SAFETY DATA SHEET

1. Identification

Product identifier: Triamcinolone Acetonide Related Compound C

Other means of identification

Catalog number: 1679037

Chemical name: 9-Fluoro-11,21,21-trihydroxy-16,17-{[(1-methylethylidene)bis(oxy)]-(11beta,16alpha)-pregna-1,4-diene-3,20-dione

Recommended use: Specified quality tests and assay use only.

Recommended restrictions: Not 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 & Canada 1-800-424-9300

CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards: Not classified.

Health hazards:

Reproductive toxicity: Category 2

Specific target organ toxicity, repeated exposure: Category 2 (endocrine system)

Environmental hazards: Not classified.

OSHA defined hazards: Not classified.

Label elements

Signal word: Warning

Hazard statement: Suspected of damaging fertility or the unborn child. May cause 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. Wear protective gloves/protective clothing/eye protection/face protection.

Response: 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.

Hazard(s) not otherwise classified (HNOC): Not classified.

Other hazards which do not result in classification: None known.

3. Composition/information on ingredients

Substance
4. First-aid measures

**Inhalation**
Move to fresh air. 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.

**Most important symptoms/effects, acute and delayed**
Prolonged exposure may cause chronic effects.

**Indication of immediate medical attention and special treatment needed**
Provide general supportive measures and treat symptomatically.

**General information**
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

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

**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**
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.

**Specific methods**
Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

**Personal precautions, protective equipment and emergency procedures**
Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.

**Methods and materials for containment and cleaning up**
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

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. Use of a designated area is recommended for handling of potent materials.

**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

**Biological limit values**
No biological exposure limits noted for the ingredient(s).

**Exposure guidelines**
No exposure standards allocated.

**Appropriate engineering controls**
Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.
Individual protection measures, such as personal protective equipment

Eye/face protection
Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin protection

Hand protection
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy. To reduce the risk of contamination of skin and surfaces, wear two pairs of gloves. Remove the outer gloves after handling and cleanup of the material, and remove the inner gloves only after removing other personal protective equipment.

Other
For handling of laboratory scale quantities, a disposable lab coat or isolation gown over street clothes is recommended. Where significant quantities are handled, work clothing and booties may be necessary to prevent take-home contamination.

Respiratory protection
Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

General hygiene considerations
Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance
White powder.

Physical state
Solid.

Form
Powder.

Odor
Not available.

Odor threshold
Not available.

pH
Not available.

Melting point/freezing point
Not available.

Initial boiling point and boiling range
Not available.

Flash point
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
Not applicable.

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
Not available.

Vapor density
Not available.

Relative density
Not available.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other information

Molecular formula
C24H31FO7

Molecular weight
450.5

10. Stability and reactivity

Reactivity
Not available.

Chemical stability
Material is stable under normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
None known.

Incompatible materials
None known.

Hazardous decomposition products
F- Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.
11. Toxicological information

Information on likely routes of exposure

**Ingestion**  
Due to lack of data the classification is not possible.

**Inhalation**  
Due to lack of data the classification is not possible.

**Skin contact**  
Due to lack of data the classification is not possible.

**Eye contact**  
Due to lack of data the classification is not possible.

**Symptoms related to the physical, chemical, and toxicological characteristics**


It is not known if this material causes the same effects.

**Delayed and immediate effects of exposure**


It is not known if this material causes the same effects.

**Cross sensitivity**  
Persons sensitive to one corticosteroid may be sensitive to this material also.

**Medical conditions aggravated by exposure**


It is not known if this material causes the same effects.

**Acute toxicity**  
Due to lack of data the classification is not possible.

**Skin corrosion/irritation**  
Due to lack of data the classification is not possible.

**Serious eye damage/eye irritation**  
Due to lack of data the classification is not possible.

**Respiratory or skin sensitization**

**Respiratory sensitization**  
Due to lack of data the classification is not possible.

**Skin sensitization**  
Due to lack of data the classification is not possible.

**Germ cell mutagenicity**  
Due to lack of data the classification is not possible.

**Carcinogenicity**  
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.

**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.

**Specific target organ toxicity - single exposure**  
Based on available data, the classification criteria are not met.

**Specific target organ toxicity - repeated exposure**  
May cause damage to organs (endocrine system) through prolonged or repeated exposure.

**Aspiration hazard**  
Based on available data, the classification criteria are not met.

12. Ecological information

**Ecotoxicity**

No ecotoxicity data noted for the ingredient(s).

**Persistence and degradability**

No data is available on the degradability of this product.

**Bioaccumulative potential**

Not available.

**Mobility in soil**

Not available.

**Other adverse effects**

Not available.

13. Disposal considerations

**Disposal instructions**

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.

**Local disposal regulations**

Not available.

**Hazardous waste code**

Not regulated.

**Waste from residues / unused products**

Dispose of in accordance with local regulations. 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
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.

14. Transport information

DOT
Not regulated as dangerous goods.

IATA
Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not available.

15. Regulatory information

US federal regulations
CERCLA/SARA Hazardous Substances - Not applicable.

One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - No
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
Not regulated.

US state regulations
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.

US. California Proposition 65
Not Listed.

International Inventories

Country(s) or region
Inventory name
On inventory (yes/no)*
Australia
Australian Inventory of Chemical Substances (AICS)
No
Canada
Domestic Substances List (DSL)
No
Canada
Non-Domestic Substances List (NDSL)
No
China
Inventory of Existing Chemical Substances in China (IECSC)
No
Europe
European Inventory of Existing Commercial Chemical Substances (EINECS)
No
Europe
European List of Notified Chemical Substances (ELINCS)
No
Japan
Inventory of Existing and New Chemical Substances (ENCS)
No
Korea
Existing Chemicals List (ECL)
No
New Zealand
New Zealand Inventory
No
Philippines
Philippine Inventory of Chemicals and Chemical Substances (PICCS)
No
United States & Puerto Rico
Toxic Substances Control Act (TSCA) Inventory
No

* A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s).
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).

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

Issue date
09-15-2015

Version #
01

Further information
Not available.
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