

**SDS: Calcipotriene Topical Solution, 0.005%
(Scalp Solution)**

SAFETY DATA SHEET

1. Identification

Product Identifier: Calcipotriene Topical Solution, 0.005% (Scalp Solution)

Synonyms: 9,10-Secochole-5,7,10(19),22-tetraene-1,3,24-triol, 24-cyclopropyl-,(1-alpha,3-beta,5Z,7E,22E,24S)-/ 9,10-Secochole-5,7,10(19),22-tetraene-1,3,24-triol, 24-cyclopropyl-,(1-alpha,3-beta,5Z,7E,22E,24S)-, monohydrate

National Drug Code (NDC): 50383-732-02

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.
1925 West Field Court, Suite 300
Lake Forest, Illinois 60045

Contact Telephone: 1-800-932-5676

E mail: customer.service@akorn.com

Emergency Phone Number: CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. Hazard(s) Identification

Physical Hazards: Highly flammable liquid and Vapor Category 2

Health Hazards: Not classifiable.

Symbol(s):



Signal Word:

Danger.

Hazard Statement(s):

H225 Highly flammable liquid and vapor.

Precautionary Statement(s):

P240 Ground/bound container and receiving equipment.

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P241 Use explosion – proof electrical/ ventilating/ lighting/ equipment.

P242 Use only non – sparking tools.

P243 Take precautionary measures against static discharge.

SDS: Calcipotriene Topical Solution, 0.005% (Scalp Solution)

- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P353 Rinse skin with water/shower.
- P361 Take off immediately all contaminated clothing.
- P370 In case of fire: Use water, carbon dioxide, dry chemical or foam as necessary.
+
P378
- P303 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
+
P361
+
P353
- P403 Store in a well-ventilated place. Keep cool.
+
P235
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazards Not Otherwise Classified: Not classifiable.
Supplementary Information: None.

3. Composition/Information on Ingredients

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Calcipotriene Monohydrate	147657-22-5	9,10-Secochola-5,7,10(19), 22-tetraene-1,3,24-triol,24-cyclopropyl-,(1-alpha,3-beta,5Z,7E,22E,24S)-/9,10-Secochola-5,7,10(19),22-tetraene-1,3,24-triol,24-cyclopropyl-,(1-alpha,3-beta,5Z,7E,22E,24S)-, monohydrate	C ₂₇ H ₄₀ O ₃ •H ₂ O	430.6	0.005%

*The formula also contains Hydroxypropyl Cellulose, Isopropyl Alcohol (51% v/v), Menthol, Propylene Glycol, Purified Water, and Sodium Citrate.

4. First Aid Measures

Ingestion:

If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.

SDS: Calcipotriene Topical Solution, 0.005% (Scalp Solution)

Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).
Signs and Symptoms:	Symptoms of poisoning are: Tiredness, headache, loss of appetite, strong thirst, vomiting, diarrhea and rise in blood calcium. Symptoms of poisoning may only appear several hours later. Symptoms are similar to symptoms of vitamin D poisoning.
Medical Conditions Aggravated by Exposure:	Not determined.
Notes to Physician:	Treat supportively and symptomatically.

5. Firefighting Measures

Suitable Extinguishing Media:	CO ₂ , powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Unsuitable Extinguishing Media:	Water with full jet. Use the same protection equipment as with chemical fires.

Specific Hazards Arising from the Chemical:

Hazardous Combustion Products:	Keep ignition sources away - do not smoke. Protect against electrostatic charges.
Other Specific Hazards:	Not determined.

**SDS: Calcipotriene Topical Solution, 0.005%
(Scalp Solution)**

**Special Protective Equipment/
Precautions for Firefighters:**

Wear self-contained breathing apparatus and full and protective gear.

6. Accidental Release Measures

Personal Precautions:

Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

Personal Protective Equipment:

For personal protection see section 8.

Methods for Cleaning Up:

Remove all ignition sources. Soak up with inert absorbent material. Collect in suitable container for disposal. The exposed area is washed with water and soap and rinsed with plenty of water.

Environmental Precautions:

Prevent seepage into sewage system, workpits and cellars. Do not allow to enter sewers/surface or ground water.

Reference to Other Sections:

Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling:

Use efficient ventilation with all work processes by use of encapsulating the process and ventilating the encapsulated area or effective local exhaust directly at the source of emission. If mechanical ventilation is not possible use suitable respiratory protection equipment. Ensure good interior ventilation, especially at floor level. (Fumes are heavier than air). Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,
Including Any Incompatibilities:**

Store in a cool location 20°C – 25°C (68°F – 77°F). Protect from heat and direct sunlight. Keep container tightly sealed. Store in cool, dry conditions in well-sealed receptacles. No smoking. Store according to label and/or product insert information.

Specific End Use:

Pharmaceuticals.

8. Exposure Controls/Personal Protection

Occupational Exposure Guidelines:

Common or Chemical Name	Employee Exposure Limits
Calcipotriene Monohydrate	Teva OEL: $1 > x \geq 0.1 \text{ ug/m}^3$

SDS: Calcipotriene Topical Solution, 0.005% (Scalp Solution)

Engineering Controls:	Provide efficient ventilation at the workplace so dangerous substances in the air are removed directly at the source. Engineering controls should be used as the primary means to control exposures.
Respiratory Protection:	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eyes Protection:	Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Hand Protection:	Chemically compatible gloves are recommended. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Skin Protection:	Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

9. Physical and Chemical Properties

Physical State/Color:	Clear fluid.
Odor:	Alcohol-like odor.
Odor Threshold:	No data available.
pH:	No data available.
Melting Point:	Undetermined.
Freezing Point:	No data available.
Boiling Point:	82°C.
Flash Point:	21°C.
Evaporation Rate:	No data available.
Flammability (solid, gas):	No data available.
Flammability Limit - Lower:	2.0 Vol %.
Flammability Limit - Upper:	12.0 Vol %.
Vapor Pressure:	43 hPa.
Vapor Density:	No data available.
Relative Density:	No data available.
Solubility(ies):	Fully miscible in water.
Partition Coefficient (n-octanol/water):	No data available.
Auto-Ignition Temperature:	No data available.
Decomposition Temperature:	No data available.
Viscosity:	No data available.
Other Information:	Product is not explosive. However, formation of explosive air/vapor mixtures are possible.

**SDS: Calcipotriene Topical Solution, 0.005%
(Scalp Solution)**

10. Stability and Reactivity

Reactivity: No data available.

Chemical Stability: No decomposition if used according to specifications.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static discharge, shock, or vibration): No data available.

Incompatible Materials: No dangerous reactions known.

Hazardous Decomposition Products: No dangerous decomposition products known.

11. Toxicological Information

Information on the Likely Routes of Exposure:

Inhalation: No data available.

Ingestion: No data available.

Skin Contact: Contact with facial skin may cause irritation and inflammation of the skin (dermatitis).

Eye Contact: Contact with eyes may cause irritation.

Symptoms Related to the Physical, Chemical and Toxicological Characteristics: See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of Exposure: No data available.

Acute Toxicity:

Compound	Species	Route	Test Type	Dose
Calcipotriene Monohydrate	Rat	Oral	LD ₅₀	19 mg/kg
Isopropyl Alcohol	Rat	Oral	LD ₅₀	5,045 mg/kg
Isopropyl Alcohol	Rabbit	Dermal	LD ₅₀	12,800 mg/kg
Isopropyl Alcohol	Rat	Inhalation	LC ₅₀ /4 Hour	30 mg/kg

Corrosivity: No data available.

Dermal Irritation: No data available.

Eye Irritation: No data available.

Sensitization: No sensitizing effects known.

Toxicokinetics/Metabolism: No data available.

Target Organ Effects: No data available.

Reproductive Effects: No data available.

Carcinogenicity: No data available.

SDS: Calcipotriene Topical Solution, 0.005% (Scalp Solution)

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

Mutagenicity: No data available.

Aspiration Hazard: No data available.

12. Ecological Information

Ecotoxicity

Aquatic: No data available.

Terrestrial: No data available.

Persistence and Degradability: No data available.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Mobility in Environment: No data available.

Other Adverse Effects: No data available.

Water Hazard Class: Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

13. Disposal Considerations

To be disposed of as chemical waste containing drug substances. European waste catalogue 180109. Dispose of all waste in accordance with Federal, State and Local regulations.

14. Transport Information

UN Number: 1993

UN Proper Shipping Name: FLAMMABLE LIQUID, N.O.S. (ISOPROPANOL (ISOPROPYL ALCOHOL))

Transport Hazard Class(es): 3

Packing Group: III

Department of Transportation: Not Available.

International Air Transport Association (IATA): Regulated as a dangerous good.

International Maritime Dangerous Good (IMDG): Regulated as a dangerous good.

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(Scalp Solution)**

15. Regulatory Information

US Federal Regulations:

Toxic Substance Control Act (TSCA): Not listed.

CERCLA Hazardous Substance and Reportable Quantity: Not listed.

SARA 313: Not listed.
SARA 302: Not listed.

State Regulations

Massachusetts: Not listed.

New Jersey: Not listed.

Pennsylvania: Not listed.

California Proposition 65: Not listed.

16. Other Information

NFPA Rating:

Health: 3

Flammability: 3

Reactivity: 0

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