SAFETY DATA SHEET

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture	VERAMYST NASAL SPRAY
Registration number	-
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
Issue date	11-November-2013
Version number	06
Revision date	11-November-2013

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses	Medicinal Product This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.
Uses advised against	No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES::
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information Not applicable.

2.3. Other hazards Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
MICROCRYSTALLINE CELLULOSE	1 - < 3	9004-34-6 232-674-9	-	-	
Classification: **DSD:** -					
CLP: -					
FLUTICASONE FUROATE	0.05< 0.2	397864-44-7 -	-	-	
Classification: **DSD:** Repr. Cat. 2;R61, Repr. Cat. 3;R62, Xn;R48/20/21					
CLP: Repr. 1B;H360, Repr. 1B;H360D, Repr. 2;H361, Repr. 2;H361f, STOT RE 2;H373					
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT	< 0.1	139-33-3 2053583	-	-	
Classification: **DSD:** Xi;R36/38, R52/53					
CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319, Aquatic Chronic 3;H412					
POLYOXYETHYLENE (20) SORBITAN MONOLAURATE	< 0.1	9005-64-5 500-018-3	-	-	
Classification: **DSD:** -					
CLP: -					

Other components below reportable levels >95

CLP: Regulation No. 1272/2008.
DSD: Directive 67/548/EEC.
M: M-factor
vPvB: very persistent and very bioaccumulative substance.
PBT: persistent, bioaccumulative and toxic substance.
#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

4.1. Description of first aid measures

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

Skin contact Take off contaminated clothing and wash before reuse. Immediately flush skin with plenty of water. Get medical attention if symptoms occur.

Eye contact Get medical attention if irritation develops and persists. Immediately flush eyes with plenty of water for at least 15 minutes.

Ingestion If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control centre immediately.

4.2. Most important symptoms and effects, both acute and delayed The following adverse effects have been noted with therapeutic use of this material: headache; nosebleed.

4.3. Indication of any immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards No unusual fire or explosion hazards noted.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO_2).

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

Special protective equipment for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Special fire fighting procedures	Move containers from fire area if you can do so without risk.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.
6.2. Environmental precautions	Avoid release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. Avoid discharge into drains, water courses or onto the ground.
6.3. Methods and material for containment and cleaning up	Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Prevent product from entering drains. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills in original containers for re-use.
6.4. Reference to other sections	For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling	Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.
7.2. Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS).
7.3. Specific end use(s)	Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components	Type	Value	Note
ETHYLENEDIAMINE TETRAACETIC ACID, DISODIUM SALT (CAS 139-33-3)	8 HR TWA	3000 mcg/m3	
	OHC	1	
FLUTICASONE FUROATE (CAS 397864-44-7)	8 HR TWA	6 mcg/m3	
	OHC	4	Reproductive hazard
		4	Skin
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	OHC	1	
POLYOXYETHYLENE (20) SORBITAN MONOLAURATE (CAS 9005-64-5)	OHC	1	

UK. EH40 Workplace Exposure Limits (WELs)

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	STEL	20 mg/m3	Inhalable dust.
	TWA	4 mg/m3	Respirable dust.
		10 mg/m3	Inhalable dust.

Recommended monitoring procedures	Follow standard monitoring procedures.
Derived No Effect Level (DNEL)	Not available.
Predicted no effect concentrations (PNECs)	Not available.

8.2. Exposure controls

Appropriate engineering controls	Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

Individual protection measures, such as personal protective equipment

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Not normally needed.
Skin protection	
- Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).
- Other	The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace. Not normally needed.
Respiratory protection	Not available.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
Hygiene measures	Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

Environmental exposure controls

Hazard guidance and control recommendations	Contain spills and prevent releases and observe national regulations on emissions.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state	Liquid.
Form	Liquid.
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.

Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.
9.2. Other information	No relevant additional information available.

SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

Ingestion	Expected to be a low ingestion hazard.
Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Direct contact with eyes may cause temporary irritation.
Symptoms	The following adverse effects have been noted with therapeutic use of this material: headache; nosebleed.

11.1. Information on toxicological effects

Acute toxicity Expected to be a low hazard for usual industrial or commercial handling by trained personnel.

Components	Species	Test results
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT (CAS 139-33-3)		
Acute		
Oral		
LD50	Rat	> 2000 mg/kg
FLUTICASONE FUROATE (CAS 397864-44-7)		
Acute		
Inhalation		
LCLo	Rat	> 0.133 mg/l
Oral		
LD50	Mouse	> 2000 mg/kg
	Rat	> 2000 mg/kg
Subacute		
Inhalation		
LOEL	Dog	<= 10.4 mg/kg/day, 4 weeks, Pharmacological effects
		<= 9 mg/kg/day, 4 weeks, Pharmacological effects
	Rat	<= 6.9 mg/kg/day, 4 weeks, Pharmacological effects
Subchronic		
Inhalation		
LOEL	Dog	<= 13 mcg/kg/day, 39 weeks, Pharmacological effects

Components	Species	Test results
		<= 11 mcg/kg/day, 13 weeks, Pharmacological effects
	Mouse	<= 7 mcg/kg/day, 13 weeks, Pharmacological effects
	Rat	<= 24 mcg/kg/day, 13 weeks, Pharmacological effects
		<= 20 mcg/kg/day, 26 weeks, Pharmacological effects

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

Acute		
Dermal		
LD50	Rabbit	> 2000 mg/kg
Oral		
LD50	Rat	> 2000 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Corrosivity

FLUTICASONE FUROATE
OECD 404
Result: negative
Species: Rabbit

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

FLUTICASONE FUROATE
0.05 % Acute Occular irritation
Result: negative
Species: Rabbit
Read across, Read across, Fluticasone propionate
Result: negative
Species: Rabbit

Respiratory sensitisation None known.

Skin sensitisation This product is not expected to cause skin sensitisation.

Sensitisation

FLUTICASONE FUROATE
Read across, Fluticasone propionate
Result: negative
Species: Guinea pig

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Germ cell mutagenicity

Mutagenicity

FLUTICASONE FUROATE
Ames
Result: negative
Chromosomal aberration assay
Result: negative
Mouse Lymphoma Cell (L5178Y) Assay
Result: negative
Rat Micronucleus Assay
Result: negative

Carcinogenicity

FLUTICASONE FUROATE
ICH S1B - Inhalation
Result: negative
Species: Mouse
ICH S1B - Inhalation
Result: negative
Species: Rat

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

Reproductive toxicity

Reproductivity

FLUTICASONE FUROATE
8 mcg/kg/day Embryofetal Development
Result: NOAEL
Species: Rabbit

Reproductivity

FLUTICASONE FUROATE	91 mcg/kg/day Female Fertility / Early Embryonic Development Result: reduced foetal bodyweight, minor skeletal variations Species: Rat >= 47 mcg/kg/day Embryofetal Development Result: Maternal weight loss/ Foetal abortion Species: Rabbit Male Fertility Result: No effect Species: Rat

Specific target organ toxicity - single exposure None known.

Specific target organ toxicity - repeated exposure Immune system. Adrenal glands. Bone tissue.

Aspiration hazard Not likely, due to the form of the product.

Mixture versus substance information No information available.

Other information Not available.

SECTION 12: Ecological information

12.1. Toxicity No information is available about the potential of this product to produce adverse environmental effects. Contains a substance which causes risk of hazardous effects to the environment. The product contains a substance which may cause long-term adverse effects in the environment.

Components		Species	Test results
ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT (CAS 139-33-3)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	19.6 mg/l, 48 hours, Static test
	NOEC	Water flea (Daphnia magna)	3.7 mg/l, 48 hours, Static test
Fish	EC50	Bluegill sunfish (Adult Lepomis macrochirus)	47.5 mg/l, 96 hours, Static test
		Channel catfish (Adult Ictalurus punctatus)	148.4 mg/l, 96 hours, Static test
		Fathead minnow (Adult Pimephales promelas)	68.8 mg/l, 96 hours, Static test
FLUTICASONE FUROATE (CAS 397864-44-7)			
Acute			
	NOEC	Activated sludge	1000, 3 hours, Nominal
Other	IC50	Activated sludge of a predominantly domestic sewage	> 1000 mg/l, 3 hours, Nominal
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 4.2 mg/l, 48 hours, Static renewal test
	NOEC	Water flea (Daphnia magna)	4.2 mg/l, 48 hours, Static renewal test
Terrestrial			
Acute			
Earthworm	EC50	Manure worm (Eisenia foetida)	> 1000 mg/kg, 14 days, Measured
	NOEC	Manure worm (Eisenia foetida)	1000 mg/kg, 14 days

* Estimates for product may be based on additional component data not shown.

12.2. Persistence and degradability

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT	37 %, 14 days Zahn-Wellens, Activated sludge
FLUTICASONE FUROATE	0 %, 28 days Modified MITI (II) Test., Activated sludge

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT	28 %, 28 days Sturm test

Percent degradation (Aerobic biodegradation-soil)

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT	13 - 45 %, 15 weeks
FLUTICASONE FUROATE	2 - 3 %, 64 days, Soil

12.3. Bioaccumulative potential

Partition coefficient n-octanol/water (log Kow)

FLUTICASONE FUROATE	2.61 (Measured).

Bioconcentration factor (BCF)

ETHYLENEDIAMINETETRAACETIC ACID, DISODIUM SALT	0.8 - 1.8 Measured, Lepomis macrochirus, bluegill sunfish

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

FLUTICASONE FUROATE	3.6 - 4.2 Measured

Mobility in general Not available.

12.5. Results of PBT and vPvB assessment Not available.

12.6. Other adverse effects Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Residual waste 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.

EU waste code The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

Special precautions Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine environment. These materials may not be transported in bulk.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed.

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations	The product is classified and labelled in accordance with EC directives or respective national laws. This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.
National regulations	Follow national regulation for work with chemical agents.
15.2. Chemical safety assessment	No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations	Not available.
References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R36/38 Irritating to eyes and skin. R48/20/21 Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with skin. R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment. R61 May cause harm to the unborn child. R62 Possible risk of impaired fertility. H315 Causes skin irritation. H319 Causes serious eye irritation. H360 May damage the unborn child. H360D May damage the unborn child. H361 Suspected of damaging fertility. H361f Suspected of damaging fertility. H412 Harmful to aquatic life with long lasting effects.

Revision information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Ingredients Physical & Chemical Properties: Transport Information: Agency Name and Packaging Type/Transport Mode Selection Regulatory Information: United States GHS: Classification
Training information	Follow training instructions when handling this material.
Disclaimer	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.