Dermal irritation: Itching, Rashes, Burning.

Indication of immediate medical attention and special treatment needed, if necessary
Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable Extinguishing Media
No information available.
Specific Hazards Arising from the Chemical
No information available.

Explosion Data
- Sensitivity to Mechanical Impact: None.
- Sensitivity to Static Discharge: None.

Protective Equipment and Precautions for Firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal Precautions
Avoid contact with skin, eyes and clothing. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Refer to Section 8 for personal protective equipment.

Environmental Precautions
See Section 12 for additional Ecological Information.

Methods and materials for containment and cleaning up

Methods for Containment
Small spills: Wipe up with absorbent material (e.g. cloth, fleece). Large spills: Prevent further leakage or spillage if safe to do so. Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see Section 13).

Methods for Cleaning Up
Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling

Handling
Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothing. Wear personal protective equipment. Refer to Section 8.

Conditions for safe storage, including any incompatibilities

Storage
Keep containers tightly closed in a dry, cool and well-ventilated place.

Incompatible Products
Oxidizing agents.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control parameters

Exposure Guidelines
Allergan OEL: Tazarotene: 25 ug/m³ (8 hr. TWA)

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexylene glycol</td>
<td>Ceiling: 25 ppm</td>
<td>(vacated) Ceiling: 25 ppm</td>
<td>Ceiling: 25 ppm</td>
</tr>
<tr>
<td>107-41-5</td>
<td></td>
<td>(vacated) Ceiling: 125 mg/m³</td>
<td>Ceiling: 125 mg/m³</td>
</tr>
</tbody>
</table>

Appropriate engineering controls

Engineering Measures
Showers
Eyewash stations
Ventilation systems
Individual protection measures, such as personal protective equipment

**Eye/Face Protection**
No special protective equipment required. Risk of contact, wear: Safety glasses with side-shields.

**Skin and Body Protection**
Lightweight protective clothing. Latex gloves. Chemical resistant gloves.

**Respiratory Protection**
None required under normal usage.

**Hygiene Measures**
Handle in accordance with good industrial hygiene and safety practice. Do not eat, drink or smoke when using this product. Keep away from food, drink and animal feeding stuffs. Provide regular cleaning of equipment, work area and clothing. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and immediately after handling the product.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Information on basic physical and chemical properties**

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
<th>Remarks/ - Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical State</td>
<td>Gel (compressed)</td>
<td>Appearance</td>
</tr>
<tr>
<td>Odor</td>
<td>Slight</td>
<td>Odor Threshold</td>
</tr>
<tr>
<td>Flammable Properties</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Explosive Properties</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Melting Point/Range</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Boiling Point/Boiling Range</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flash Point</td>
<td>&gt;93.3 °C / &gt;200 °F</td>
<td>None known</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flammability Limits in Air</td>
<td></td>
<td></td>
</tr>
<tr>
<td>upper flammability limit</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>lower flammability limit</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Vapor Pressure</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Vapor Density</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>1.06</td>
<td>None known</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Soluble in water.</td>
<td>None known</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Autoignition Temperature</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
<td>None known</td>
</tr>
<tr>
<td>Flammable Properties</td>
<td></td>
<td>Not flammable</td>
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<tr>
<td>Explosive Properties</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Oxidizing Properties</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Other information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>VOC Content (%)</td>
<td>No data available</td>
<td></td>
</tr>
</tbody>
</table>

### 10. STABILITY AND REACTIVITY

**Reactivity**
Not reactive under normal conditions.

**Chemical stability**
Stable under recommended storage conditions.

**Possibility of hazardous reactions**
None under normal processing.
Hazardous Polymerization

Hazardous polymerization does not occur.

Conditions to avoid

Heat.

Incompatible materials

Oxidizing agents.

Hazardous decomposition products

None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

<table>
<thead>
<tr>
<th>Route</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Not an expected route of exposure.</td>
</tr>
<tr>
<td>Eye Contact</td>
<td>Contact with eyes may cause irritation.</td>
</tr>
<tr>
<td>Skin Contact</td>
<td>Repeated or prolonged contact may cause localized dermal effects including contact dermatitis, dry skin, or rash.</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>LD50 Oral</th>
<th>LD50 Dermal</th>
<th>LC50 Inhalation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexylene glycol</td>
<td>3692 mg/kg (Rat)</td>
<td>12,3000 mg/kg (Rabbit)</td>
<td>&gt; 310 mg/m³ (Rat) 1 h</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>1230 mg/kg (Rat)</td>
<td>2000 mg/kg (Rabbit)</td>
<td>8.8 mg/L (Rat) 4 h</td>
</tr>
<tr>
<td>Tazarotene</td>
<td>&gt;2000 mg/kg (rat)</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

In sensitive individuals, repeated or prolonged skin contact may result in skin dryness, itching, redness, peeling or burning. Overexposure may affect liver function causing hypertriglyceridemia, skeletal abnormalities, and kidney effects. Other symptoms may include conjunctival irritation, hair loss, headache, edema, fatigue, dermatitis, nausea, and visual disturbances.

Delayed and immediate effects and also chronic effects from short and long term exposure

Skin corrosion/irritation

Daily dermal application of Tazarotene up to 0.5 mg/kg/day for 3 months and 0.25 mg/kg/day to swine for 12 months to the skin caused dose dependent skin reactions with minimal to moderate to marked irritation occurring as the dose increased. 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.

Sensitization

No information available.

Mutagenic Effects

In vitro tests did not show mutagenic effects.

Carcinogenicity

Did not show carcinogenic effects in animal experiments. This product does not contain any ingredient designated by IARC, NTP, ACGIH, or OSHA as a probable or suspected human carcinogen. Petroleum products are known to cause cancer because of carcinogenic components (e.g. benzene, DMSO). These carcinogenic components are typically found in crude petroleum products and are removed through the refinement process.

Reproductive Toxicity

Animal testing did not show any effects on fertility.
Developmental Toxicity

Dermal administration of Tazarotene to rats and rabbits produced no evidence of teratogenicity. 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. 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.

STOT - single exposure
STOT - repeated exposure
Chronic Toxicity

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

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 vertebræ, and deformity of the joints were observed. 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).

Other Adverse Effects

Aspiration Hazard

No information available.

Numerical measures of toxicity - Product

The following values are calculated based on chapter 3.1 of the GHS document:

LD50 Oral >5000 mg/kg; Acute toxicity estimate

12. ECOLOGICAL INFORMATION

Ecotoxicity

The environmental impact of this product has not been fully investigated.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Toxicity to Algae</th>
<th>Toxicity to Fish</th>
<th>Toxicity to Microorganisms</th>
<th>Daphnia Magna (Water Flea)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexylene glycol</td>
<td>LC50 96 h: 10500 - 11000 mg/L flow-through (Pimephales promelas)</td>
<td>EC50 = 3038 mg/L 5 min</td>
<td>EC50 48 h: 2700 - 3700 mg/L (Daphnia magna)</td>
<td></td>
</tr>
<tr>
<td>107-41-5</td>
<td>LC50 96 h: = 10000 mg/L static (Lepomis macrochirus)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 96 h: = 8690 mg/L flow-through (Pimephales promelas)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 96 h: = 10700 mg/L static (Pimephales promelas)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>EC50 3 h: = 35 mg/L (Anabaena variabilis)</td>
<td>LC50 96 h: = 10 mg/L static (Lepomis macrochirus)</td>
<td>EC50 = 50 mg/L 5 min</td>
<td></td>
</tr>
<tr>
<td>100-51-6</td>
<td></td>
<td>LC50 96 h: = 460 mg/L static (Pimephales promelas)</td>
<td>EC50 = 63.7 mg/L 15 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EC50 = 63.7 mg/L 5 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EC50 = 71.4 mg/L 30 min</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>EC50 48 h: = 23 mg/L (water flea)</td>
<td></td>
</tr>
</tbody>
</table>

Persistence and Degradability

No information available.

Bioaccumulation

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Log Pow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexylene glycol</td>
<td>0.13986</td>
</tr>
</tbody>
</table>

Page 6 / 8
Other Adverse Effects
No information available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal Methods
Dispose of in accordance with local regulations.

Contaminated Packaging
Do not re-use empty containers.

14. TRANSPORT INFORMATION

DOT
Not regulated.

TDG
Not regulated.

MEX
Not regulated.

IATA
Not regulated.

IMDG/IMO
Not regulated.

15. REGULATORY INFORMATION

International Inventories
TSCA Exempt
DSL Exempt

Legend
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

U.S. Federal Regulations
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories
Acute Health Hazard Yes
Chronic Health Hazard Yes
Fire Hazard No
Sudden Release of Pressure Hazard No
Reactive Hazard No

Clean Water Act

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Regulations
California Proposition 65
This product does not contain any Proposition 65 chemicals.
Butylated hydroxyanisole | 25013-16-5 | Carcinogen

### U.S. State Right-to-Know Regulations

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
<th>Illinois</th>
<th>Rhode Island</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexylene glycol</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>-</td>
<td>X</td>
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</tr>
<tr>
<td>Butylated hydroxyanisole</td>
<td>X</td>
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</table>

### U.S. EPA Label Information

**EPA Pesticide Registration Number** Not applicable

### 16. OTHER INFORMATION

<table>
<thead>
<tr>
<th>NFPA</th>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Instability</th>
<th>Physical and Chemical Hazards</th>
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<tbody>
<tr>
<td></td>
<td>1</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>HMIS</th>
<th>Health Hazard</th>
<th>Flammability</th>
<th>Physical Hazard</th>
<th>Personal Protection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1*</td>
<td>0</td>
<td>0</td>
<td>X</td>
</tr>
</tbody>
</table>

*Indicates a chronic health hazard.

**Prepared By**

Product Stewardship  
23 British American Blvd.  
Latham, NY 12110  
1-800-572-6501

**Issuing Date**  02-Oct-2007

**Revision Date**  22-Dec-2014

**Revision Note**  Update to Format.

**General Disclaimer**

The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

**End of Safety Data Sheet**