

SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: Clobetasol Propionate Ointment **PRODUCT No.:** 51672-1259
USP, 0.05%

Distributor: Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive, Hawthorne, New York 10532
Telephone: 1-888-TARO-USA

Recommended Use: Clobetasol propionate gel, cream and ointment are super-high potency corticosteroid formulations indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses. Treatment beyond 2 consecutive weeks is not recommended, and the total dosage should not exceed 50 g per week because of the potential for the drug to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Use in pediatric patients under 12 years of age is not recommended. As with other highly active corticosteroids, therapy should be discontinued when control has been achieved. If no improvement is seen within 2 weeks, reassessment of the diagnosis may be necessary.

Restrictions on Use: Clobetasol propionate gel, cream and ointment are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

SUBSTANCE CLASS: Corticosteroid; Topical anti-inflammatory/immunosuppressive

FORMULA: $C_{25}H_{32}ClFO_5$

M.W.: 467

SECTION 2: HAZARD(S) IDENTIFICATION

Note: This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

Physical Hazards: Not classified.

Health Hazards:	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 1 (endocrine system)

OSHA Hazard(s): Not classified.

Label Elements

Signal Word: Danger

Hazard Statement: Suspected of damaging fertility or the unborn child. Causes damage to organs (endocrine system) through prolonged or repeated exposure.

Precautionary Statement

Prevention: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Do not breathe dust.

Response: If exposed or concerned: Get medical advice/attention.

Storage: Store locked up.

Disposal: Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) Not Otherwise Classified (HNOC): Not classified.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient: Clobetasol Propionate CAS#: 25122-46-7

Inactive Ingredients: Propylene glycol, sorbitan sesquioleate, and white petrolatum.

SECTION 4: FIRST-AID MEASURES

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

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

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

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. (Poisindex)

General Information: 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. In the United States, the national poison control center phone number is 1-800-222-1222. 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.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO₂.

Unsuitable Extinguishing Media: None known.

Specific Hazards arising from the Chemical: *Explosion hazard:* Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

Special Protective Equipment and Precautions for Firefighters: Wear suitable protective equipment.

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.

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: Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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, see section 13 of the SDS. 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. Combustible dust clouds may be created where operations produce fine material (dust). Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.

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.

Store at 20°-25°C (68°-77°F) [see USP Controlled Room Temperature]. DO NOT REFRIGERATE

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit Values

Industrial Use

<u>Material</u>	<u>Type</u>	<u>Value</u>	<u>Form</u>
Clobetasol Propionate (CAS 25122-46-7)	TWA	2 micrograms/m ³	skin

Biological Limit Values: No biological exposure limits noted for the ingredient(s).

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.

Individual Protection Measures, Such As Personal Protective Equipment

Eye/Face Protection: Safety glasses with sideshields 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.

Skin Protection

Hand Protection: Chemically compatible gloves. 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 nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other: For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

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).

Thermal Hazards: Not available.

General Hygiene Considerations: Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Boiling Point:	Not determined, melting point of 195°C.
Physical State (Liquid/Solid/Gas):	Liquid
Specific Gravity (H₂O=1):	Not determined.
Evaporation Rate (Butyl Acetate=1):	Not determined.
Solubility:	Not determined for Clobetasol Propionate Ointment USP, 0.05%. Clobetasol propionate, the active ingredient in this product is soluble in isopropyl alcohol, ethanol and acetone and insoluble in water.
Appearance:	White to off-white translucent ointment.
Odor Description:	Odorless.

SECTION 10: STABILITY AND REACTIVITY

Reactivity: No reactivity hazards known.

Chemical Stability: Stable at normal conditions.

Possibility of Hazardous Reactions: No dangerous reaction known under conditions of normal use.

Conditions to Avoid: None known.

Incompatible Materials: Oxidizing agents. Acids. Alkalis.

Hazardous Decomposition Products: Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on Likely Routes of Exposure

Ingestion: Based on available data, the classification criteria are not met.

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: Mineralocorticoid effects: Swelling. Confusion. Lightheadedness. Nausea. Vomiting. Numbness. Tremors. Glucocorticoid effects: Bone fractures. Back pain. Joint pain or stiffness. Weakness. Increased appetite. Infection. Delayed wound healing. Thinning skin. Bruising. Purple lines on skin. Increased hair growth. Acne. Redistribution of body fat. Menstrual irregularities. Impotence. Headache. Increased sweating. Eye pain. Change in vision. Mental or behavioral changes.

Chronic Effects: Causes damage to organs through prolonged or repeated exposure. Adrenal suppression. Immune system depression. Hypercorticism or Cushing's syndrome. Withdrawal effects after chronic exposure is discontinued include fever, muscle pain, joint pain, and malaise.

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

Product	Species	Test Results
Clobetasol Propionate (CAS 25122-46-7)		
Acute		
<i>Oral</i>		
LD50	Mouse	> 3 g/kg
	Rat	> 3 g/kg

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.

Sensitization: There are reports of hypersensitivity and anaphylaxis following corticosteroid exposure.

Germ Cell Mutagenicity: Due to lack of data the classification is not possible.

Data from germ cell mutagenicity tests were not found.

Mutagenicity: Ames test Result: Negative.

E. coli B WP2 fluctuation assay Result: Negative.

S. cerevisiae gene conversion assay Result: Negative.

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.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity

Product		Species	Test Results
Clobetasol Propionate (CAS 25122-46-7)			
<i>Acute</i>			
Crustacea	EC50	Daphnia magna	> 1.4 mg/l, 48 hours
Fish	EC50	Oncorhynchus mykiss	> 0.75 mg/l, 96 hours
Other	IC50	Pseudokirchnerella subcapitata	> 4.2 mg/l, 72 hours

Persistence and Degradability: Not readily biodegradable.

Bioaccumulative Potential: Not available.

Mobility in Soil: Not available.

Other Adverse Effects: Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal Instructions: 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 (see: Disposal instructions).

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

DOT: Not regulated as a hazardous material by DOT.

IATA: Not regulated as a dangerous good.

Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: No information available.

SECTION 15: REGULATORY INFORMATION

US Federal Regulations: CERCLA/SARA Hazardous Substances - Not applicable.
One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard Categories: Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely Hazardous Substance: No

SARA 311/312 Hazardous Chemical: No

Other federal regulations

Safe Drinking Water Act (SDWA): Not regulated.

Food and Drug Administration (FDA): Not regulated.

US State Regulations: WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

SECTION 16: OTHER INFORMATION

Contact: Taro Pharmaceuticals U.S.A., Inc., Regulatory Affairs Department
3 Skyline Drive, Hawthorne, NY 10532

Preparation and/or Revision Date: October 2015

DISCLAIMER

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