

Safety Data Sheet

Fluocinolone Acetonide Topical Solution

SECTION 1: IDENTIFICATION

Product identifier	Fluocinolone Acetonide	
Other means of identification		
Catalog number	1275009	
Chemical name	Pregna-1,4-diene-3,20-dione,6,9-difluoro-11,21-dihydroxy-16,17-[(1-methylethylidene)bis(oxy)]-,(6alpha,11beta,16alpha)-	
Synonym(s)	Fluocinolone 16,17-Acetonide	
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		
Company name	GAVIS Pharmaceuticals, LLC	
Address	400 Campus Drive Somerset NJ 08873	
Telephone	908-603-6080	
Website	www.gavispharma.com	
Emergency phone number	In case of emergency call	911
	US Posion Control Center	1-800-222-1222

SECTION 2: HAZARDS IDENTIFICATION

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 4
	Reproductive toxicity	Category 2
	Specific target organ toxicity, repeated exposure	Category 1 (endocrine system)
OSHA hazard(s)	Not classified.	
Label elements		



Signal word	Danger
Hazard statement	Harmful if swallowed. 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. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. 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.



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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Fluocinolone Acetonide	Fluocinolone 16,17-Acetonide	67-73-2	100

SECTION 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	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth.
Most important symptoms/effects, acute and delayed	Fluid and electrolyte disturbances. Mood or mental changes.
Indication of immediate medical attention and special treatment needed	Treatment of corticosteroid overdose should be symptomatic and supportive and may include the following: Toxicity is low after acute ingestion. Gastrointestinal decontamination is generally not necessary. (Poisindex)
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.

SECTION 5: FIRE-FIGHTING MEASURES

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
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.

SECTION 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.
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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.

SECTION 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.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure limit values

Industrial Use

Material

Type

Value

Fluocinolone Acetonide
(CAS 67-73-2)

TWA

0.04
Micrograms/m³

Biological limit values

No biological exposure limits noted for the ingredient(s).

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. Avoid any open handling of this material, particularly for grinding, crushing, weighing, or other dust-generating or aerosol-generating procedures. Use a laboratory fume hood, vented enclosure, glovebox, or other effective containment.

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.



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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).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White or practically white crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	509 - 525.2 °F (265 - 274 °C) (with decomposition)
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	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Insoluble.
Partition coefficient (n-octanol/water)	2.48
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Corticosteroid.
Molecular formula	C ₂₄ H ₃₀ F ₂ O ₆
Molecular weight	452.5 g/mol
Solubility (other)	Soluble in acetone, in methanol, and in ethanol; slightly soluble in ether and in chloroform; practically insoluble in hexane; sparingly soluble in dichloromethane.

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SECTION 10: STABILITY AND REACTIVITY

Reactivity	No reactivity hazards known.
Chemical	Stability Stable at normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	None known.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition Products	F-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Ingestion	Harmful if swallowed.
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	Based on available data, the classification criteria are not met.

Symptoms related to the physical, chemical, and toxicological characteristics
 Corticosteroids: Nausea. Vomiting. Headache. Acne. Increased hair growth. Lightheadedness. Weakness. Increased sweating. Eye pain. Vision changes. Mental or behavioral changes. Swelling. Numbness. Infection. Delayed wound healing. Thinning skin. Bruising. Purple lines on skin. Bone fractures. Back pain. Joint pain or stiffness. Increased appetite. Redistribution of body fat. Menstrual irregularities. Impotence. Tremors.

Delayed and immediate effects of exposure
 Corticosteroids: Fluid and electrolyte imbalance. Cushing's syndrome. Adrenal suppression. Immune system depression. Withdrawal.

Cross sensitivity
 Persons sensitive to other corticosteroids may also be sensitive to this material.

Medical conditions aggravated by exposure
 Corticosteroids: Heart disease. High blood pressure. Diabetes. Epilepsy. Glaucoma. Hypothyroidism. Osteoporosis. Peptic ulcer. Systemic fungal infection. Mental disorders. Impaired liver or kidney function.

Acute toxicity
 Harmful if swallowed.

Product	Species	Test Results
Fluocinolone Acetonide (CAS 67-73-2)		
Acute		
<i>Oral</i>		
LD50	Rat	400- 1200 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Based on available data, the classification criteria are not met.	
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. Data from germ cell mutagenicity tests were not found.	



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Mutagenicity

Ames test

Result: Negative.

In vivo mouse bone marrow micronucleus test

Result: Negative.

Mouse lymphoma TK assay

Result: Negative.

Syrian hamster embryo cell transformation assay, viral enhanced

Result: Positive.

Carcinogenicity

Due to lack of data the classification is not possible.

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.

Reproductivity

0.05 mg/kg/day Reproductivity and development study in rabbits and rats, administered subcutaneously during gestation.

Result: Maternal toxicity, fetal death and teratogenicity.

0.125 mg/kg Reproductivity and development study in rabbits, administered subcutaneously during gestation.

Result: Maternal toxicity and fetal death.

Specific target organ toxicity - single exposure

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

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.

SECTION 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.

SECTION 13: DISPOSAL CONSIDERATIONS

Disposal instructions for hazardous waste.

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 available.



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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.

SECTION 14: TRANSPORT INFORMATION

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

SECTION 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 - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations Not regulated.

Safe Drinking Water Act (SDWA)

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.

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International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
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)

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Issue date	11/1/2015
Revision date	10/27/2015
Version #	01
Further information	Not available.
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