

## SAFETY DATA SHEET



GlaxoSmithKline

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

<b>Material</b>	<b>FLOVENT HFA</b>
<b>Synonym(s)</b>	FLOVENT HFA INHALATION AEROSOL * FLIXOTIDE AEROSOL 134A * FLIXOTIDE INHALER CFC FREE * FLIXOTIDE EVOHALER * ATEMUR MITE INHALER HFA 134A 50 MCG * ATEMUR MITE INHALER HFA 134A 125 MCG * ATEMUR FORTE INHALER HFA 134A 250 MCG * AXOTIDE INHALER HFA * BREXOVENT INHALER HFA * FLUTIDE MITE 50 DOSIER-AEROSOL * FLUTIDE 125 DOSIER-AEROSOL FCKW-FREI * FLUTIDE FORTE 250 DOSIER-AEROSOL FCKW-FREI * FLIXOTAIDE INHALER HFA * NDC NO: 0173-0718-20 * NDC NO: 0173-0719-20 * NDC NO: 0173-0720-20 * FLUTICASONE PROPIONATE, FORMULATED PRODUCT
<b>Company Name</b>	<p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK</p> <p>UK General Information: +44-20-8047-5000 Transport Emergency (EU) +44-1865-407333 Medical Emergency +1-612-221-3999, Ext 221 Information and Advice: US number, available 24 hours Multi-language response</p> <p>GlaxoSmithKline, Corporate Environment, Health &amp; Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US</p> <p>US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response</p>

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
1,1,1,2-TETRAFLUOROETHANE	811-97-2	99.66 to 99.91	
FLUTICASONE PROPIONATE	80474-14-2	0.09 to 0.34	

### 3. HAZARDS IDENTIFICATION

<b>Fire and Explosion</b>	This product is classified as non-flammable.
<b>Health</b>	Caution - Potent pharmaceutical agent. Health effects information is based on hazards of components. May cause steroid withdrawal rash.
<b>Environment</b>	No information is available about the potential of this product to produce adverse environmental effects.

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## 4. FIRST-AID MEASURES

<b>Ingestion</b>	Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.
<b>Inhalation</b>	Physical form suggests that risk of inhalation exposure is negligible.
<b>Skin Contact</b>	Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.
<b>Eye Contact</b>	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

### NOTES TO HEALTH PROFESSIONALS

<b>Medical Treatment</b>	Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of glucocorticosteroid.
<b>Medical Conditions Caused or Aggravated by Exposure</b>	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
<b>Antidotes</b>	No specific antidotes are recommended.

## 5. FIRE-FIGHTING MEASURES

<b>Fire and Explosion Hazards</b>	Aerosol containers may violently rupture when exposed to the heat of fire. This product is non-flammable.
<b>Special Firefighting Procedures</b>	Since toxic, corrosive or flammable vapours might be evolved from fires involving this material, self contained breathing apparatus and full protective equipment are recommended for firefighters.
<b>Hazardous Combustion Products</b>	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

## 6. ACCIDENTAL RELEASE MEASURES

<b>Personal Precautions</b>	Wear protective clothing and equipment consistent with the degree of hazard. Ventilate area to dispel vapours present. Instruct all personnel not involved in clean-up operations to keep at a designated safe distance.
<b>Environmental Precautions</b>	Do not allow this material to enter surface drainage systems, sewers and poorly ventilated areas.
<b>Decontamination Procedures</b>	No specific decontamination or detoxification procedures have been identified for this product. Water can be used for clean-up and decontamination operations.

## 7. HANDLING AND STORAGE

### HANDLING

**General Requirements** No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

### STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy. Store in a well ventilated area away from heat. The recommended temperature for storage is 15-25 °C.

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<b>INGREDIENT</b>	FLUTICASONE PROPIONATE	
<b>GSK Occupational Hazard Category</b>	4	
<b>GSK Occupational Exposure Limit</b>	3 mcg/m <sup>3</sup> (8 HR TWA)	SKIN

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**ENGINEERING CONTROLS**

**Containment** Consider use of enclosures.

**PERSONAL PROTECTIVE EQUIPMENT**

**Eye Protection** Wear approved safety glasses with side shields if eye contact is possible.

**Other Equipment or Procedures** Wear appropriate clothing to avoid skin contact. Wash hands and arms thoroughly after handling.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

**Packaging** Aerosol container.

**Flash Point** Non-flammable.

## 10. STABILITY AND REACTIVITY

**Stability** This product is expected to be stable.

**Conditions to Avoid** Avoid direct sunlight, conditions that might generate heat and sources of ignition.

## 11. TOXICOLOGY INFORMATION

**Pharmacological Effects** This material is a selective glucocorticoid receptor agonist. Adverse effects of overexposure might include: suppression of adrenal glands; temporary decrease in white blood cell counts; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); increased susceptibility to infection.

**Target Organ Effects** Adverse effects might occur in the following organ(s) following overexposure: adrenal glands; immune system.

**Routes of Exposure**

**Oral Toxicity** Not expected to be toxic following ingestion.

**Skin Effects** Irritation is not expected following direct contact. Pharmacological effects may occur following skin absorption.

**Eye Effects** Minor irritation might occur following direct contact with eyes.

**Sensitisation** Allergic skin reactions might occur following dermal exposure. Assessment based upon information from human exposure.

**Genetic Toxicity** Not expected to be genotoxic under occupational exposure conditions.

**Carcinogenicity** Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

**Reproductive Effects** Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

**Other Adverse Effects** None known for occupational exposure.

## 12. ECOLOGICAL INFORMATION

**Summary** This material contains an active pharmaceutical ingredient that has had limited testing and no adverse environmental effects were observed in the tests conducted. There is insufficient information to determine the scope of the environmental effects this material may cause. Until there is additional testing to determine other potential adverse effects on the environment, appropriate precautions should be taken to limit release of this compound to the environment. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

**ECOTOXICITY****Aquatic**

**Activated Sludge Respiration** This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50: > 1000 mg/l, 3 Hours, Activated sludge

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<b>Daphnid</b>	No toxicity to daphnids was observed for the active pharmaceutical ingredient in this mixture, but the upper range of the test was limited by the low water solubility of this compound. EC50: > 0.55 mg/l, 48 Hours, Daphnia magna, Static test
<b>Terrestrial</b>	
<b>Earthworm</b>	This mixture contains an active pharmaceutical ingredient that is not toxic to earthworms. EC50: > 1000 mg/kg, 28 Days, Eisenia foetida, manure worm,
<b>MOBILITY</b>	
<b>Solubility</b>	This material contains an active pharmaceutical ingredient that for environmental fate predictions has very low solubility in water.
<b>Volatility</b>	This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.
<b>Adsorption</b>	This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. This material contains an active pharmaceutical ingredient that is likely to adsorb to sludges and other biomass. Soil Sediment Sorption (log Koc): 3.41 to 3.83, Measured Sludge Biomass Distribution Coefficient (log Kd): 3.13 to 3.55 Estimated
<b>Partitioning</b>	This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient will not have the tendency to distribute into fats.
<b>PERSISTENCE/DEGRADATION</b>	
<b>Hydrolysis</b>	This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism. Half-Life, Neutral: > 1 Years, Measured
<b>Biodegradation</b>	This material contains an active pharmaceutical ingredient that is not readily biodegradable but is inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and is not expected to persist in the environment. Aerobic - Ready Percent Degradation: < 44 %, 28 days Aerobic - Soil Percent Degradation: 9 to 50 %, 64 days
<b>Bioaccumulation</b>	This material contains an active pharmaceutical ingredient that will not have a tendency to bioaccumulate in the food chain.

### 13. DISPOSAL CONSIDERATIONS

<b>Disposal Recommendations</b>	Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used. The recommended method of disposal is incineration. Wherever possible, disposal should be in an on-site licenced chemical incinerator, if allowed by the incinerator licence or permit. If no on-site incinerator is available, dispose of material in a licenced commercial chemical incinerator.
<b>Regulatory Requirements</b>	Observe all local and national regulations when disposing of this material.

### 14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

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**UN Classification and Labelling**

**Proper Shipping Name** Aerosols, non-flammable  
**UN Number** UN 1950  
**Class/Division** 2.2  
**Subsidiary Risk** None  
**Packing Group** Not applicable  
**Risk Label(s)** Class 2.2 Compressed Gas



**International Air Transport (IATA Requirements)**

**Classification and Labelling** See IATA Special Provision A98.

**International Maritime Transport (IMDG Requirements)**

**Classification and Labelling** See IMDG Special Provision 190.

**US Domestic Transport (DOT Requirements)**

**Classification and Labelling** See US DOT Special Permit 14254.

**European Ground Transport (ADR/RID Requirements)**

**Classification and Labelling** See ADR Special Provision 190.

**15. REGULATORY INFORMATION**

The information included below is an overview of the major regulatory requirements. It should not be considered to be an exhaustive summary. Local regulations should be consulted for additional requirements.

**EU Classification and Labelling**

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

**US OSHA Standard (29 CFR Part 1910.1200)**

**Classification** This dosage form is exempt from the requirements of the OSHA Hazard Communication Standard.

**Other US Regulations**

**TSCA Status** Exempt

**16. OTHER INFORMATION**

**References** GSK Hazard Determination

**SDS Version Number** 13

**SDS Sections Updated**

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY	