SAFETY DATA SHEET

GlaxoSmithKline

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

Material **VENTOLIN HFA**

Synonyms VENTOLIN HFA INHALATION AEROSOL * ALBUTEROL INHALATION AEROSOL * ALBUTEROL 134A 200 ACTN * AEROLIN INHALER HFA * FESEMA INHALER HFA * SULBUTAN INHALADOR * SULTANOL INHALER HFA * SULTANOL N INHALER HFA * VENTILAN INALADOR * VENTOLIN EVOHALER 100 MCG 200 DOSE * VENTOLINE INHALER HFA * VENTORLIN EVOHALER * NDC NO 0173-0682-00 * NDC NO 0173-0682-20 * ALBUTEROL SULFATE (SALBUTAMOL SULPHATE), FORMULATED PRODUCT

Company Name

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US General Information:	+1-888-825-5249
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2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
ALBUTEROL SULFATE	51022-70-9	0.17 to 0.3
1,1,1,2-TETRAFLUOROETHANE	811-97-2	99.7 to 99.83

3. HAZARDS IDENTIFICATION

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

Health Caution - Pharmaceutical agent.
Exposure might occur via skin; eyes.
Inhaler propellant can cause skin irritation or frostbite.
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.

Inhalation Using appropriate personal protective equipment, move exposed subject to fresh air. If breathing is difficult or ceases, ensure and maintain ventilation. Give oxygen as appropriate. The exposed subject should be kept warm and at rest. Obtain medical attention in cases of known or possible over exposure, or with symptoms including chest pain, difficulty breathing, loss of consciousness or other adverse effects, which may be delayed.

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 Beta2 adrenergic agonist. Treat according to locally accepted protocols. For additional guidance, refer 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 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, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Ventilate area to dispel vapours present. Wear protective clothing and equipment consistent with the degree of hazard. Instruct all personnel not involved in clean-up operations to keep at a designated safe distance.

Environmental Precautions Prevent entry into waterways, sewers, surface drainage systems and poorly ventilated areas.

Clean-up Methods Allow any released liquid to evaporate.

Decontamination Procedures No specific decontamination or detoxification procedures have been identified for this product.

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	ALBUTEROL SULFATE
GSK Occupational Hazard Category	4
GSK Occupational Exposure Limit	10 mcg/m3 (8 HR TWA)

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection	Wear approved safety glasses with side shields if eye contact is possible.
Other Equipment or Procedures	None required for normal handling. Wash hands and arms thoroughly after handling.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form	Aerosol.

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.
Inhalation Toxicity	Substance likely to cause pharmacologically mediated or other adverse effects upon inhalation.
Skin Effects	Irritation is not expected following direct contact.
Eye Effects	Irritation is not expected following direct contact with eyes.
Target Organ Effects	No specific target organ effects have been identified.
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 beta 2 adrenergic agonist.
Other Adverse Effects	Inhaler propellant can cause skin irritation or frostbite.

12. ECOLOGICAL INFORMATION

Summary

This material contains an active pharmaceutical ingredient that has been tested, and no environmental effects have been identified. Local regulations and procedures should be consulted prior to environmental release.

Specific information on the active pharmaceutical ingredient is provided below.

ECOTOXICITY

Aquatic

Activated Sludge Respiration

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

IC50: > 830 mg/l, 3 Hours, Activated sludge

Daphnid

This material contains an active pharmaceutical ingredient that is not toxic to daphnids.

EC50: 243 mg/l, 48 Hours, Daphnia magna, Static test

NOEL: 83.2 mg/l, 48 Hours, Daphnia magna, Static test

MOBILITY

Solubility

This material contains an active pharmaceutical ingredient that for environmental fate predictions has 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. This material contains an active pharmaceutical ingredient that will not readily enter into air from water.

Henry's Law Constant 5.00E-14 atm m^3/mol, Calculated at 20 C

Adsorption

This material contains an active pharmaceutical ingredient that is not likely to adsorb to soil or sediment if released directly to the environment.

Soil Sediment Sorption (log Koc): -1.6 to -1.15, Measured

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 unlikely to undergo photodegradation.

UV/Visible Spectrum: 225 nm

Biodegradation

This material contains an active pharmaceutical ingredient that is not readily biodegradable (as defined by 1993 OECD Testing Guidelines).

Aerobic - Ready

Percent Degradation: 1 %, 28 days, Modified Sturm test.

Aerobic - Soil

Percent Degradation: 1.3 to 38.7 %, 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 US DOT Special Permit 14254.

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.

Other US Regulations

TSCA Status Exempt

16. OTHER INFORMATION

References GSK Hazard Determination

Date Approved/Revised 20-Nov-2006 **SDS Version Number** 10

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.