SAFETY DATA SHEET

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

Material **ADVAIR HFA**

Synonyms ADVAIR HFA INHALATION AEROSOL * SERETIDE EVOHALER * SALMETEROL/FLUTICASONE PROPIONATE INHALATION AEROSOL * SALMETEROL/FLUTICASONE PROPIONATE INHALER 25/50 MCG 120 ACTN * SALMETEROL/FLUTICASONE PROPIONATE INHALER 25/125 MCG 120 ACTN * SALMETEROL/FLUTICASONE PROPIONATE INHALER 25/250 MCH 120 ACTN * SALMETEROL/FLUTICASONE PROPIONATE 134A 120 ACTN * VIANI EVOHALER * VIANI DOSIER-AEROSOL FCKW-FREI * VIANI FORTE DOSIER-AEROSOL FCKW-FREI * VIANI MITE DOSIER-AEROSOL FCKW-FREI * SALMETEROL XINOFOATE AND FLUTICASONE PROPIONATE, FORMULATED PRODUCT

Company Name

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Transport Emergency (non EU)	+1-703-527-3887
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	Multi-language response

2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
SALMETEROL XINAFOATE	94749-08-3	0.05
FLUTICASONE PROPIONATE	80474-14-2	0.08 to 0.34
1,1,1,2-TETRAFLUOROETHANE	811-97-2	99.6 to 99.87

3. HAZARDS IDENTIFICATION

Fire and Explosion This product is classified as non-flammable.

Health Caution - Potent pharmaceutical agent.
Health effects information is based on hazards of components.
May cause steroid withdrawal rash.

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.
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	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.
Medical Conditions Caused or Aggravated by Exposure	Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.
Antidotes	No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards	Aerosol containers may violently rupture when exposed to the heat of fire. This product is non-flammable.
Special Firefighting Procedures	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.
Hazardous Combustion Products	Toxic or corrosive thermal decomposition products are expected when this material is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions	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.
Environmental Precautions	Do not allow this material to enter surface drainage systems, sewers and poorly ventilated areas.
Decontamination Procedures	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	Normal room ventilation is expected to be adequate for the routine control of fire and explosion hazards during handling of this material.

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

INGREDIENT	SALMETEROL XINAFOATE	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	1 mcg/m3 (8 HR TWA)	HIGHLY POTENT
INGREDIENT	FLUTICASONE PROPIONATE	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	3 mcg/m3 (8 HR TWA)	SKIN

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. TOXICOLOGICAL INFORMATION

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.

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

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.

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.

Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION

*** Summary** This material contains two or more active pharmaceutical ingredients that have been tested, one of which may be harmful if released directly to the environment. Specific information on that active pharmaceutical ingredient is provided below. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

ECOTOXICITY

Aquatic

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

IC50: > 998 mg/l, 3 Hours, Activated sludge

*** Daphnid** This material contains an active pharmaceutical ingredient that is harmful to daphids.

EC50: 20 mg/l, 48 Hours, Daphnia pulex

NOEL: 6.7 mg/l, 48 Hours, Daphnia pulex

Terrestrial

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

Eisenia foetida, manure worm

EC50: 334 mg/kg, 28 Days,

Eisenia foetida, manure worm

NOEL: 209 mg/kg, 28 Days,

MOBILITY

*** Solubility** This material contains an active pharmaceutical ingredient that for environmental fate predictions has limited solubility in water.

*** Volatility** 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.

*** Adsorption** 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): 3.84 to 4.52

*** Partitioning** 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.

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. Half-Life, Neutral: > 1 Years, Measured
*** Photolysis**	This material contains an active pharmaceutical ingredient that is likely to undergo photodegradation. UV/Visible Spectrum: 338 nm
*** Biodegradation**	This material contains an active pharmaceutical ingredient that has been tested and is expected to be biodegradable. Aerobic - Ready Percent Degradation: 50 %, 12.8 days, Sturm test Aerobic - Soil Percent Degradation: 29.9 to 49.9 %, 64 days

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. 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.
Regulatory Requirements	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.

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)

UN/ID Number	ID 8000
Proper Shipping Name/Description	Consumer Commodity
ICAO/IATA Class/Division	9
Subsidiary Risk	None
Packing Group	Not applicable (use packing instruction 910).
Hazard Label(s)	Class 9

International Maritime Transport (IMDG Requirements)

Classification and Labelling	Not subject to provisions of IMDG Code, see SP 190 and 191.

US Domestic Transport (DOT Requirements)

Proper Shipping Name	Consumer Commodity, ORM-D
DOT Hazard Class/Division	ORM-D
UN/NA Number	Not applicable.
Packing Group	Not applicable
Marine Pollutant Status	Not listed
US Emergency Response Guide Number	171

European Ground Transport (ADR/RID Requirements)

Classification and Labelling	Not subject to provisions of ADR, see SP 190 and 191.

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

Date Approved/Revised 24-Nov-2004 **SDS Version Number** 9

SDS Sections Updated

Sections	Subsections
COMPOSITION / INFORMATION ON INGREDIENTS	
ECOLOGICAL INFORMATION	Activated Sludge Respiration
	Adsorption
	Algal
	Algal Degradation
	Bioaccumulation
	Biodegradation
	Daphnid
	Distribution
	Earthworm
	Ecotoxicity
	Fish
	Hydrolysis
	Microbial Growth Inhibition
	Microtox
	Mobility
	Other Adverse Effects
	Other Species - Aquatic
	Other Species - Terrestrial
	Partitioning
	Persistence/Degradation
	Photolysis
	Solubility
	Summary
	Volatility