SAFETY DATA SHEET

1. Identification

Product identifier **VERAMYST NASAL SPRAY**

Other means of identification Not available.

Synonym(s) 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

Recommended use 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.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

GlaxoSmithKline US
5 Moore Drive
Research Triangle Park, NC 27709 USA
US General Information (normal business hours): +1-888-825-5249
Email Address: msds@gsk.com
Website: www.gsk.com
EMERGENCY PHONE NUMBERS -
TRANSPORT EMERGENCIES::
US / International toll call +1 703 527 3887
available 24 hrs/7 days; multi-language response

2. Hazard(s) identification

Classified hazards

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

Label elements

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

Hazard(s) not otherwise classified (HNOC)

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

3. Composition/information on ingredients

Mixtures

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
MICROCRYSTALLINE CELLULOSE	AVICEL PH MICROCRYSTALLINE CELLULOSE ABICEL ALPHA-CELLULOSE ARBOCEL ARBOCELL B 600/30 ARBOCELL BC 200 AVICEL PH101 AVICEL PH102 AVICEL PH103 AVICEL PH105 AVICEL PH112 AVICEL PH200 BETA-AMYLOSE CELLEX MX CELLULOSE (8CI9CI) CELLULOSE 248 CELLULOSE CRYSTALLINE CELLULOSE, FOOD GRADE CELUFI CRYSTALLINE CELLULOSE EMOCEL MCC MICROCRYSTALLINE CELLULOSE POWDERED CELLULOSE RTECS FJ5691460 SOLKA FLOC BW200 CELLULOSA (FIBRA PAPEL) CELLULOSE (PAPER FIBRES) CELLULOSE-PAPER FIBER CELULOSA (FIBRA PAPEL) TSELLULOOS	9004-34-6	1.275
FLUTICASONE FUROATE	GW685698X FURAN-2-CARBOXYLIC ACID 6,9-DIFLUORO-17-FLUOROMETHYLSULFA 3-OXO-6,7,8,9,10,11,12,13,14,15,16,17-DOD ESTER 2080 (GW ACN) (6ALPHA,11BETA,16ALPHA,17ALPHA)-6,9-I 2-FURANCARBOXYLATE	397864-44-7	0.05< 0.2
POLYOXYETHYLENE (20) SORBITAN MONOLAURATE	OXYETHYLATED SORBITAN MONOLAURATE POLY(OXYETHYLENE SORBITAN LAURATE) SORBITAN POLYETHOXY MONOLAURATE ETHOXYLATED SORBITAN MONOOLAURATE SORBITAN, MONODODECANOTE, POLY(OXY-1,2-ETHANEDIYL) DERIVATIVE POLYSORBATE 20 TWEEN 20 TWEEN(R) 20, ALL PRODUCTS (ICI AMERICAS INC.) OHS80107 RTECS TR7400000	9005-64-5	0.025

Hazardous components Chemical name	Common name and synonyms	CAS number	%
ETHYLENEDIAMINETETRA ACETIC ACID, DISODIUM SALT	(ETHYLENEDIAMINETETRAACETIC ACID), DISODIUM SALT ACETIC ACID, (ETHYLENEDINITRILO)TETRA-, DISODIUM SALT CHELAPLEX DISODIUM EDETATE DISODIUM EDTA DISODIUM ETHYLENEDIAMINE TETRAACETATE DISODIUM SEQUESTRENE DISODIUM VERSENATE DISODIUM VERSENE EDETATE DISODIUM EDTA DISODIUM SALT ENDRATE DISODIUM N,N'-1,2-ETHYLENEDIYLBIS(N-(CARBOXYM DISODIUM SALT RTECS AH4375000 SELEKTON B2 SODIUM (DI) ETHYLENEDIAMINE TETRAACETATE TETRACEMATE DISODIUM	139-33-3	0.015
Other components below reportable levels			>95

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. 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 center immediately.

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

Indication of 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.

General information Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. 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.

5. Fire-fighting measures

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing media None known.

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 Move containers from fire area if you can do so without risk.

Specific methods Move containers from fire area if you can do so without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.

Methods and materials 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 entry into waterways, sewer, basements or confined areas. 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. For waste disposal, see section 13 of the MSDS.

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.

7. Handling and storage

Precautions for safe handling

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Avoid contact during pregnancy/while nursing. Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Avoid release to the environment. Do not empty into drains.

Conditions for safe storage, including any incompatibilities

Store locked up. 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).

8. Exposure controls/personal protection

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	

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	PEL	5 mg/m3	Respirable fraction.
		15 mg/m3	Total dust.

US. ACGIH Threshold Limit Values

Components	Type	Value
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	TWA	10 mg/m3

US. NIOSH: Pocket Guide to Chemical Hazards

Components	Type	Value	Form
MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)	REL	5 mg/m3	Respirable.
		10 mg/m3	Total

Biological limit values

No biological exposure limits noted for the ingredient(s).

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

Eye/face protection	Not normally needed.
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.
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.
General hygiene considerations	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.

9. Physical and chemical properties

Appearance

Physical state	Liquid.
Form	Liquid.
Color	Not available.
Odor	Not available.
Odor 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.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor 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.

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.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

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 related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: headache; nosebleed.

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
		<= 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 sensitization None known.

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

Sensitization

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.

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.

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

Chronic effects Prolonged inhalation may be harmful.

12. Ecological information

Ecotoxicity 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.

Persistence and degradability

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

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

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

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

FLUTICASONE FUROATE	3.6 - 4.2 Measured

Mobility in general Not available.

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions 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.

Local disposal regulations Dispose in accordance with all applicable regulations.

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

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. Transport information

DOT

Not regulated as a dangerous good.

IATA

Not regulated as a dangerous good.

IMDG

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 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.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

SARA 304 Emergency release notification

Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

MICROCRYSTALLINE CELLULOSE (CAS 9004-34-6)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 11-11-2013

Revision date 11-11-2013

Version # 06

Further information Not available.

References GSK Hazard Determination

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.

Revision Information Product and Company Identification: Product and Company Identification
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties: Multiple Properties
Transport Information: Agency Name, Packaging Type, and Transport Mode Selection
Regulatory Information: United States
GHS: Classification