

SAFETY DATA SHEET



GlaxoSmithKline

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

Material	VERAMYST NASAL SPRAY
Synonyms	VERAMYST NASAL SPRAY 0.05% W/W * AVAMYS NASAL SPRAY * ALLERMIST NASAL SPRAY * GW685698X INTRANASAL SPRAY * NDC NO: 0173-0753-00 * FLUTICASONE FUROATE, FORMULATED PRODUCT
Company Name	GlaxoSmithKline, Corporate Environment, Health & Safety 980 Great West Road Brentford, Middlesex TW8 9GS UK 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 GlaxoSmithKline, Corporate Environment, Health & Safety One Franklin Plaza, 200 N 16th Street Philadelphia, PA 19102-1225 US US General Information: +1-888-825-5249 Transport Emergency (non EU) +1-703-527-3887 US number, available 24 hours Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
FLUTICASONE FUROATE	397864-44-7	0.05 to 0.2
NON-HAZARDOUS INGREDIENTS	Unassigned	99.8 to 99.95

3. HAZARDS IDENTIFICATION

Fire and Explosion	Expected to be non-combustible.
Health	Handling this product in its final form presents minimal risk from occupational exposure. Health effects information is based on hazards of components.
Environment	No information is available about the potential of this product to produce adverse environmental effects.

4. FIRST-AID MEASURES

Ingestion	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.
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Inhalation	Physical form suggests that risk of inhalation exposure is negligible.
Skin Contact	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.
Eye Contact	Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment	Medical treatment in cases of overexposure should be treated as an overdose of glucocorticosteroid. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.
Medical Conditions Caused or Aggravated by Exposure	None for occupational exposure.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Not expected for the product, although the packaging is combustible.
Extinguishing Media	No special requirements needed.
Special Firefighting Procedures	For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.
Hazardous Combustion Products	Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	Wear protective clothing and equipment consistent with the degree of hazard.
Environmental Precautions	For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.
Clean-up Methods	Collect and place it in a suitable, properly labelled container for recovery or disposal.
Decontamination Procedures	No specific decontamination or detoxification procedures have been identified for this product.

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.
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STORAGE

No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

INGREDIENT	FLUTICASONE FUROATE	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	6 mcg/m ³ (8 HR TWA)	SKIN
Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.	

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour	White.
Physical Form	Suspension.

10. STABILITY AND REACTIVITY

Stability	This product is expected to be stable.
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGICAL INFORMATION

Oral Toxicity	Not expected to be toxic following ingestion.
Inhalation Toxicity	Adverse effects might occur following inhalation.
Skin Effects	Irritation is not expected following direct contact. Recurrent repeated contact with some steroids during manufacture or packing may lead to a rash which appears when exposure to the steroid ceases (e.g. when on holiday) and disappears on re-exposure to the substance.
Eye Effects	Irritation is not expected following direct contact with eyes.
Target Organ Effects	Adverse effects might occur in the following organ(s) following overexposure: immune system; adrenal glands.
Sensitisation	Sensitisation (allergic skin reaction) is not expected.
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.
Pharmacological Effects	This preparation contains ingredient(s) with the following activity: a selective glucocorticoid receptor agonist.
Other Adverse Effects	None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary	This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Specific information on the active pharmaceutical ingredient is provided below. Local regulations and procedures should be consulted prior to environmental release.
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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, Nominal

NOEC: 1000 , 3 Hours, Activated sludge, Nominal

Daphnid 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: > 4.2 mg/l, 48 Hours, Daphnia magna, Static renewal test

NOEL: 4.2 mg/l, 48 Hours, Daphnia magna, Static renewal test

Terrestrial

Earthworm This mixture contains an active pharmaceutical ingredient that is not toxic to earthworms.

Eisenia foetida, manure worm

EC50: > 1000 mg/kg, 14 Days, Measured

NOEL: 1000 mg/kg, 14 Days,

MOBILITY

Solubility This mixture contains an active pharmaceutical ingredient that for environmental fate predictions has very low solubility in water.

Adsorption This mixture contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. This mixture contains an active pharmaceutical ingredient that is likely to adsorb to sludges and other biomass.

Soil Sediment Sorption 3.6, Calculated
(log Koc):

Partitioning This mixture 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.

PERSISTENCE/DEGRADATION

Hydrolysis 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.

Biodegradation This mixture contains an active pharmaceutical ingredient that is not readily nor inherently biodegradable (as defined by 1993 OECD Testing Guidelines) and may persist in the environment. This mixture contains an active pharmaceutical ingredient that slowly undergoes biodegradation in soil.

Aerobic - Inherent

Percent Degradation: 0 %, 28 days, Modified MITI (II) Test., Activated sludge

Aerobic - Soil

Percent Degradation: 2 to 3 %, 64 days, , Soil

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations 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.

Regulatory Requirements Observe all local and national regulations when disposing of this product.

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.

UN Classification and Labelling

Transport Information Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

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 product is classified as hazardous according to the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 15-May-2007

SDS Version Number 4

SDS Sections Updated

Sections

IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF COMPANY

Subsections

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.