Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Betamethasone Dipropionate USP Micronized
Commercial Name Not available.
Product Use Active Pharmaceutical Ingredient
Restrictions On Use Any use apart from the active pharmaceutical ingredient

Product Code 55-1454

Company
PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Skin corrosion/irritation Category 2 Serious eye damage/eye irritation Category 2B Reproductive toxicity Category 2 Specific target organ toxicity, repeated exposure Category 1 (endocrine system)

Signal Word DANGER

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

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

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

Response If on skin: Wash with plenty of water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash before reuse. 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 exposed or concerned: Get medical advice/attention.

Storage Store locked up.

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

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Betamethasone Dipropionate
% By Weight 100
CAS# 5593-20-4
Molecular Weight 504.6 g/mole
Chemical Formula C26H37FO7
Synonym(s) Betamethasone dipropionate, Diproderm, Diprolene, Diprosis, Diprosone

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Betamethasone Dipropionate	5593-20-4	100	Not Available.	Not Available.

Section 4: First-Aid Measures

Inhalation	If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin Contact	Remove contaminated clothing. Rinse skin with water/shower. Get medical attention if irritation develops and persists
Eye Contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. 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.
Symptoms/Effects	
Acute	Endocrine system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
Delayed	Endocrine system effects. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Immediate Medical Attention
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.

Section 5: Fire-Fighting Measures

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

Unsuitable Extinguishing Media
Not available

Products of Combustion
No unusual fire or explosion hazards noted

Firefighters Special Equipment and Precautions
Wear suitable protective equipment 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 Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS 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.

Section 7: Handling and Storage

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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	TWA 1 micrograms/m3
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

Personal Protection	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. Chose respiratory protection appropriate to the task and the level of existing engineering controls. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene consideration: 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.

Section 9: Physical and Chemical Properties

Appearance	White light cream powder. Solid.
Odor	Odourless.
Odor Threshold	Not available

Melting Point	338 - 354.2 °F (170 - 179 °C)	**pH**	Not available
Freezing Point	Not available.	**Vapor Pressure**	< 0.0000001 kPa at 25 °C
Boiling Point/Range	Not available	**Vapor Density**	Not available.
Decomposition temperature	Not available	**Viscosity**	Not available.
Partition Coefficient: n-octanol/water	Not available	**Evaporation Rate**	Not available
Flash Point	Not available.	**Autoignition temperature**	Not available
Flammability	Not available	**Flammability or Explosive Limits:**	
		Lower	Not available
		Upper	Not available

Solubility(ies)	Insoluable in water.
Other	Methanol: Sparingly soluble. Ethanol: Sparingly soluble. Chloroform: Freely soluble. Acetone: Freely soluble. Chemical family Corticosteroid. Molecular formula C28H37FO7 Molecular weight 504.59

Section 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
Hazardous Polymerization	No dangerous reaction known under conditions of normal use
Conditions to Avoid	Contact with incompatible materials
Incompatible Materials	Acids. Oxidizing agents. Reducing agents. Strong bases
Hazardous Decomposition Products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. HF

Section 11: Toxicological Information

RTECS TU4058000

Acute Toxicity
Oral LD50 Mouse > 5 g/kg Rat > 4 g/kg

Skin Corrosion/Irritation
Causes skin irritation

Serious Eye Damage/Irritation
Causes eye irritation

Respiratory or Skin Sensitization
Not available.

Germ Cell Mutagenicity
Not available.

Carcinogenicity
Not available.

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.

Routes of Entry
Skin. Eye. Ingestion.

Symptoms Related to Exposure
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.

Potential Health Effects
Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects

Target Organ(s) Causes damage to organs (endocrine system) through prolonged or repeated exposure.

Section 12: Ecological Information

Ecotoxicity
The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistance and Degradability
Minimally biodegradable

Bioaccumulative Potential
Not available

Mobility in Soil
Not 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

Section 13: Disposal Considerations

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

Disposal of Container
Since emptied containers may retain product residue, follow label warnings even after container is emptied.

Other Considerations
Not available.

Section 14: Transport Information

DOT Classification
Not a DOT controlled material (United States). This material is not classified dangerous good according to international transportation regulations (ADR/RID-IMDG-ICAO/IATA).

Section 15: Regulatory Information

Regulations
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 1910.1001-1050) Not regulated. Superfund Amendments and Reauthorization Act of 1986 (SARA) Immediate Hazard - Yes Delayed Hazard - Yes Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No Hazard categories SARA 302 Extremely hazardous substance Not listed. YesSARA 311/312 Hazardous chemical 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. Not regulated.Safe Drinking Water Act (SDWA) California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins

Other
Not available.

Section 16: Other Information

This document aims to provide guidance for appropriate handling and precaution of this product by qualified personnel or operating under the supervision of personnel trained in handling chemicals. The product should not be used for unless adequate written information on how to handle the purposes other than those mentioned in section 1, material are given. the dangers of use or interaction with other The provider of this document can not provide any warnings about chemicals or materials. It is responsibility of the user the safe use of the product, the product suitability for the purpose for which it is applied and proper disposal. The information below should not be considered a declaration or guarantee, either expressed or implied, of merchantability, fitness for a particular purpose, quality, or any other. The information contained in this SDS are in accordance with Annex I of Regulation No 453/2010/EU.