

Section 1: Identification

Product Name Methylrednisolone Acetate USP Micronized
Commercial Name Not available.
Product Use Active Pharmaceutical Ingredient (API): corticosteroid with glucocorticoid activity
Restrictions On Use Other uses are not expected
Product Code 30-1332
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: Reproduction toxicity Category 2 Specific target organ toxicity, repeated exposure Category 1 (endocrine system)
CFR 1910.1200
Signal Word DANGER
Hazard Statement(s) Suspected of damaging 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. Wear protective gloves/protective clothing/eye protection/face protection. Do not breathe dust. Wash thoroughly after handling.
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 regulation

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Methylprednisolone acetate
% By Weight 100
CAS# 53-36-1
Molecular Weight 416.51 g/mole
Chemical Formula C₂₄H₃₂O₆
Synonym(s) 11,17,21-Trihydroxy-6-methyl-1,4-pregnadiene-3,20-dione acetate Methylprednisolone *
 Depo-Methylprednisolone acetate * Depot- medrol * Medrol acetate * Methylprednisolone acetate *
 Methylprednisolone 21-acetate * 6-Methylprednisolone acetate * 6- alpha-Methylprednisolone acetate *
 Pregna-1,4-diene-3,20-dione, 21- (acetyloxy)-11,17-dihydroxy-6-methyl-, (6-alpha,11-beta)- * U 8210 *
 Urbason crystal suspension

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Methylprednisolone acetate	53-36-1	100	Not available.	Not available.

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

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	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

Provide general supportive measures and treat symptomatically. Acute toxicity following overdose is uncommon. Gastrointestinal decontamination is generally not necessary. 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**

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. Cool containers exposed to flames with water until well after the fire is out

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. 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. 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	4 micrograms/m ³ Skin
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.

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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: 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: Handle in accordance with good industrial hygiene and safety practice. 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. Off-white. solid. Crystalline powder		
Odor	Odorless		
Odor Threshold	Not available		
Melting Point	437 °F (225 °C)	pH	Not applicable
Freezing Point	Not available	Vapor Pressure	< 0.000001 kPa at 25 °C
Boiling Point/Range	Not applicable to solids	Vapor Density	Not available.
Decomposition temperature	Not available	Viscosity	Not available
Partition Coefficient: n-octanol/water	Not available	Evaporation Rate	Not applicable to solids
Flash Point	Not applicable to solids	Autoignition temperature	Not available
Flammability	There is no experimental data	Flammability or Explosive Limits:	
		Lower	No data
		Upper	No data
Solubility(ies)	Practically insoluble in water. Dioxane: Soluble. Acetone: Sparingly soluble. Ethanol: Sparingly soluble. Chloroform: Sparingly soluble. Methanol: Sparingly soluble. Ether: Slightly soluble.		
Other	Not available.		

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

Section 11: Toxicological Information

RTECS TU4154050

Acute Toxicity

LD50 Mouse > 500 mg/kg Rat > 10 g/kg

Skin Corrosion/Irritation

Not available

Serious Eye Damage/Irritation

Not available

Respiratory or Skin Sensitization

Not available

Germ Cell Mutagenicity

Not available

Carcinogenicity

Methylprednisolone was negative for carcinogenicity in the DNA-cell-binding (DCB) assay

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.

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Routes of Entry

Not available

Symptoms Related to Exposure

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. Withdrawal effects: Fever. Muscle pain. Joint pain. Malaise.

Potential Health Effects

Causes damage to organs (endocrine system) through prolonged or repeated exposure

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.

Persistence and Degradability

Not available.

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

Disposal of Container

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.

Other Considerations

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

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 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 - No 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. Safe Drinking Water Act (SDWA) Not regulated 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.

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Other

WHMIS Not controlled under WHMIS (Canada). (Canada);DSCL (EEC) R36/38- Irritating to eyes and skin.;Gloves.;Lab coat.;Dust respirator. Be sure to use an approved/certified respirator or equivalent.;Splash goggles.

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 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 reported information 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.