

SAFETY DATA SHEET



1. IDENTIFICATION OF THE SUBSTANCE AND COMPANY

Product Name **ProCure Signature- Fluticasone Propionate Nasal Spray, 50 mcg**
Product Code **PCOTC106**
Company Name **Twin Med LLC.**
(Supplier of SDS)
Address **11333 Greenstone Ave. • Santa Fe Springs, CA 90670**
Contact **1-877-TwinMed (894-6633)**
Emergency **1-877-TwinMed (894-6633)**
Relevant Use **Used as an Antifungal cream. Relieves itching, burning, cracking, & scaling.**

2. HAZARD IDENTIFICATION

Classification of the substance or mixture : As per 29 CFR 1910.1200 (b)(6) and according to Article 1, item 5 a) of CLP Regulation (EC) 1272/2008, medicinal products (drugs) when it is in the solid, final form for direct administration to the patient or are packaged by the manufacturer for sale to consumers in a retail establishment are exempt from the requirements of classification, labels and SDS's.

GHS label elements : Exempt from requirements.

Hazards not otherwise classified : Exempt from requirements.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Name	CAS #	% (w/w)
Fluticasone propionate	80474-14-2	0-1
Specific chemical identity and/or percentage of composition has been withheld as a trade secret.		

Chemical name : Not applicable.
Synonyms : Not available.
Chemical family : Synthetic corticosteroid.
Molecular weight : Not applicable.
Chemical formula : Not applicable.

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4. FIRST AID MEASURES

- Eye contact** : Flush with copious quantities of water. If irritation persists, obtain medical advice.
- Skin contact** : Flush with copious amounts of water. Seek medical attention if irritation persist.
- Inhalation** : Remove from exposure. Persons developing serious hypersensitivity reactions must receive immediate medical attention. If not breathing give artificial respiration. If breathing is difficult give oxygen.
- Ingestion** : Never give anything by mouth if victim is losing consciousness, or is unconscious or convulsing. Rinse mouth thoroughly with water. If breathing is difficult, give oxygen. If breathing has stopped, trained personnel should begin artificial respiration, or if the heart has stopped, cardiopulmonary resuscitation (CPR) immediately. Seek medical attention.
- Potential acute and delayed health effects** : Refer to Sec. 11

5. FIRE FIGHTING MEASURES

- Specific hazard arising from the chemical** : During fire, gases hazardous to health may be formed.
- Suitable extinguishing media and special protective equipment for firefighters** : Extinguisher media: Use extinguishing media suitable for surrounding materials.
Special fire fighting procedures: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing.

6. ACCIDENTAL RELEASE MEASURES

- Methods and materials for containment and cleaning up** : Assess hazard levels. Contain and clean up spillage and place into an appropriate labeled waste disposal container. Avoid generating dust or aerosols. Wash spill surface using appropriate cleaning solutions. Should clothing be contaminated, wash before reuse.
- Protective equipment and personal precautions** : Keep unnecessary personnel away. Wear appropriate personal protective equipment.

7. HANDLING AND STORAGE

- Precautions for safe handling** : Avoid contact with eyes.
- Conditions for safe storage** : Store as directed by product packaging.

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls	: General room ventilation. Local exhaust ventilation and/or process enclosures where applicable. Fume hoods where available. Additional respiratory protection is not required when working in a fume hood.
Personal Protection	: Skin: Lab coat Respiratory: Under normal work conditions, the use of respiratory protective equipment is not expected to be required. If the physical state of the finished product is altered by crushing, grinding or breakage or for spill cleaning, an approved NIOSH respirator may be required. Hand: Nitrile gloves Eye: Safety glasses
Occupational exposure limits	: Not established.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state and appearance	: Milky suspension.	Odor	: Not available.
pH	: Not available.	Odor threshold	: Not available.
Melting point/Freezing point	: Not available.	Conditions of instability	: No additional remark.
Boiling point	: Not available.	Decomposition temperature	: Not available.
Volatility	: Not available.	Partition Coefficient:	: Not available.
Specific gravity	: Not available.	Viscosity	: Not available.
Evaporation rate	: Not available.	Flash points	: Not available.
Vapor density	: Not available.	Flammable limits	: Not available.
Relative density	: Not available.	Autoignition temperature	: Not applicable.
Vapor pressure	: Not applicable.		
Flammability	: Not applicable.		
Solubility	: Not available.		

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10. STABILITY AND REACTIVITY

Reactivity	: Not available.
Chemical Stability	: The product is stable.
Possibility of hazardous reactions	: Not available.
Hazardous decomp. products	: When heated to decomposition material emits toxic fumes.
Incompatible materials/ Conditions to avoid	: Not available

11. TOXICOLOGICAL INFORMATION

Information on the likely routes of exposure : Ingestion. Inhalation. Eye contact.

Toxicity data : Fluticasone propionate:
RTECS: BV7980000
LD50: >2000 mg/kg (oral-rat)
LC: >40.770 mg/m³/1Hour (inhalation-rat)

Delayed and immediate effects and also chronic effects from short and long term exposure : Target Organs: Causes damage to organs (endocrine system) through prolonged or repeated exposure.

Carcinogenicity: Not listed as carcinogen by IARC, NTP, ACGIH, or OSHA. No evidence of carcinogenicity was found in two 18-month studies in mice receiving fluticasone propionate topically (as an 0.05% ointment), orally, or by inhalation at 57 micrograms/kg for 104 weeks.

Reproductive Toxicity: No evidence of impairment of fertility was observed in reproductive studies conducted in male and female rats at subcutaneous doses up to 50 mcg/kg (approximately 2 times the maximum recommended daily intranasal dose in adults on a mcg/m² basis). Prostate weight was significantly reduced at a subcutaneous dose of 50 mcg/kg.

Teratogenicity: Pregnancy Category C. Studies in mice and rats given fluticasone propionate subcutaneously in doses of 45 micrograms/kg and 100 micrograms/kg, respectively, showed fetal toxicity characteristic of potent glucocorticoids, including embryonic growth retardation, abdominal wall defects, cleft palate, and retarded cranial ossification. In rabbits, fetal weight reduction and cleft palate were observed following subcutaneous doses of 4 micrograms/kg. However, following oral administration of fluticasone to rabbits in doses of 300 micrograms/kg, no maternal effects or increased incidence of fetal defects were shown. 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.

Mutagenicity: Fluticasone propionate revealed no evidence of mutagenic potential based on the results of five in vitro genotoxicity tests (Ames assay, E. coli fluctuation test, S. cerevisiae gene conversion test, Chinese hamster ovary cell chromosome aberration assay, and human lymphocyte chromosome aberration assay) and one in vivo genotoxicity test (mouse micronucleus assay).

Remark
No additional remark.

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Symptoms related to the physical, chemical and toxicological characteristics : The incidence of adverse effects from the therapeutic use of corticosteroids increases with dose and duration of exposure; effects are rare with administration of less than three weeks. Glucocorticoid effects may include bone fractures, back pain, joint pain or stiffness, weakness, high blood pressure, 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, and mental or behavioral changes. Possible allergic reaction to material if inhaled, ingested, or in contact with skin.

12. ECOLOGICAL INFORMATION

Ecotoxicity : Fluticasone propionate:
Toxicity (Daphnia): EC₅₀: 0.55 mg/l at 48 hours (no effect at 0.19 µg/l)
Persistence and degradability:
- Aerobic biodegradation (water): Not readily biodegradable (<45% in 28 days).
- Aerobic biodegradation (soil): Readily biodegradable in sandy loam and silty clay >50%
- Hydrolysis rate: Does not hydrolyze (half life greater than one year at 25°C)
Bioaccumulative potential:
Fluticasone propionate is not readily biodegradable in soils other than clay and is unlikely to bioaccumulate. It is potentially toxic to receptors in terrestrial environment at levels greater than 1000 mg/l.
Mobility in soil:
- Very strong adsorption 25%
- Sub acute toxicity in earthworms: >1000 mg/kg
- Activated sludge respiration inhibition test: >1000 mg/l

Persistence and degradability : Not available.

Bioaccumulative potential : Not available.

Mobility in soil : Not available.

Other adverse effects : Not available.

13. DISPOSAL CONSIDERATIONS

Waste Disposal : Follow all appropriate safe work procedures and local regulations for disposal. Use only licensed disposal and waste hauling companies.

14. TRANSPORT INFORMATION

Regulatory information	UN number	Proper shipping name	Class	Packing group	Additional information
TDG- road Canada/U.S.			Not regulated.		
ICAO/IATA			Not regulated.		
IMDG Class			Not regulated.		

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15. REGULATORY INFORMATION

Canada Regulations : Covered by Food & Drug Act and therefore not regulated under WHMIS
Not on the DSL list.

Other Regulations : Not available.

16. OTHER INFORMATION

References : RTECS Database
PDR Electronic Library
Apotex Product Monograph
U. S. Pharmacopeia

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