usp

SAFETY DATA SHEET

1. Identification

Product identifier Fluocinonide

Other means of identification

Catalog number1276001CAS number356-12-7SynonymsFluocinolide

Chemical name Pregna-1,4-diene-3,20-dione,

21-(acetyloxy)-6,9-difluoro-11-hydroxy-16,17-[(1-methylethylidene)bis (oxy)]-, (6alpha, 11beta,

16alpha)

Recommended use Specified quality tests and assay use only.

Recommended restrictionsNot 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 & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 2

Serious eye damage/eye irritation Category 2A Reproductive toxicity Category 2

Specific target organ toxicity, repeated Category 1 (Endocrine system)

exposure

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statementFatal 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.

Precautionary statement

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.

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If swallowed: Immediately call a poison center/doctor. Rinse mouth. If in eyes: Rinse cautiously Response

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.

Store locked up. **Storage**

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

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Fluocinonide	Fluocinolide	356-12-7	100

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.

physiological effects. Endocrine system effects.

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if Eye contact

present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without Ingestion

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

Potent pharmacologically active material. Occupational exposure to small amounts may cause

respiratory medical device.

Most important

symptoms/effects, acute and

delayed

Indication of immediate medical attention and special

treatment needed **General information** 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.

5. Fire-fighting measures

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

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment

and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

equipment/instructions

Specific methods General fire hazards 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.

No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

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.

Material name: Fluocinonide USP SDS US **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. 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

Exposure limit values

Industrial Use

Material	Туре	Value	
Fluocinonide (CAS	TWA	10 micrograms/m3	
356-12-7)			

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.

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 stateSolid.FormPowder.ColorWhite. Cream.

Odor Slight.

Odor threshold Not available. PH Not available.

Melting point/freezing point 586.4 - 591.8 °F (308 - 311 °C)

Initial boiling point and boiling

range

Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

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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 (77 °F (25 °C))

Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Practically insoluble.

Solubility (other) Methyl alcohol: Slightly soluble.

Dioxan: Slightly soluble.
Acetone: Sparingly soluble.
Chloroform: Sparingly soluble.
Ether: Very slightly soluble.
Ethanol: Slightly soluble.

Auto-ignition temperature Not available.

Decomposition temperature Not available.

Viscosity Not available.

Other information

Chemical family Corticosteroid.

Molecular formula C26H32F2O7

Molecular weight 494.52

10. Stability and reactivity

ReactivityThe 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 avoidContact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. F-.

11. Toxicological information

Information on likely routes of exposure

InhalationKnowledge about health hazard is incomplete.Skin contactKnowledge about health hazard is incomplete.

Eye contact Causes serious eye irritation.

Ingestion Fatal if swallowed.

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 Fatal if swallowed.

Product Species Test Results

Fluocinonide (CAS 356-12-7)

Oral

LD50 Mouse > 6000 mg/kg

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Product Species Test Results

Solid

LD50 Rat 14 mg/kg

Skin corrosion/irritation Based on available data, the classification criteria are not met.

Serious eye damage/eye

irritation

Causes serious eye irritation.

Local effects

Eve

Result: Moderate irritation.

Species: Rabbit

Skin (0.5 gel, up to 0.7 g/kg, 3x day/3 weeks)

Result: Non-irritating. Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete.

Skin sensitization Based on available data, the classification criteria are not met.

Sensitization test Result: Negative. Species: Guinea pig

Knowledge about mutagenicity is incomplete. Germ cell mutagenicity

> Mutagenicity Ames test

Result: Negative.

In vitro chromosomal aberration assay (human lymphocytes)

Result: Negative.

In vivo mouse micronucleus assay Result: Positive for clastogenic potential.

Carcinogenicity Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Suspected of damaging fertility or the unborn child. Reproductive toxicity

> 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.

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 No ecotoxicity data noted for the ingredient(s).

Persistence and degradability No data is available on the degradability of this substance.

Bioaccumulative potential No data available. Mobility in soil No data available.

No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation Other adverse effects

potential, endocrine disruption, global warming potential) are expected from this component.

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13. Disposal considerations

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

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

UN number UN2811

UN proper shipping name Transport hazard class(es) Toxic solids, organic, n.o.s. (Fluocinonide)

Class 6.1 Subsidiary risk Ш Packing group Packaging exceptions 153 Packaging non bulk 212 Packaging bulk 242

IATA

UN number UN2811

UN proper shipping name

Transport hazard class(es)

Class 6.1 Subsidiary risk Packing group Ш

Other information

Passenger and cargo

aircraft

Cargo aircraft only

Transport in bulk according to Annex II of MARPOL 73/78 and

the IBC Code

Toxic solid, organic, n.o.s. (Fluocinonide)

Allowed with restrictions.

Allowed with restrictions.

Not applicable.

DOT; IATA



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.

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.

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SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

Yes

chemical

Classified hazard Acute toxicity (any route of exposure)
categories Serious eye damage or eye irritation

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

Not regulated.

(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.

International Inventories

Yes
Yes
No
No
Yes
No
Yes
No

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

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

 Issue date
 09-08-2010

 Revision date
 12-28-2020

Version # 03

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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).

Disclaimer

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