Safety Data Sheet

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

Section 1: Identification

Product Name Fluocinonide USP Micronized
Commercial Name Flucinar, Lidex E, Metosyn, Topsym
Product Use Active Pharmaceutical Ingredient
Restrictions On Use Any use apart from the active Dharmaceutical ingredient

Product Code 55-1616

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

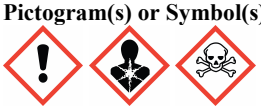
Section 2: Hazard(s) Identification

OSHA Haz Com: CFR 1910.1200 Acute toxicity, oralHealth hazards Category 2 Serious eye damage/eye irritation Category 2A Reproductive toxicity Category 2 Specific target organ toxicity, repeated exposure Category 1 (Endocrine system)

Signal Word DANGER

Hazard Statement(s) Fatal if swallowed. Causes serious 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/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.

Response If swallowed: Immediately call a poison center/doctor. Rinse mouth. 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 regulations

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components 1) Fluocinonide USP Micronized
% By Weight 100
CAS# 356-12-7
Molecular Weight 494.54 g/mole
Chemical Formula C26H32F2O7
Synonym(s) 21-(Acetoxy)-6alpha,9-difluoro-11beta-hydroxy-16alpha,17-[(1-methylethylidene)bis(oxy)]pregna-1,4-diene-3,20-dione;

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
1) Fluocinonide USP Micronized	356-12-7	100	Not Available.	LD50): Acute: 14 mg/kg [Rat]. 6000 mg/kg [Mouse].

Section 4: First-Aid Measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin Contact Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye Contact Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device

Symptoms/Effects

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

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

Immediate Medical Attention

Provide general supportive measures and treat symptomatically. Acute toxicity following overdose is uncommon. 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.Special protective equipment and precautions for firefighters As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to cool unopened containers. Fire fighting equipment/instructions Use standard firefighting procedures and consider the hazards of other involved materials.Specific methods No unusual fire or explosion hazards noted.General fire hazards 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. Personal precautions, protective equipment and emergency procedures 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. For waste disposal, see section 13 of the SDS. Methods and materials for containment and cleaning up 2 / 8 Material name: Fluocinonide 1276001 Version #: 03 Revision date: 12-28-2020 Issue date: 09-08-2010 Wear suitable protective equipment. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to cool unopened containers. 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: 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. For waste disposal, see section 13 of the SDS 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 10 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. 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.

Section 9: Physical and Chemical Properties

Appearance	White . Cream. powder solid.
Odor	Not available
Odor Threshold	Not available

Melting Point	586.4 - 591.8 °F (308 - 311 °	**pH**	Not available
Freezing Point	Not available	**Vapor Pressure**	< 0.0000001 kPa (77 °F (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 found after bibliographic research
		Upper	Not found after bibliographic research

Solubility(ies)	Practically insoluble in water.
Other	Methyl alcohol: Slightly soluble. Dioxan: Slightly soluble. Acetone: Sparingly soluble. Chloroform: Sparingly soluble. Ether: Very slightly soluble. Ethanol: Slightly soluble. Chemical family Corticosteroid. Molecular formula C26H32F2O7 Molecular weight 494.52

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

Section 11: Toxicological Information

RTECS TU3831000

Acute Toxicity
Fatal if swallowed Oral LD50 Mouse > 6000 mg/kg Solid LD50 Rat 14 mg/kg

Skin Corrosion/Irritation
Not available

Serious Eye Damage/Irritation
Causes serious 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. Animal studies with some corticosteroids have shown cleft palate and inhibited fetal growth. Most studies have concluded that therapeutic use of corticosteroids by pregnant women does not cause adverse effects on the fetus. A small increase in 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
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
Not available

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 of contents/container in accordance with local/regional/national/international 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
UN number: UN2811UN UN proper shipping name: Toxic solids, organic, n.o.s. (Fluocinonide) Transport hazard class(es) Class 6.1 Subsidiary risk - Packing group II Packaging exceptions 153 Packaging non bulk 212 Packaging bulk 242

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 Toxic Substances Control Act (TSCA) 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 1910.1001-1053) Not listed. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical Acute toxicity (any route of exposure) Serious eye damage or eye irritation Reproductive toxicity Specific target organ toxicity (single or repeated exposure) Classified hazard categories 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) US state regulations California Proposition 65 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. For more information go to www.P65Warnings.ca.gov.

Other
Not available.

Section 16: Other Information

This document aims to provide guidance for appropriate handling and precautions 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.