

Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • **DERMATOP® Ointment, 0.1 %**

Synonyms • Prednicarbate ointment, 0.1%

Product Code • NDC 0187-5183-60

Product Description • Topical corticosteroid ointment.

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Finished Pharmaceutical Product; DERMATOP Ointment 0.1% is a medium potency corticosteroid indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

Restrictions on use • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals North America, LLC

Bridgewater, NJ 08807

United States

valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

Manufacturer • +1 352-323-3500 - International - Infotrac

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Skin Mild Irritation 3
Reproductive Toxicity 2

Label elements

UN GHS

WARNING



Hazard statements • Causes mild skin irritation
Suspected of damaging fertility or the unborn child.

Precautionary statements

Prevention ● Wash thoroughly after handling.
Keep container tightly closed.
Use personal protective equipment as required.

Response ● IF exposed or concerned: Get medical advice/attention.
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.
IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
If skin irritation occurs: Get medical advice/attention.

Storage/Disposal ● Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. use before expiration date marked on carton and/or container.

Other hazards

UN GHS ● No data available

Section 3 - Composition/Information on Ingredients

Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition			
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive
Glycerol monostearate	CAS:123-94-4 EINECS:204-664-4	5% TO 15%	UN GHS: NDA
Octyldodecanol	CAS:5333-42-6 EINECS:226-242-9	5% TO 15%	UN GHS: NDA
Petrolatum	CAS:8009-03-8 EINECS:232-373-2	> 75%	UN GHS: NDA
Prednicarbate	CAS:73771-04-7 EINECS:277-590-3	0.1%	UN GHS: NDA

See Section 11 for Toxicological Information.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- Normal use of this product does not pose an inhalation hazard. However, should respiratory tract irritation develop, discontinue use and remove to fresh air. Get medical attention if irritation or other symptoms develop or persist.

Skin

- Wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash clothing separately before reuse.

Eye

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion

- If swallowed, wash out mouth with water provided person is conscious. Seek medical

attention.

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Notes to Physician

- Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Recovery of HPA-axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Section 5: Fire-Fighting Measures

Extinguishing media

- Suitable Extinguishing Media**
- SMALL FIRES: Dry chemical, CO₂, water spray or regular foam.
LARGE FIRE: Water spray, fog or regular foam.

- Unsuitable Extinguishing Media**
- No data available

Special hazards arising from the substance or mixture

- Unusual Fire and Explosion Hazards**
- None known.

- Hazardous Combustion Products**
- None known.

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

- Personal Precautions**
- No special controls or personal protection required under conditions of intended use. In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

- Emergency Procedures**
- Ventilate area. Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. Dispose of in accordance with Section 13. Keep unauthorized personnel away. Stop leak if you can do it without risk.

Environmental precautions

- Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

- Containment/Clean-up Measures**
- Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Dispose of in accordance with Section 13.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. use before expiration date marked on carton and/or container.

Incompatible Materials or Ignition Sources

- None specified.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls

- 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 to an acceptable level.

Personal Protective Equipment

Respiratory

- No special controls or personal protection required under conditions of intended use.

Eye/Face

- Wear protective eyewear (goggles, face shield, or safety glasses).

Hands

- Latex is not an effective barrier for corticosteroids. Wear nitrile gloves.

Skin/Body

- Avoid contact with skin. Wear long sleeves and/or protective coveralls.

General Industrial Hygiene Considerations

- Wash thoroughly after handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Ointment	Color	White to off-white.
Odor	No data available	Odor Threshold	No data available
General Properties			
Boiling Point	No data available	Melting Point	No data available
Decomposition Temperature	No data available	pH	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	insoluble
Solvent Solubility	methanol; ethanol	Viscosity	No data available
Volatility			
Vapor Pressure	No data available	Vapor Density	No data available
Evaporation Rate	No data available		
Flammability			

Flash Point	No data available	UEL	No data available
LEL	No data available	Autoignition	No data available
Flammability (solid, gas)	No data available		
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information • Toxicological information refers to raw materials only. Concentrations and toxicological effects may be substantially reduced in the product.

Components		
Prednicarbate (0.1%)	73771-04-7	Irritation: Skin-Woman • 1 % • Moderate irritation

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Mild Irritation 3
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Toxic to Reproduction 2
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

Potential Health Effects**Inhalation**

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - No data available.

Skin

- Acute (Immediate)**
 - Causes mild skin irritation.
- Chronic (Delayed)**
 - Causes mild skin irritation. Repeated and prolonged exposure may cause sensitization.

Eye

- Acute (Immediate)**
 - May cause irritation.
- Chronic (Delayed)**
 - No data available.

Ingestion

- Acute (Immediate)**
 - May be harmful if swallowed.
- Chronic (Delayed)**
 - No data available.

Reproductive Effects

- There are no adequate and well-controlled studies in pregnant women on teratogenic effects of prednicarbate. Therefore, DERMATOP Ointment(prednicarbate ointment) 0.1% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. In a study of the effect of prednicarbate on fertility, pregnancy and postnatal development in rats, no effect was noted on the fertility or pregnancy of the parent animals or postnatal development of the offspring after administration of up to 0.80 mg/kg of prednicarbate subcutaneously. Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. Prednicarbate has been shown to be teratogenic and embryo toxic in Wistar rats and Himalayan rabbits when given subcutaneously during gestation at doses 1900 times and 45 times, respectively, the recommended topical human dose, assuming a percutaneous absorption of approximately 3%.

Section 12 - Ecological Information**Toxicity**

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available.

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects**Section 13 - Disposal Considerations****Waste treatment methods****Product waste**

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	NDA	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
ADN	NDA	NDA	NDA	NDA	NDA
ADR/RID	NDA	NDA	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications • Acute

Inventory				
Component	CAS	Canada DSL	EU EINECS	TSCA
Octyldodecanol	5333-42-6	Yes	Yes	Yes
Glycerol monostearate	123-94-4	Yes	Yes	Yes
Petrolatum	8009-03-8	Yes	Yes	Yes
Prednicarbate	73771-04-7	No	Yes	No

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Octyldodecanol	5333-42-6	Not Listed
• Petrolatum	8009-03-8	Uncontrolled product according to WHMIS classification criteria
• Glycerol monostearate	123-94-4	Not Listed
• Prednicarbate	73771-04-7	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Octyldodecanol	5333-42-6	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Glycerol monostearate	123-94-4	Not Listed
• Prednicarbate	73771-04-7	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Octyldodecanol	5333-42-6	Not Listed
• Petrolatum	8009-03-8	Carc.Cat.2; R45
• Glycerol monostearate	123-94-4	Not Listed
• Prednicarbate	73771-04-7	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Octyldodecanol	5333-42-6	Not Listed
• Petrolatum	8009-03-8	T R:45 S:53-45
• Glycerol monostearate	123-94-4	Not Listed
• Prednicarbate	73771-04-7	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Octyldodecanol	5333-42-6	Not Listed
• Petrolatum	8009-03-8	S:53-45
• Glycerol monostearate	123-94-4	Not Listed
• Prednicarbate	73771-04-7	Not Listed

United States**Environment****U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities**

• Octyldodecanol	5333-42-6	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Glycerol monostearate	123-94-4	Not Listed
• Prednicarbate	73771-04-7	Not Listed

United States - California**Environment****U.S. - California - Proposition 65 - Carcinogens List**

• Octyldodecanol	5333-42-6	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Glycerol monostearate	123-94-4	Not Listed
• Prednicarbate	73771-04-7	Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity

• Octyldodecanol	5333-42-6	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Glycerol monostearate	123-94-4	Not Listed
• Prednicarbate	73771-04-7	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Octyldodecanol	5333-42-6	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Glycerol monostearate	123-94-4	Not Listed
• Prednicarbate	73771-04-7	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Octyldodecanol	5333-42-6	Not Listed
• Petrolatum	8009-03-8	Not Listed
• Glycerol monostearate	123-94-4	Not Listed
• Prednicarbate	73771-04-7	Not Listed

Section 16 - Other Information

- Last Revision Date**
- 14/April/2015
- Preparation Date**
- 14/April/2015
- Disclaimer/Statement of Liability**
- The above information and recommendations contained in the Safety Data Sheet have been compiled from sources believed to be accurate and reliable and to represent the most reasonable current opinion on the subject as of the date the SDS was prepared. No warranty, guaranty, or representation is made as to the correctness or sufficiency of the information. Such data are offered solely for consideration, investigation, and verification but do not purport to be all inclusive and should be used only as a guide. The user of this product must decide what safety measures are necessary to safely use this product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under any applicable federal or state laws.
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