SAFETY DATA SHEET

SECTION 1: IDENTIFICATION

PRODUCT NAME: Clobetasol Propionate Topical Solution USP, 0.05%
PRODUCT No.: 51672-1293
Distributor: Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive, Hawthorne, New York 10532
Telephone: 1-888-TARO-USA
Recommended Use: Short-term topical treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses of the scalp.
Restrictions on Use: Patients with primary infections of the scalp, or in patients who are hypersensitive to clobetasol propionate, other corticosteroid, or any ingredient in this preparation.
SUBSTANCE CLASS: Corticosteroid
FORMULA: C_{25}H_{32}CIFO_{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: Carbomer 934P, isopropyl alcohol (39.3%), purified water, and sodium hydroxide.

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 in tight containers. Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Do not refrigerate. Do not use near an open flame.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limit Values

<table>
<thead>
<tr>
<th>Material</th>
<th>Type</th>
<th>Value</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clobetasol Propionate (CAS 25122-46-7)</td>
<td>TWA</td>
<td>2 micrograms/m3</td>
<td>skin</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point: Data not available</td>
</tr>
<tr>
<td>Physical State (Liquid/Solid/Gas): Liquid</td>
</tr>
<tr>
<td>Specific Gravity (H₂O=1): 0.945</td>
</tr>
<tr>
<td>Evaporation Rate (Butyl Acetate=1): Slower than ether</td>
</tr>
<tr>
<td>Solubility: Freely miscible in water</td>
</tr>
<tr>
<td>Appearance: Clear, colorless liquid</td>
</tr>
<tr>
<td>Odor Description: Characteristic odor</td>
</tr>
</tbody>
</table>
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.


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.


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.


Acute Toxicity

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clobetasol Propionate (CAS 25122-46-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>&gt; 3 g/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>&gt; 3 g/kg</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Product</th>
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<tr>
<td>Clobetasol Propionate (CAS 25122-46-7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Crustacea EC50</td>
<td>Daphnia magna</td>
<td>&gt; 1.4 mg/l, 48 hours</td>
</tr>
<tr>
<td>Fish EC50</td>
<td>Oncorhynchus mykiss</td>
<td>&gt; 0.75 mg/l, 96 hours</td>
</tr>
<tr>
<td>Other IC50</td>
<td>Pseudokirchnerella subcapitata</td>
<td>&gt; 4.2 mg/l, 72 hours</td>
</tr>
</tbody>
</table>

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

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