



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

1. Identification

Product Name: XHANCE
Synonyms: S-(fluoromethyl)6 α ,9-difluoro-11 β -17-dihydroxy-16 α -methyl-3-oxoandrost-1,4-diene-17 β -carbothioate, 17-propionate
CAS Number: Mixture
Product Use: XHANCE is a corticosteroid indicated for the treatment of chronic rhinosinusitis with or without nasal polyps.
Manufacturer/Supplier: OptiNose US, Inc.
Address: 777 Township Line Road, Ste. 300, Yardley, PA 19067
Emergency Contact: 1-833-678-6673

General Use: This Safety Data Sheet (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

Safety Data Sheet prepared in accordance with OSHA's Hazard Communication Standard (29 CFR 1910.1200); and the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).

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> No hazard statements apply	<u>Precautionary Statements</u> No precautionary statements apply

3. Composition / Information on Ingredients

Component	C.A.S Number	Amount (%)
Fluticasone propionate	80474-14-2	0.09
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 US EPA 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	Occupational Exposure Limit (OEL)	OSHA PEL (TWA)	ACGIH TLV (TWA)	NIOSH REL
Fluticasone propionate (reported for fluticasone furoate by GlaxoSmithKline)	2 µg/m ³ 8-hour time-weighted average (TWA)	Not available	Not available	Not available
Microcrystalline cellulose	Not available	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

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: This product is nonreactive under normal conditions of use, storage, and transport.

Chemical stability: This product 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 Exposure: Headache, nasopharyngitis, bronchitis, upper respiratory tract infection, epistaxis, nasal ulceration, and dyspnea.

Information on toxicological effects: Route of entry – May be absorbed by inhalation, ingestion, and skin and eye contact.

Acute Toxicity:

Compound	Type	Route	Species	Dose
Fluticasone propionate	LD ₅₀	Oral	Rat	> 2,000 mg/kg
Dextrose	LD ₅₀	Oral	Rat	25,800 mg/kg
Microcrystalline cellulose	LD ₅₀	Oral	Rat	> 5,000 mg/kg
Edetate disodium	LD ₅₀	Oral	Rat	2,000 mg/kg
Polysorbate 80	LD ₅₀	Oral	Rat	25,000 mg/kg
Benzalkonium chloride	LD ₅₀	Oral	Rat	240 mg/kg

Skin Corrosion/Irritation: No data available.

Serious Eye Damage/Irritation: No data available.

Respiratory or Skin Sensitization: No data available.

Germ Cell Mutagenicity: Fluticasone propionate showed no signs of mutagenicity in the standard battery of genotoxicity tests.

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

Reproductive/Developmental Effects: Fluticasone propionate showed possible reproductive and developmental effects. There is no information available on the presence of fluticasone furoate in human milk, the effects on the breastfed child, or the effects on

milk production. Low concentrations of other inhaled corticosteroids have been detected in human milk.

Specific Target Organ Toxicity (STOT) – Single Exposure: No data available.

Specific Target Organ Toxicity (STOT) – Repeated Exposure: No data available.

Aspiration Hazard: No data available.

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 nonhazardous 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, microcrystalline cellulose, and water 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.

European Inventory of Existing Chemicals (EINECS): Dextrose, microcrystalline cellulose, 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: 1 Flammability: 0 Reactivity: 0 Other: 0

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