SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
US - OSHA Hazard Communication Standard (29 CFR 1910.1200)

Issuing Date 13-May-2024 **Revision Date** 13-May-2024 **Revision Number** 1

1. Identification

Product identifier

Product Name Tazarotene Cream, 0.05% and 0.1%

Other means of identification

Product Code(s) 0670, 0764, 0765

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use Medicinal products

Restrictions on use Use only as directed

Details of the supplier of the safety data sheet

Manufacturer Address
Cosette Pharmaceuticals, Inc.
1877 Kawai Rd.
Lincolnton, NC 28092
(704) 735-5700

E-mail sds@cosettepharma.com

Emergency telephone number

Emergency telephone Chemtrec 1-800-424-9300

2. Hazard(s) identification

Classification

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

Skin sensitization	Category 1
Reproductive toxicity	Category 2

Hazards not otherwise classified (HNOC)
Not applicable.

Label elements

Warning



Hazard statements
May cause an allergic skin reaction.
Suspected of damaging fertility or the unborn child.
Precautionary Statements - Prevention
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Wear protective gloves/clothing and eye/face protection.
Avoid breathing dust/fume/gas/mist/vapors/spray.
Contaminated work clothing must not be allowed out of the workplace.
Precautionary Statements - Response
IF exposed or concerned: Get medical advice/attention.
IF ON SKIN: Wash with plenty of water and soap.
If skin irritation or rash occurs: Get medical advice/attention.
Wash contaminated clothing before reuse.
Precautionary Statements - Storage
Store locked up.

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

Other information
Causes mild skin irritation.

3. Composition/information on ingredients

Substance

Not applicable.

Mixture

Chemical name	CAS No.	Weight-%	Trade secret
Decanoic acid, ester with 1,2,3-propanetriol octanoate	65381-09-1	2.5	*
Benzyl alcohol	100-51-6	1	*
Sodium hydroxide	1310-73-2	0.61	*
Tazarotene	118292-40-3	0.1	*

4. First-aid measures

Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation Remove to fresh air.

Eye contact Rinse thoroughly with plenty of water, also under the eyelids.

Skin contact Wash with soap and water. May cause an allergic skin reaction. In the case of skin irritation or allergic reactions see a physician.

Ingestion Rinse mouth.

Most important symptoms and effects, both acute and delayed

Symptoms Itching. Rashes. Hives. Prolonged contact may cause redness and irritation.

Effects of Exposure May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility.

Indication of any immediate medical attention and special treatment needed

Note to physicians May cause sensitization in susceptible persons. 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 Product is or contains a sensitizer. May cause sensitization by skin contact.

Explosion data
Sensitivity to mechanical impact None.
Sensitivity to static discharge None.

Special protective equipment and precautions for fire-fighters Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

Methods and material for containment and cleaning up

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

Methods for cleaning up Pick up and transfer to properly labeled containers.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

7. Handling and storage

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off

contaminated clothing and wash before reuse. Remove contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

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

8. Exposure controls/personal protection

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Chemical name	ACGIH TLV	OSHA PEL	NIOSH
Sodium hydroxide 1310-73-2	Ceiling: 2 mg/m³	TWA: 2 mg/m³ (vacated) Ceiling: 2 mg/m³	IDLH: 10 mg/m³ Ceiling: 2 mg/m³

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Hand protection Wear suitable gloves.

Skin and body protection Wear suitable protective clothing.

Respiratory protection No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. Physical and chemical properties

Information on basic physical and chemical properties

Appearance Cream
Physical state Solid
Color White to off-white
Odor Not determined
Odor threshold Not determined

Property	Values	Remarks • Method
pH	7.0 - 8.0	
pH (as aqueous solution)		No data available
Melting point / freezing point		Not determined
Initial boiling point and boiling range		Not applicable

Flash point	Not applicable
Evaporation rate	Not applicable
Flammability	Not determined
Flammability Limit in Air	Not applicable
Upper flammability or explosive limits	No data available
Lower flammability or explosive limits	No data available
Vapor pressure	Not applicable
Relative vapor density	Not applicable
Relative density	Not determined
Water solubility	Not applicable
Solubility(ies)	No data available
Partition coefficient	Not determined
Autoignition temperature	Not determined
Decomposition temperature	Not applicable
Kinematic viscosity	No data available
Dynamic viscosity	40,000 - 110,000 cP

Other information

Explosive properties	Not applicable
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	No information available
VOC content	Not applicable
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity None under normal use conditions.

Chemical stability Stable under normal conditions.

Possibility of hazardous reactions None under normal processing.

Conditions to avoid None known based on information supplied.

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

Product Information

Inhalation Specific test data for the substance or mixture is not available.

Eye contact Specific test data for the substance or mixture is not available.

Skin contact Specific test data for the substance or mixture is not available. May cause sensitization by skin contact. Causes mild skin irritation. (based on components). Repeated or prolonged skin contact may cause allergic reactions with susceptible persons.

Ingestion Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Itching. Rashes. Hives. Prolonged contact may cause redness and irritation.

Acute toxicity .

Numerical measures of toxicity

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

ATEmix (oral) 77,339.00 mg/kg
ATEmix (dermal) 68,636.40 mg/kg
ATEmix (inhalation-dust/mist) 159.10 mg/l

Component Information

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
Benzyl alcohol 100-51-6	= 1230 mg/kg (Rat)	= 2 g/kg (Rabbit)	> 4178 mg/m³ (Rat) 4 h
Sodium hydroxide 1310-73-2	= 325 mg/kg (Rat)	= 1350 mg/kg (Rabbit)	-

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

Skin corrosion/irritation Classification based on data available for ingredients. Causes mild skin irritation.

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicity No information available.

Carcinogenicity No information available.

Reproductive toxicity Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.

STOT - single exposure No information available.

STOT - repeated exposure No information available.

Aspiration hazard No information available.

Other adverse effects No information available.

Interactive effects No information available.

12. Ecological information

Ecotoxicity

Chemical name	Algae/aquatic plants	Fish	Toxicity to microorganisms	Crustacea
Decanoic acid, ester with 1,2,3-propanetriol octanoate 65381-09-1	EC50: >100mg/L (72h, Desmodesmus subspicatus) EC50: =50mg/L (96h, Desmodesmus subspicatus)	LC50: >10000mg/L (96h, Brachydanio rerio)	-	EC50: =17mg/L (48h, Daphnia magna)

Benzyl alcohol 100-51-6	-	LC50: =460mg/L (96h, Pimephales promelas) LC50: =10mg/L (96h, Lepomis macrochirus)	EC50 = 50 mg/L 5 min EC50 = 63.7 mg/L 15 min EC50 = 63.7 mg/L 5 min EC50 = 71.4 mg/L 30 min	EC50: =23mg/L (48h, water flea)
Sodium hydroxide 1310-73-2	-	LC50: =45.4mg/L (96h, Oncorhynchus mykiss)	-	-

Persistence and degradability No information available.

Bioaccumulation

Component Information

Chemical name	Partition coefficient
Benzyl alcohol 100-51-6	1.05

Other adverse effects No information available.

13. Disposal considerations

Disposal methods

Waste from residues/unused products Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.

Contaminated packaging Do not reuse empty containers.

California Hazardous Waste Status This product contains one or more substances that are listed with the State of California as a hazardous waste.

14. Transport information

DOT Not regulated

IATA Not regulated

IMDG Not regulated

15. Regulatory information

International Inventories
Contact supplier for inventory compliance status

US Federal Regulations

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
Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)
This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

Chemical name	CWA - Reportable Quantities	CWA - Toxic Pollutants	CWA - Priority Pollutants	CWA - Hazardous Substances
Sodium hydroxide 1310-73-2	1000 lb	-	-	X

CERCLA
This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302).

Chemical name	Hazardous Substances RQs	Extremely Hazardous Substances RQs	Reportable Quantity (RQ)
Sodium hydroxide 1310-73-2	1000 lb	-	RQ 1000 lb final RQ RQ 454 kg final RQ

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
Benzyl alcohol 100-51-6	-	X	X
Sodium hydroxide 1310-73-2	X	X	X

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA **Health hazards** 2 **Flammability** 0 **Instability** 0 **Special hazards** -
HMIS **Health hazards** 2 * **Flammability** 0 **Physical hazards** 0 **Personal protection** X
Chronic Hazard Star Legend ** = Chronic Health Hazard*

Key or legend to abbreviations and acronyms used in the safety data sheet

Legend
SVHC: Substances of Very High Concern for Authorization:
PBT: Persistent, Bioaccumulative, and Toxic (PBT) Substances
vPvB: Very Persistent and very Bioaccumulative (vPvB) Substances
STOT: Specific Target Organ Toxicity
ATE: Acute Toxicity Estimate
LC50: 50% Lethal Concentration
LD50: 50% Lethal Dose

Legend Section 8: Exposure controls/personal protection

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	Sk*	Skin designation
+	Sensitizers		

Key literature references and sources for data used to compile the SDS
Agency for Toxic Substances and Disease Registry (ATSDR)
U.S. Environmental Protection Agency ChemView Database
European Food Safety Authority (EFSA)
Environmental Protection Agency
Acute Exposure Guideline Level(s) (AEGL(s))
U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act
U.S. Environmental Protection Agency High Production Volume Chemicals
Food Research Journal
Hazardous Substance Database
International Uniform Chemical Information Database (IUCLID)
Japan GHS Classification
Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
NIOSH (National Institute for Occupational Safety and Health)
National Library of Medicine's ChemID Plus (NLM CIP)
National Library of Medicine’s PubMed database (NLM PUBMED)
U.S. National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

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Disclaimer

The information provided in this 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