




SAFETY DATA SHEET

1. Identification

| | | |
|---|---|-----------------|
| Product identifier | Clobetasol Propionate | |
| Other means of identification | | |
| Catalog number | 1138405 | |
| CAS number | 25122-46-7 | |
| Synonyms | Clobetasol 17-propionate | |
| Chemical name | Pregna-1,4-diene-3,20-dione, 21-chloro-9-fluoro-11-hydroxy-16-methyl-17-(1-oxopropoxy)-, (11beta,16beta)- | |
| Recommended use | Specified quality tests and assay use only. | |
| Recommended restrictions | Not for use as a drug. Not for administration to humans or animals. | |
| Manufacturer/Importer/Supplier/Distributor information | | |
| Manufacturer | | |
| Company name | U. S. Pharmacopeia | |
| Address | 12601 Twinbrook Parkway Rockville MD 20852-1790 United States | |
| Telephone | RS Technical Services | 301-816-8129 |
| Website | www.usp.org | |
| E-mail | RSTECH@usp.org | |
| Emergency phone number | CHEMTREC within US & Canada | 1-800-424-9300 |
| | CHEMTREC outside US & Canada | +1 703-527-3887 |

2. Hazard(s) identification

| | | |
|--------------------------------|---|-------------------------------|
| Physical hazards | Not classified. | |
| Health hazards | Reproductive toxicity | Category 2 |
| | Specific target organ toxicity, repeated exposure | Category 1 (endocrine system) |
| Environmental hazards | Not classified. | |
| OSHA defined hazards | 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. Do not breathe dust. Wear protective gloves/protective clothing/eye protection/face protection. | |
| Response | If exposed or concerned: Get medical advice/attention. Get medical advice/attention if you feel unwell. | |
| Storage | Store locked up. | |
| Disposal | Dispose of contents/container in accordance with local/regional/national/international regulations. | |

Hazard(s) not otherwise classified (HNOC) 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.

Supplemental information Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

| Chemical name | Common name and synonyms | CAS number | % |
|-----------------------|--------------------------|------------|-----|
| Clobetasol Propionate | Clobetasol 17-propionate | 25122-46-7 | 100 |

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 Endocrine system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Indication of immediate medical attention and special treatment needed Provide general supportive measures and treat symptomatically. Treatment of corticosteroid overdose may include the following: Toxicity is low after acute ingestion. Gastrointestinal decontamination is generally not necessary.

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.

5. Fire-fighting measures

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

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.

General fire hazards No unusual fire or explosion hazards noted.

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. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. For personal protection, see section 8 of the SDS. 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.

Methods and materials for containment and cleaning up For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

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.

Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions.

Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

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.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use

Material

Type

Value

Form

Clobetasol Propionate (CAS 25122-46-7)

TWA

2 micrograms/m³ skin

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

White. Cream.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

383 - 386.6 °F (195 - 197 °C)

Initial boiling point and boiling range

Not available.

| | |
|---|---|
| Flash point | Not available. |
| Evaporation rate | Not available. |
| Flammability (solid, gas) | Not available. |
| Upper/lower flammability or explosive limits | |
| Flammability limit - lower (%) | Not available. |
| Flammability limit - upper (%) | Not available. |
| Explosive limit - lower (%) | Not available. |
| Explosive limit - upper (%) | Not available. |
| Vapor pressure | < 0.0000001 kPa at 25 °C |
| Vapor density | Not available. |
| Relative density | Not available. |
| Solubility(ies) | |
| Solubility (water) | Practically insoluble. |
| Solubility (other) | Acetone: Sparingly soluble. Alcohol: Soluble. Chloroform: Soluble. Dimethyl sulfoxide: Soluble. Ethanol: Sparingly soluble. Methanol: Soluble. |
| Partition coefficient (n-octanol/water) | 3.5 |
| Auto-ignition temperature | Not available. |
| Decomposition temperature | Not available. |
| Viscosity | Not available. |
| Other information | |
| Chemical family | Corticosteroid. |
| Dust explosion properties | |
| Kst | 195 bar.m/s |
| Minimum ignition energy (MIE) - dust cloud | 3 - 4 mJ |
| Molecular formula | C ₂₅ H ₃₂ ClFO ₅ |
| Molecular weight | 466.97 466.97 g/mol |
| pH in aqueous solution | 6.8 - 7 Solution: 10% |

10. Stability and reactivity

| | |
|---|---|
| Reactivity | The product is stable and non-reactive under normal conditions of use, storage and transport. |
| Chemical stability | Material is stable under normal conditions. |
| Possibility of hazardous reactions | No dangerous reaction known under conditions of normal use. |
| Conditions to avoid | Contact with incompatible materials. |
| Incompatible materials | Oxidizing agents. Acids. Alkalis. |
| Hazardous decomposition products | Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. Cl-. F-. |

11. Toxicological information

Information on likely routes of exposure

| | |
|---------------------|--|
| Inhalation | Knowledge about health hazard is incomplete. |
| Skin contact | Based on information from therapeutic use, this material may cause: Endocrine effects. |
| Eye contact | Knowledge about health hazard is incomplete. |
| Ingestion | Knowledge about health hazard is incomplete. |

Symptoms related to the physical, chemical, and toxicological characteristics

Corticosteroids: Fluid and electrolyte imbalance. Adrenal suppression. Immunosuppression. Cushing's syndrome. High blood pressure. Gastrointestinal disturbances. Headache. Lightheadedness. Weakness. Visual disturbances. Mood or mental status changes. Infection. Thinning skin. Swelling. Bruising. Bone fractures. Back pain. Joint pain. Tremors. Menstrual irregularities. Impotence.

Information on toxicological effects

Acute toxicity

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

Skin corrosion/irritation Knowledge about health hazard is incomplete.

Serious eye damage/eye irritation Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Knowledge about health hazard is incomplete.

Germ cell mutagenicity Knowledge about mutagenicity is incomplete.

Mutagenicity

Ames test

Result: Negative.

Mutagenicity: E. coli B WP2 fluctuation assay

Result: Negative.

Mutagenicity: S. cerevisiae gene conversion assay

Result: Negative.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

Suspected of damaging fertility or the unborn child. Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. A small increase in the incidence of cleft palate was seen in some human studies. Infants born to mothers who received substantial doses of corticosteroids during pregnancy should be observed for signs of hypoadrenalism.

Reproductivity

0.003 - 0.01 mg/kg Reproductivity / Developmental

Result: Teratogenic.

Species: Rabbit

0.03 - 1 mg/kg Reproductivity / Developmental, administered subcutaneously.

Result: Fetotoxic at high dose; teratogenic at 0.03 mg/kg.

Species: Mouse

0.05 mg/kg/day Reproductivity / Developmental, administered subcutaneously.

Result: Embryotoxic and fetotoxic.

Species: Rat

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Causes damage to organs (endocrine system) through prolonged or repeated exposure.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

12. Ecological information

Ecotoxicity

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

Persistence and degradability Not readily biodegradable.

Bioaccumulative potential

Octanol/water partition coefficient log Kow
3.5

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

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 Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products 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 Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

General information It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Classified hazard categories Yes
Combustible dust
Reproductive toxicity
Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Proposition 65

California Proposition 65 - CRT: Listed date/Developmental toxin

Clobetasol Propionate (CAS 25122-46-7) Listed: May 15, 1998

California Proposition 65 - CRT: Listed date/Female reproductive toxin

Clobetasol Propionate (CAS 25122-46-7) Listed: May 15, 1998

International Inventories

| Country(s) or region | Inventory name | On inventory (yes/no)* |
|-----------------------------|--|------------------------|
| Australia | Australian Inventory of Chemical Substances (AICS) | Yes |
| Canada | Domestic Substances List (DSL) | Yes |
| Canada | Non-Domestic Substances List (NDSL) | No |
| China | Inventory of Existing Chemical Substances in China (IECSC) | No |
| Europe | European Inventory of Existing Commercial Chemical Substances (EINECS) | Yes |
| Europe | European List of Notified Chemical Substances (ELINCS) | No |
| Japan | Inventory of Existing and New Chemical Substances (ENCS) | No |
| Korea | Existing Chemicals List (ECL) | No |
| New Zealand | New Zealand Inventory | Yes |
| Philippines | Philippine Inventory of Chemicals and Chemical Substances (PICCS) | No |
| Taiwan | Taiwan Chemical Substance Inventory (TCSI) | Yes |
| United States & Puerto Rico | Toxic Substances Control Act (TSCA) Inventory | No |

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

| | |
|----------------------------|---|
| Issue date | 02-27-2009 |
| Revision date | 12-13-2018 |
| Version # | 04 |
| Further information | Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. |

Disclaimer

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