



SAFETY DATA SHEET
for
XHANCE (fluticasone propionate) nasal spray, for intranasal use, 93mcg

1. Identification

Product Name: XHANCE
Synonyms: S-(fluoromethyl)6 α ,9-difluoro-11 β -17-dihydroxy-16 α -methyl-3-oxoandrosta-1,4-diene-17 β -carbothioate, 17-propionate
CAS Number: Mixture
Product Use: XHANCE is a corticosteroid indicated for the treatment of nasal polyps in patients 18 years old and older.
Manufacturer/Supplier: OptiNose US, Inc
Address: 1020 Stony Hill Road, Ste. 300, Yardley, PA 19067
Emergency Contact: 1-833-678-6673

General Use: This SDS is intended for people that could handle this product in an occupational setting such as but not limited to: Transporters, wholesalers, distributors, medical providers/staff and pharmacist/staff. This SDS is not intended for the patient or consumer of this product.

2. Hazards Identification

GHS Classification:

Health	Environmental	Physical
Acute Toxicity, Oral: Not classified	Not classified	Not classified

GHS Label:

Symbols: None	
Signal word: None	
<u>Hazard Statements</u>	<u>Precautionary Statements</u>
No hazard statements apply	No precautionary statements apply

3. Composition / Information on Ingredients

The manufacturer lists no ingredients as hazardous according to OSHA 29 CFR 1910.1200.

Component	C.A.S Number	Amount (%)
Fluticasone propionate	80474-14-2	< 1.0

Dextrose, anhydrous	50-99-7	5.0
Microcrystalline cellulose	9004-34-6	1.0
Purified water	7732-18-5	Qs
All other ingredients	-	< 1.0

4. First Aid Measures

- Eye:** Rinse with water. Get medical attention if irritation develops and persists.
- Skin:** Wash off with soap and water. Get medical attention if irritation develops and persists.
- Inhalation:** Move to fresh air. Call a physician if symptoms develop or persist.
- Ingestion:** Rinse mouth. Get medical attention if symptoms occur. If ingestion of a large amount does occur, call a poison control center immediately.

5. Fire Fighting Measures

- Suitable extinguishing media:** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).
- Unsuitable extinguishing media:** Do not use water jet as an extinguisher, as this will spread the fire.
- Specific hazards arising from the chemical:** During fire, gases hazardous to health may be formed.
- Special protective equipment and precautions for firefighters:** Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
- Fire fighting equipment/instructions:** Use water spray to cool unopened containers.
- Specific methods:** Use standard firefighting procedures and consider the hazards of other involved materials.
- General fire hazards:** 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 (See Section 8).

Methods and materials for

containment and cleaning up: Wipe up with absorbent material. Following product recovery, flush area with water. Incineration of waste at an approved USEPA incinerator is recommended.

Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

7. Handling and Storage

General Handling

When handling, use appropriate personal protective equipment (see Section 8). Avoid contact with eyes, skin, and clothing. Wash hands thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste-water and waste disposal measures to prevent occupational exposure or environmental releases.

Storage

Store at room temperature (between 15°C and 25°C; 59°F and 77°F), excursions permitted from 15°C to 30°C (59°F to 86°F). Avoid exposure to extreme heat, cold or light.

8. Exposure Controls / Personal Protection

Exposure Limits

Component Name	WEEL (TWA)	OSHA PEL (TWA)	ACGIH TLV (TWA)	NIOSH REL
Microcrystalline cellulose	N.E.	15 mg/m ³ 5 mg/m ³	10 mg/m ³	10 mg/m ³ 5 mg/m ³

Engineering Controls: In a manufacturing setting, local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. If user operations generate dust, fume or mist, use ventilation to keep exposure to airborne contaminants below the exposure limit.

Personal Protective Equipment (PPE)

In a manufacturing setting, the following personal protective equipment requirements apply:

Eye Protection: Wear appropriate chemical safety goggles, safety glasses or face shield as described by OSHA's eye and face protection regulations in 29 CFR 1910.133. Have eyewash stations available where eye contact can occur.

Skin Protection: Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including the use of an apron, face shield, boots, or full body protection. A safety shower should be located in the work area.

Respiratory Protection: If exposure limits are exceeded, approved respiratory protection should be worn. Seek professional assistance for proper selection of respiratory protection.

9. Physical and Chemical Properties

Flash Point: Not available

Autoignition Temperature:

Not available

Boiling Point: Not available

Melting Point: Not available

Vapor Pressure: Not available

Vapor Density: Not available

% Solubility in Water:

Not available

Pour Point: Not available

Molecular Formula: Mixture

Odor/Appearance: White to off-white liquid suspension

Lower Flammability Limit: Not available

Upper Flammability Limit:

Not available

Specific Gravity: Not available

% Volatile: Not available

Evaporation Rate (Water=1): Not available

Viscosity: Not available

Octanol/Water Partition Coefficient:

Not available

pH: Not available

Molecular Weight: Mixture

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.

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

Conditions to avoid: Contact with incompatible materials. Exposure to light.

Incompatible materials: Strong oxidizing agents.

Hazardous decomposition Products: No hazardous decomposition products are known.

11. Toxicology Information

Signs and Symptoms of Overexposure: Headache, pharyngitis, epistaxis, nasal burning/irritation, nausea, vomiting, asthma symptoms and cough.

Eye Contact: May be irritating to eyes. Avoid contact with eyes.

Skin Contact: Not expected to be hazardous in its final form. Avoid contact with skin.

Inhalation: Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Ingestion: May be harmful if swallowed in large quantities. May cause irritation and malaise.

Reproductive Effects: Fluticasone propionate is classified as FDA Pregnancy Category C, meaning that animal reproduction studies have shown an adverse effect on the fetus and there are no adequate and well-controlled studies in humans. It is not known whether this product is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when administering to a nursing woman.

Chronic Effects: Fluticasone propionate showed no signs of carcinogenicity in the standard battery of tests.

Genotoxic Effects: Fluticasone propionate showed no signs of mutagenicity in the standard battery of genotoxicity tests.

Acute Toxicity Values:

LD₅₀ (rat, oral) > 2,000 mg/kg (for Fluticasone propionate)

LD₅₀ (rat, oral) = 25,800 mg/kg (for Dextrose)

LD₅₀ (rat, oral) > 5,000 mg/kg (for Microcrystalline cellulose)

LD₅₀ (rat, oral) = 2,000 mg/kg (for Edetate disodium)

LD₅₀ (rat, oral) = 25,000 mg/kg (for Polysorbate 80)

LD₅₀ (rat, oral) = 240 mg/kg (for Benzalkonium chloride)

12. Ecological Information

The product is not classified as environmentally hazardous.

13. Disposal Considerations

Disposal instructions: Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

Local disposal regulations: Dispose in accordance with all applicable regulations.

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. Transportation Information

Based on available data this product has been determined non-hazardous according to USDOT/IATA criteria.

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

15. Regulatory Information

U. S. Federal Regulations: This product is not regulated by OSHA under the Hazard Communication Standard (29 CFR 1910.1200).

Toxic Substance Control Act (TSCA): Dextrose and Microcrystalline cellulose are included on the TSCA inventory.

Clean Water Act (CWA): There are no ingredients in this mixture listed in the CWA.

Clean Air Act (CAA): There are no ingredients in this mixture listed under the CAA.

Superfund Amendments and Reauthorization Act (SARA) Title III Information: There are no ingredients in this mixture listed under SARA.

California: This product contains one chemical(s) known to the State of California to cause cancer, birth defects or reproductive harm: Fluticasone propionate.

Canadian Environmental Protection Act: Benzalkonium chloride, Dextrose, Edetate disodium, Microcrystalline cellulose, Polysorbate 80, and Water are listed on the Canadian Domestic Substances list (DSL).

European Inventory of Existing Chemicals (EINECS): Benzalkonium chloride, Dextrose, Microcrystalline cellulose, Polysorbate 80, and Water are included on the European Inventory of Existing Commercial Chemical Substances.

EU Classification: European labeling in accordance with EC directives.

16. Other Information

National Fire Protection Association (NFPA) Warnings

Health: 0 Flammability: 0 Reactivity: 0 Other: 0

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