Safety Data Sheet
DESOXIMETASONE OINTMENT, USP
Strength: 0.25% **Pack Size:** 15 gm, 60 gm, 100 gm. NDC 72578-095-01, 72578-095-02, 72578-095-03 **Revision No.:** 00

Emergency Overview

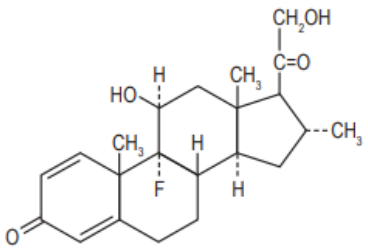
Desoximetasone Ointment USP, 0.25% contains the active synthetic corticosteroid Desoximetasone. The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

Section 1 : Identification

Product Name: Desoximetasone Ointment USP, 0.25%

Formula: $C_{22}H_{29}FO_4$

Chemical Name: Pregna-1, 4-diene-3, 20-dione, 9-fluoro-11, 21-dihydroxy-16-methyl-,(11b,16α)-.



Molecular Weight: 376.47 g/mol

Description: Desoximetasone Ointment USP, 0.25% contains the active synthetic corticosteroid desoximetasone. The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents.

Dosage forms and strengths: Ointment, Each gram of Desoximetasone Ointment USP, 0.25% contains 2.5 mg of desoximetasone in an ointment base consisting of fractionated coconut oil and white petrolatum. and is available in three packs 15 gm, 60 gm and 100 gm.

Manufacturer / supplier identification

Company	Cadila Healthcare Ltd. Ahmedabad, India
Address	Zydus Cadila, Topical Formulation facility. Plot No. 254, Opp. Laxmi Narayan Petrol Pump, N. H 8A, Ahmedabad -382210 India
Contact for information	Tel.:+91 2717-616430 Fax: +91 2717-616430
Emergency Telephone No	Tel.:+91 2717-616401
Recommended use / Therapeutic Category	Desoximetasone Ointment USP, 0.25% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
Restriction on Use / Contraindications	Desoximetasone ointment, 0.25% is contraindicated in those patients with a history of hypersensitivity to any of the components of the preparation.

Section 2 : Hazard (s) Identification

Dose and Administration	Apply a thin film of Desoximetasone Ointment USP, 0.25% to the affected skin areas twice daily. Rub in gently.
Adverse effects	The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae and miliaria. In controlled clinical studies the incidence of adverse reactions was low (0.3%) for Desoximetasone Ointment USP, 0.25% and consisted of development of comedones at the site of application.
Over Dose Effect	Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.
Pregnancy Comments	**Teratogenic Effects** **Pregnancy Category C** 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. Desoximetasone has been shown to be teratogenic and embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration in doses 3 to 30 times the human dose of desoximetasone ointment USP, 0.25%. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, desoximetasone ointment USP, 0.25% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time. **Nursing Mothers:** It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Section 3: Composition / information on ingredients

Each gram contains:	Active: 2.5 mg of Desoximetasone
CAS	382-67-2

Section 4: First -aid measures

General

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

Skin Exposure: Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye Exposure: Rinse with water. Get medical attention if irritation develops and persists.

Inhalation: Move to fresh air. Call a physician if symptoms develop or persist.

Ingestion: Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most Important Symptoms/Effects, Acute and Delayed: Adrenal suppression.

Indication of Immediate Medical Attention and Special Treatment Needed: Treatment of corticosteroid overdose should be symptomatic and supportive and may include the following: Toxicity is low after acute ingestion. Gastrointestinal decontamination is generally not necessary.

Signs and Symptoms

Ointment is intended for topical use only under guidance of a physician. Ointment is not considered hazardous under normal conditions.

Overdose Treatment

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects

Section 5: Fire -fighting measures

Fire-Fighting Equipment/Instructions:	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Suitable Extinguishing Media:	Use fire-extinguishing media appropriate for surrounding materials. Water, foam, dry chemical or CO_2.
Unsuitable Extinguishing Media:	None known.
Specific Hazards Arising From the Chemical:	No unusual fire or explosion hazards noted.
Special Protective Equipment and Precautions for Firefighters:	Wear suitable protective equipment.
Specific Methods:	Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures:	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and Materials for Containment and Cleaning Up:	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal. Clean surface thoroughly to remove residual contamination.

Section 7: Handling and Storage

Precautions for Safe Handling:	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.
Conditions for Safe Storage, Including Any Incompatibilities:	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.
Storage Conditions	Store at 20° to 25°C (68° to 77°F), excursions permitted to 15° to 30°C (59° to 86°F). [See USP Controlled Room Temperature]

Section 8: Exposure controls/personal protection

Biological Limit Values:	No biological exposure limits noted for the ingredient(s).
Exposure Guidelines:	No exposure standards allocated.
Appropriate Engineering Controls:	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

Section 9: Physical and chemical properties

Boiling Point:	Not determined.
Physical State (liquid/solid/gas):	Semi-solid
Specific Gravity (H2O = 1):	Not determined.
Evaporation Rate (Butyl Acetate = 1):	Not determined.
Solubility:	Not miscible with water.
Appearance:	White to off-white ointment with characteristic odour.
Odor Description:	Odorless.

Section 10: Stability and reactivity

Reactivity:	No reactivity hazards known.
Chemical Stability:	Material is stable under normal conditions.
Possibility of Hazardous Reactions:	No dangerous reaction known under conditions of normal use.
Conditions to Avoid:	None known.
Incompatible Materials:	None known.
Hazardous Decomposition Products:	F-, irritating and/or toxic fumes or gases, emits toxic fumes under fire conditions.

Section 11: Toxicological information

Information on Likely Routes of Exposure
Ingestion: Harmful if swallowed.
Inhalation: Due to lack of data the classification is not possible.
Skin Contact: Due to lack of data the classification is not possible.
Eye Contact: Due to lack of data the classification is not possible.

Symptoms Related to the Physical, Chemical, and Toxicological Characteristics:	Corticosteroids: nausea, vomiting, headache, acne, increased hair growth, lightheadedness**,** weakness, increased sweating, eye pain, vision changes, mental or behavioral changes**,** swelling, numbness, infection, delayed wound healing, thinning skin, bruising, purple lines on skin, bone fractures, back pain, joint pain or stiffness, increased appetite, redistribution of body fat, menstrual irregularities, impotence, tremors.
Cross Sensitivity:	Persons sensitive to one corticosteroid may be sensitive to this material also.
Medical Conditions Aggravated by Exposure:	Corticosteroids: heart disease, high blood pressure, diabetes, epilepsy, glaucoma, hypothyroidism, osteoporosis, peptic ulcer, systemic fungal infection, mental disorders, impaired liver or kidney function.
Acute Toxicity:	Harmful if swallowed.
Skin Corrosion/Irritation:	Due to lack of data the classification is not possible.
Serious Eye Damage/Eye Irritation:	Due to lack of data the classification is not possible.
Respiratory Sensitization:	Due to lack of data the classification is not possible.
Skin Sensitization:	Due to lack of data the classification is not possible.
Germ Cell Mutagenicity:	Due to lack of data the classification is not possible. Data from germ cell mutagenicity tests were not found.
Mutagenicity:	S. typhimurium Ames assay Result: Negative (with or without activation).
Carcinogenicity:	Due to lack of data the classification is not possible. This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

Product	Species	Test Results
Desoximetasone (CAS 382-67-2)		
Oral		
LD50	Mouse	1519 mg/kg
	Rat	1469 mg/kg

Section 12: Ecological information

Ecotoxicity:	No ecotoxicity data noted for the ingredient(s).
Persistence and Degradability:	No data is available on the degradability of this product.
Bioaccumulative Potential:	Not available.
Mobility in Soil:	Not available.
Other Adverse Effects:	Not available.

Section 13: Disposal consideration

Disposal recommendation	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local Disposal Regulations:	Not available.
Hazardous Waste Code:	Not available.
Waste from Residues / Unused Products:	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner.
Contaminated Packaging:	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Section 14: Transport information

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorized persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

DOT: Not regulated as a hazardous material by DOT.
IATA: Not regulated as a dangerous good.

UN Classification and Labelling Transport Information
Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

Section 15: Regulatory information

Generic Medicine. NDC no- 72578-095-01 (15 gm), 72578-095-02 (60 gm) and 72578-095-03 (100 gm)

Section 16: Other information

None

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product

Date of issue: 28/09/2020 **Supersedes edition:** New Edition