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

Product identifier
Product Name: AVAGE (Tazarotene Cream) 0.10%

Other means of identification
Product Code: FG00010
Synonyms: None

Recommended use of the chemical and restrictions on use
Recommended Use: Used to treat psoriasis, acne and sun damaged skin (photodamage). Dermatologic Agent
Keratolytic Agent

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer: Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525
E-mail address: SDS@Allergan.com

Emergency telephone number
Emergency Telephone: Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification
OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Reproductive toxicity: Category 1B

Label elements

Emergency Overview

Danger

Hazard statements
H360 - May damage fertility or the unborn child
Precautionary statements
P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P281 - Use personal protective equipment as required
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P405 - Store locked up
P501 - Dispose of contents/container to an approved waste disposal plant
P280 - Wear protective gloves/protective clothing/eye protection/face protection

Other Information
Unknown Acute Toxicity  63.9% of the mixture consists of ingredient(s) of unknown toxicity

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral Oil</td>
<td>8012-95-1</td>
<td>232-384-2</td>
<td>10 - 30*</td>
</tr>
<tr>
<td>Medium Chain Triglycerides</td>
<td>73398-61-5</td>
<td>277-452-2</td>
<td>7 - 13*</td>
</tr>
<tr>
<td>SORBITAN MONOOLEATE NF</td>
<td>1338-43-8</td>
<td>215-665-4</td>
<td>3 - 7*</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100-51-6</td>
<td>202-859-9</td>
<td>1 - 5*</td>
</tr>
<tr>
<td>Tazarotene</td>
<td>118292-40-3</td>
<td>N/A</td>
<td>0.1 - 1*</td>
</tr>
</tbody>
</table>

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Eye contact
Rinse immediately with plenty of water and seek medical advice.

Skin Contact
Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation
Remove to fresh air.

Ingestion
Consult a physician if necessary.

5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Fire may produce irritating, corrosive and/or toxic gases.

Explosion data
Sensitivity to Mechanical Impact  Not impact sensitive.
Sensitivity to Static Discharge  
Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

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  
Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions  
See Section 12 for additional ecological information.

Methods for containment  
Prevent further leakage or spillage if safe to do so.

Methods for cleaning up  
Avoid creating dust.

7. HANDLING AND STORAGE

Advice on safe handling  
Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions  
Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials  
None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL (ug/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral Oil 8012-95-1</td>
<td>TWA: 5 mg/m³ inhalable particulate matter excluding metal working fluids, highly &amp; severely refined TWA: 5 mg/m³ inhalable particulate matter excluding metal working fluids</td>
<td>TWA: 5 mg/m³ (vacated) TWA: 5 mg/m³</td>
<td>IDLH: 2500 mg/m³ TWA: 5 mg/m³ STEL: 10 mg/m³</td>
<td>N/A</td>
</tr>
<tr>
<td>Tazarotene 118292-40-3</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>10</td>
</tr>
</tbody>
</table>

NIOSH IDLH  Immediately Dangerous to Life or Health

Other Information  
Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering Controls  
The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection  
No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be
Skin and body protection  
During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection  
Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical state</td>
<td>Gel Compressed</td>
</tr>
<tr>
<td>Color</td>
<td>white</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>No information available</td>
</tr>
<tr>
<td>Appearance</td>
<td>gel</td>
</tr>
<tr>
<td>Odor</td>
<td>Slight</td>
</tr>
<tr>
<td>pH</td>
<td>No information available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No information available</td>
</tr>
<tr>
<td>Boiling point / boiling range</td>
<td>No information available</td>
</tr>
<tr>
<td>Flash point</td>
<td>&gt; 93.3</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No information available</td>
</tr>
<tr>
<td>Flammability Limit in Air</td>
<td></td>
</tr>
<tr>
<td>Upper flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Lower flammability limit:</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No information available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No information available</td>
</tr>
<tr>
<td>Specific Gravity</td>
<td>No information available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No information available</td>
</tr>
<tr>
<td>Partition coefficient</td>
<td>No information available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No information available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>No information available</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No information available</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No information available</td>
</tr>
<tr>
<td>VOC Content (%)</td>
<td>No information available</td>
</tr>
<tr>
<td>Density</td>
<td>No information available</td>
</tr>
<tr>
<td>Bulk density</td>
<td>No information available</td>
</tr>
</tbody>
</table>

10. STABILITY AND REACTIVITY

Reactivity  
Not defined As Reactive substance

Chemical stability  
Stable under normal conditions.

Possibility of Hazardous Reactions  
None under normal processing.

Conditions to avoid  
Aerosol formation.

Incompatible materials  
None known based on information supplied.

Hazardous Decomposition Products  
None known based on information supplied.
11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tazarotene</td>
<td>Not an expected route of exposure.</td>
<td>Contact with eyes may cause irritation.</td>
<td>May result in skin dryness, itching, redness, peeling or burning.</td>
<td>Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral Oil</td>
<td>&gt; 24 g/kg (Rat)</td>
<td>N/A</td>
<td>= 2062 ppm (Rat) 4 h</td>
</tr>
<tr>
<td>Medium Chain Triglycerides</td>
<td>&gt; 5000 mg/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>SORBITAN MONOOLEATE NF</td>
<td>&gt; 39800 mg/kg (Rat)</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Benzy! Alcohol</td>
<td>= 1230 mg/kg (Rat)</td>
<td>= 2 g/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>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Delayed and immediate effects as well as chronic effects from short and long-term exposure

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tazarotene</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.</td>
<td>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.</td>
<td>It is not known whether this drug is excreted in human milk. Because most drugs are excreted in human milk, if use of this drug is deemed essential, the patient should stop nursing.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>STOT - single exposure</th>
<th>STOT - repeated exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tazarotene</td>
<td>No information available.</td>
<td>No information available.</td>
</tr>
</tbody>
</table>

Target Organ Effects

Eyes, Respiratory system, Skin.

Numerical measures of toxicity - Product Information

**Unknown Acute Toxicity** 63.9% of the mixture consists of ingredient(s) of unknown toxicity

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

- ATEmix (oral) 9373 mg/kg
- ATEmix (dermal) 72200 mg/kg
- ATEmix (inhalation-dust/mist) 54.2 mg/l

12. ECOLOGICAL INFORMATION
Ecotoxicity

Toxic to aquatic life with long lasting effects

99% of the mixture consists of components(s) of unknown hazards to the aquatic environment

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium Chain Triglycerides 73398-61-5</td>
<td>N/A</td>
<td>N/A</td>
<td>2.2: 24 h Daphnia magna mg/L EC50</td>
</tr>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>35: 3 h Anabaena variabilis mg/L EC50</td>
<td>10: 96 h Lepomis macrochirus mg/L LC50 static 460: 96 h Pimephales promelas mg/L LC50 static</td>
<td>23: 48 h water flea mg/L EC50</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol 100-51-6</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Tazarotene 118292-40-3</td>
<td>No information available</td>
<td>No information available</td>
<td>No information available</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Other adverse effects

No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes
Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging
Do not reuse container. Dispose of contents/containers in accordance with local regulations.

14. TRANSPORT INFORMATION

DOT
Not regulated

TDG
Not regulated

ICAO (air)
Not regulated

IATA
Not regulated

IMDG
Not regulated

ADR
Not regulated

ADN
Not regulated

15. REGULATORY INFORMATION

International Inventories

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSCA</td>
<td>Not Listed</td>
</tr>
<tr>
<td>DSL/NDSL</td>
<td>Not Listed</td>
</tr>
<tr>
<td>EINECS/ELINCS</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
US Federal Regulations

Carcinogenicity

The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral Oil</td>
<td>A2</td>
<td>Group 1</td>
<td>Known</td>
<td>X</td>
</tr>
<tr>
<td>8012-95-1</td>
<td></td>
<td>Group 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**ACGIH (American Conference of Governmental Industrial Hygienists)**
- A2 - Suspected Human Carcinogen

**IARC (International Agency for Research on Cancer)**
- Group 1 - Carcinogenic to Humans
- Not classifiable as a human carcinogen

**OSHA (Occupational Safety and Health Administration of the US Department of Labor)**
- X - Present

**SARA 313**
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: No
- Chronic Health Hazard: No
- Fire hazard: No
- Sudden release of pressure hazard: No
- Reactive Hazard: No

**CWA (Clean Water Act)**
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**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.

**US State Regulations**

**California Proposition 65**
This product does not contain any Proposition 65 chemicals.

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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral Oil</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>8012-95-1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>-</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>100-51-6</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

**Revision Date** 02-Oct-2018
**Revision Note** No information available

**Disclaimer**
The information provided in this Material Safety Data Sheet 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 guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered 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 materials or in any process, unless specified in the text.