

SAFETY DATA SHEET



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

Material ADVAIR HFA

Synonym(s) ADVAIR HFA INHALATION AEROSOL * SERETIDE INHALER HFA * SERETIDE EVOHALER * BREXOTIDE INHALER HFA 134A * FLIXOVENT INHALER HFA 134A * SERETAIDE INHALER HFA 134A * VIANI EVOHALER * VIANI INHALER HFA * VIANI MITE 25 MCG/50 MCG DOSIER-AEROSOL FCKW-FREI * VIANI 25 MCG/125 MCG DOSIER-AEROSOL FCKW-FREI * VIANI FORTE 25 MCG/250 MCG DOSIER-AEROSOL FCKW-FREI * 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 * NDC: 0173-0715-00 * NDC: 0173-0715-20 * NDC: 0173-0716-00 * NDC: 0173-0716-20 * NDC: 0173-0717-00 * NDC: 0173-0717-20 * SALMETEROL XINAFOATE AND FLUTICASONE PROPIONATE, FORMULATED PRODUCT

Company Name

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Multi-language response

2. HAZARDS IDENTIFICATION

Fire and Explosion Hazards Overview

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.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
1,1,1,2-TETRAFLUOROETHANE	811-97-2	99.6 to 99.87	
FLUTICASONE PROPIONATE	80474-14-2	0.08 to 0.34	
SALMETEROL XINAFOATE	94749-08-3	0.05	

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

OCCUPATIONAL EXPOSURE LIMITS

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

INGREDIENT	SALMETEROL XINAFOATE	
GSK Occupational Hazard Category	5	
GSK Occupational Exposure Limit	1 mcg/m ³ (8 HR TWA)	

ENGINEERING CONTROLS

Exposure Controls	The active ingredient was formerly assigned to OHC 4 with the Highly Potent notation. 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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them. Special considerations apply in the planning, design, review and implementation of controls - seek specialist assistance from local occupational hygienist or safety department.
Containment	Open handling may result in overexposure. It is strongly advised that dedicated areas and containment, such as glove boxes, isolators, and enclosed material transfer systems be used to prevent personnel exposure and spread of contamination.
Ventilation	Local exhaust ventilation (LEV) is not appropriate at this level, since total containment should usually be used.
Administrative	Strict control of access to the working area is essential. Only trained personnel should enter the area during operations. Adopt procedures to prevent contamination of working materials and adjacent areas.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection	When isolation is not possible, chemical splash goggles or equivalent eye protection must be used with other applicable protective equipment.
Gloves	Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Glove selection must take into account any solvents and other hazards present. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided.
Respirators	When isolation is not possible, respiratory protective equipment (RPE) should be combined with applicable protective equipment.
Other Equipment or Procedures	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. When isolation is not possible in production areas, applicable protective equipment must be used. Consider additional control procedures for maintenance, cleaning and emergencies.

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 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

Material ADVAIR HFA

Algal	This material contains an active pharmaceutical ingredient that is toxic to algae. IC50: 4 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Measured NOEC: 1.9 mg/l
Daphnid	This material contains an active pharmaceutical ingredient that is harmful to daphnids. This material is harmful to daphnids in chronic toxicity studies. EC50: 20 mg/l, 48 Hours, Daphnia pulex NOEC: 6.7 mg/l, 48 Hours, Daphnia pulex Chronic LOEC: 5 mg/l, 8 Days, Ceriodaphnia dubia, Static renewal test Chronic NOEC: 1.6 mg/l, 8 Days, Ceriodaphnia dubia
Fish	This mixture contains an active pharmaceutical ingredient that is harmful to fish. Juvenile Oncorhynchus mykiss, rainbow trout EC50: 35 mg/l, 96 Hours, Static renewal test NOEC: 7.5 mg/l
Terrestrial	
Earthworm	This mixture contains an active pharmaceutical ingredient that is not toxic to earthworms. EC50: 334 mg/kg, 28 Days, Eisenia foetida, manure worm, NOEC: 209 mg/kg, 28 Days, Eisenia foetida, manure worm,
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)

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 173.306(i); After 1Oct08, see 173.306(j).

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.

Material ADVAIR HFA

Other US Regulations**TSCA Status**

Exempt

**Australian Classification
according to Hazardous
Substance and Dangerous
Goods Regulatory Framework**

This product is not classified as hazardous according to the NOHSC Approved Criteria for Classifying Hazardous Substances.

*** 16. OTHER INFORMATION****References**

GSK Hazard Determination

SDS Version Number

18

SDS Sections Updated**Sections**IDENTIFICATION OF SUBSTANCE / PREPARATION AND OF
COMPANY

OTHER INFORMATION

Subsections

Disclaimer Safety Data Sheet

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.