Safety Data Sheet

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

Section 1: Identification

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

Product Code 55-1954

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 Acute toxicity, inhalation Category 2 Reproductive toxicity Category 2 Speicific target organ toxicity, repeated exposure Category 1 (endocrine system)

Signal Word WARNING

Hazard Statement(s) MAY CAUSE DAMAGE TO ORGANS THROUGH PROLONGED OR REPEATED EXPOSURE. SUSPECTED OF DAMAGING THE UNBORN CHILD.MAY CAUSE HARM TO BREAST FED CHILDREN

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. Use only outdoors or in a well-ventilated area. Wear protective gloves/protective clothing/eye protection/face protection. In case of inadequate ventilation wear respiratory protection.

Response If inhaled: Remove person to fresh air and keep comfortable for breathing. Immediately call a poison center/doctor. If exposed or concerned: Get medical advice/attention

Storage Store in a well-ventilated place. Keep container tightly closed. Store locked up

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

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Betamethasone Acetate
% By Weight 100
CAS# 987-24-6
Molecular Weight 434.5 g/mole
Chemical Formula C24H31FO6
Synonym(s) 9-Fluoro-11,17,21-trihydroxy-16-me hylpregna-1,4-diene-3,20-dione acetate

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Betamethasone Acetate USP Micronized	987-24-6	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. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if the substance is inhaled. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Call a physician or poison control center immediately.

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.

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

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 Not available.

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 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.

Section 9: Physical and Chemical Properties

Appearance	White. Solid. (Powdered solid.)
Odor	Odorless
Odor Threshold	Not available.

Melting Point	384.8 - 406.4 °F (196 - 208 °	**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)	Practically insoluble in water.
Other	Acetone: Soluble. Chloroform: Soluble. Ethanol: Soluble Chemical family Corticosteroid. Molecular formula C24H31FO6 Molecular weight 434.5

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. Bases. Oxidizing agents. Reducing agents
Hazardous Decomposition Products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. F-

Section 11: Toxicological Information

RTECS Not available.

Acute Toxicity
Fatal if inhaled Acute Inhalation LC50 Rat 0.28 mg/l (Max. obtainable dose) Oral LD50 Rat > 5000 mg/kg, > 2000 mg/kg

Skin Corrosion/Irritation
Not available

Serious Eye Damage/Irritation
Not available

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
Inhalation. 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
Not available

Bioaccumulative Potential
Not available

Mobility in Soil
Not available

Other Adverse Effects
Not available

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). UN number: UN2811 UN proper shipping name: Toxic solid, organic, n.o.s. (Betamethasone Acetate) Transport hazard class(es) Class 6.1 Subsidiary risk - Packing group II

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

WHMIS Not controlled under WHMIS (Canada). (Canada);DSCL (EEC) This product is not classified according to the EU regulations.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent.;Safety glasses.

Section 16: Other Information

DISCLAIMER 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 purposes other than those mentioned in section 1, unless adequate written information on how to handle the material are given. The provider of this document can not provide any warnings about all the dangers of use or interaction with other 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.