

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
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Label elements

Emergency Overview

Danger

Hazard statements
H360 - May damage fertility or the unborn child



Appearance gel	Physical state Gel Compressed	Odor Slight
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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

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

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

4. FIRST AID MEASURES**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

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m ³)
Mineral Oil 8012-95-1	TWA: 5 mg/m ³ inhalable particulate matter excluding metal working fluids, highly & severely refined TWA: 5 mg/m ³ inhalable particulate matter excluding metal working fluids	TWA: 5 mg/m ³ (vacated) TWA: 5 mg/m ³	IDLH: 2500 mg/m ³ TWA: 5 mg/m ³ STEL: 10 mg/m ³	N/A
Tazarotene 118292-40-3	N/A	N/A	N/A	10

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

considered.

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

Physical state	Gel Compressed	Appearance	gel
Color	white	Odor	Slight
Odor threshold	No information available		

<u>Property</u>	<u>Values</u>
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	> 93.3
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	Soluble in water
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Other Information

Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

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

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

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Mineral Oil	> 24 g/kg (Rat)	N/A	= 2062 ppm (Rat) 4 h
Medium Chain Triglycerides	> 5000 mg/kg (Rat)	N/A	N/A
SORBITAN MONOOLEATE NF	> 39800 mg/kg (Rat)	N/A	N/A
Benzyl Alcohol	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	= 8.8 mg/L (Rat) 4 h
Tazarotene	> 2000 mg/kg (Rat)	N/A	N/A

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

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Tazarotene	Not mutagenic in the standard battery of tests.	This product does not contain any carcinogens or potential carcinogens as listed by OSHA, IARC or NTP.	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.	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.

Chemical Name	STOT - single exposure	STOT - repeated exposure
Tazarotene	No information available.	No information available.

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 component(s) of unknown hazards to the aquatic environment

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

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Benzyl Alcohol 100-51-6	N/A	N/A	N/A	1.1
Tazarotene 118292-40-3	No information available	No information available	No information available	N/A

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

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Not Listed

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).

Chemical Name	ACGIH	IARC	NTP	OSHA
Mineral Oil 8012-95-1	A2	Group 1 Group 3	Known	X

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

Chemical Name	New Jersey	Massachusetts	Pennsylvania
Mineral Oil 8012-95-1	X	X	X
Benzyl Alcohol 100-51-6	-	X	X

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.

End of Safety Data Sheet