SAFETY DATA SHEET

1. Identification

Product identifier **VENTOLIN HFA**

Other means of identification

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 * ALBUTEROL SULFATE (SALBUTAMOL SULPHATE), 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 None known.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Not available.

Hazard(s) not otherwise classified (HNOC) Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.
Pressurized container may explode when exposed to heat or flame.

Supplemental information 99.83% of the mixture consists of component(s) of unknown acute oral toxicity. 99.83% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 99.83% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
1,1,1,2-TETRAFLUOROETHANE	1,2,2,2-TETRAFLUOROETHANE C2H2F4 OHS76816 HFC 134 A Norflurane	811-97-2	99.7 - 99.83
ALBUTEROL SULFATE	ALBUTEROL SULPHATE SALBUTAMOL HEMISULPHATE AH 3365F SALBUTAMOL SULPHATE BIS[(TERT-BUTYL)(BETA,3,4-TRIHYDROXYPHENETHYL)AMMONIUM]SULFATE	51022-70-9	0.17 - 0.3

4. First-aid measures

Inhalation Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

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

Eye contact Do not rub eyes. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Rinse with water. Get medical attention if irritation develops and persists.

Ingestion In the unlikely event of swallowing contact a physician or poison control center. If swallowed, rinse mouth with water (only if the person is conscious). Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed Dusts may irritate the respiratory tract, skin and eyes.
The following adverse effects have been noted with therapeutic use of this material: altered heart rate and pulse.

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 center.

General information In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. Fire-fighting measures

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

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical Pressurized container may explode when exposed to heat or flame. 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 Use water spray to cool unopened containers.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards Pressurized container may explode when exposed to heat or flame.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Wear appropriate protective equipment and clothing during clean-up. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Refer to attached safety data sheets and/or instructions for use. Stop leak if you can do so without risk. Move the cylinder to a safe and open area if the leak is irreparable. Eliminate all ignition sources (no smoking, flares, sparks, or flames in immediate area). Keep combustibles (wood, paper, oil, etc.) away from spilled material. Take precautionary measures against static discharge. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

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

Pressurized container: Do not pierce or burn, even after use. Do not use if spray button is missing or defective. Do not spray on a naked flame or any other incandescent material. Do not smoke while using or until sprayed surface is thoroughly dry. Do not cut, weld, solder, drill, grind, or expose containers to heat, flame, sparks, or other sources of ignition. Ground and bond containers when transferring material. Do not re-use empty containers. Avoid prolonged exposure. Use only in well-ventilated areas. Practice good housekeeping.

Conditions for safe storage, including any incompatibilities

Level 1 Aerosol.

Contents under pressure. The pressure in sealed containers can increase under the influence of heat. Do not expose to heat or store at temperatures above 120°F/49°C as can may burst. Do not puncture, incinerate or crush. Do not handle or store near an open flame, heat or other sources of ignition. Store in tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

Not applicable. The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

GSK

Components	Type	Value
ALBUTEROL SULFATE (CAS 51022-70-9)	8 HR TWA	10 mcg/m3
	OHC	4

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value
1,1,1,2-TETRAFLUOROETHANE (CAS 811-97-2)	TWA	4240 mg/m3
		1000 ppm

Biological limit values

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

Exposure guidelines

Appropriate engineering controls

Good general ventilation 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. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection

Not normally needed. Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection

Not normally needed. Wear appropriate chemical resistant gloves.

Other

Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection

No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations	When using do not smoke. 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	Solid.
Form	Aerosol. Inhaler.
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	-14.8 °F (-26 °C)
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)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Explosive properties	Not available.
Oxidizing properties	Not oxidizing.

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	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Dust may irritate respiratory system. Prolonged inhalation may be harmful. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact	Prolonged skin contact may cause temporary irritation. Health injuries are not known or expected under normal use.
Eye contact	Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.
Ingestion	Expected to be a low ingestion hazard. May be harmful if swallowed. However, ingestion is not likely to be a primary route of occupational exposure. Health injuries are not known or expected under normal use.
Symptoms related to the physical, chemical and toxicological characteristics	Dusts may irritate the respiratory tract, skin and eyes. The following adverse effects have been noted with therapeutic use of this material: altered heart rate and pulse.

Information on toxicological effects

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

Product	Species	Test Results
VENTOLIN HFA		
Acute		
Inhalation		
LC50	Rat	651100 ppm estimated
LCL0	Rat	568000 ppm, 4 hour estimated
LOEC	Rat	200300 mg/day estimated

Components	Species	Test Results
1,1,1,2-TETRAFLUOROETHANE (CAS 811-97-2)		
Acute		
Inhalation		
LCL0	Rat	567000 ppm, 4 hour
LOEC	Rat	200000 mg/day CNS depression.
Subchronic		
Inhalation		
NOAEC	Rat	50000 ppm, 13 weeks
ALBUTEROL SULFATE (CAS 51022-70-9)		
Acute		
Oral		
LD50	Rat	660 mg/kg
Chronic		
Oral		
LOEL	Dog	2 mg/kg/day, 1 years
Subacute		
Oral		
LOEL	Rat	30 mg/kg/day, 30 Day
Subchronic		
Inhalation		
LOEL	Rat	600 mcg/kg/day, 26 weeks
NOAEL	Dog	1710 mcg/kg/day, 13 weeks
	Rat	512 mcg/kg/day, 6 months
		1.9 mg/kg/day, 13 weeks
NOEL	Dog	220 mcg/kg/day, 26 weeks

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

Skin corrosion/irritation Prolonged skin contact may cause temporary irritation. Health injuries are not known or expected under normal use.

Corrosivity

ALBUTEROL SULFATE — Literature search
Result: Mild irritant

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation. Health injuries are not known or expected under normal use.

Eye

ALBUTEROL SULFATE	Literature search, Ointment tested. Result: Non-irritant

Respiratory or skin sensitization

Respiratory sensitization Due to partial or complete lack of data the classification is not possible.

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

Sensitization

ALBUTEROL SULFATE	Literature search Result: Rare cases of allergic and anaphylactic reactions from clinical use.

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

Mutagenicity

1,1,1,2-TETRAFLUOROETHANE	Ames Result: Negative
ALBUTEROL SULFATE	Ames Result: Negative Chromosomal Aberration Assay In Vitro Result: Negative
1,1,1,2-TETRAFLUOROETHANE	Chromosomal Aberration Assay In Vivo Result: Negative Dominant lethal assay, Inhalation study. Result: Negative Species: Rat In vivo cytogenetics Result: Negative
ALBUTEROL SULFATE	Mouse micronucleus test Result: Negative
1,1,1,2-TETRAFLUOROETHANE	Unscheduled DNA Synthesis in vivo, Inhalation study. Result: Negative Species: Rat

Carcinogenicity Not classifiable as to carcinogenicity to humans. Carcinogenic effects are not expected as a result of occupational exposure.

1,1,1,2-TETRAFLUOROETHANE	2500 - 5000 ppm Inhalation Result: Negative Species: Rat Test Duration: 2 years 5000 ppm Inhalation Result: Negative Species: Rat Test Duration: 78 weeks
ALBUTEROL SULFATE	Result: Equivocal Species: Rat Result: Negative Species: Hamster Result: Negative Species: Mouse

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals. These effects are linked only to high doses of this substance; low doses did not produce this adverse effect.

Reproductivity

ALBUTEROL SULFATE	2.5 mg/kg/day Embryofetal Development, Species-specific Result: Developmental effects including cleft palate Species: Mouse

Reproductivity

1,1,1,2-TETRAFLUOROETHANE	40000 ppm Foetal development - inhalation Result: Maternal toxicity; Foetal NOAEL Species: Rabbit
ALBUTEROL SULFATE	50 mg/kg/day Embryofetal Development Result: Cranial malformations Species: Rabbit 50 mg/kg/day Fertility Result: Negative Species: Rat
1,1,1,2-TETRAFLUOROETHANE	50000 ppm Foetal development - inhalation Result: Maternal toxicity, delayed foetal development. Species: Rat
ALBUTEROL SULFATE	Embryofetal Development Result: Negative Species: Rat

Specific target organ toxicity - single exposure Heart.

1,1,1,2-TETRAFLUOROETHANE	Species: Dog Organ: Heart

Specific target organ toxicity - repeated exposure Heart.

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

Chronic effects Prolonged inhalation may be harmful.

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

1,1,1,2-TETRAFLUOROETHANE	0, Asphyxiant

12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components		Species	Test Results
ALBUTEROL SULFATE (CAS 51022-70-9)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 1000 mg/l, 3 days OECD 209
Crustacea	EC50	Water flea (Daphnia magna)	292 mg/l, 48 hours Static test, OECD 201
	NOEC	Water flea (Daphnia magna)	100.3 mg/l, 48 hours Static test
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	> 100 mg/l, 8 days Static renewal test, EPA 1002
	NOEC	Water flea (Ceriodaphnia dubia)	100 mg/l, 8 days

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

Persistence and degradability No data is available on the degradability of this product.

Hydrolysis

Half-life (Hydrolysis-neutral)

ALBUTEROL SULFATE	> 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

ALBUTEROL SULFATE	1 %, 28 days Modified Sturm test.

Percent degradation (Aerobic biodegradation-soil)

ALBUTEROL SULFATE	1.3 - 38.7 %, 64 days

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

1,1,1,2-TETRAFLUOROETHANE	1.274

Bioconcentration factor (BCF)

ALBUTEROL SULFATE	1 Calculated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

ALBUTEROL SULFATE	-1.6 - -1.15 Measured

Mobility in general Not available.

Volatility

Henry's law

ALBUTEROL SULFATE	0 atm m^3/mol Calculated

Distribution

Octanol/water distribution coefficient log DOW

ALBUTEROL SULFATE	-1.5, pH 5 -2.8, pH 7 -2.8, pH 9

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Contents under pressure. Do not puncture, incinerate or crush. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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). Avoid discharge into water courses or onto the ground.

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

14. Transport information

DOT

UN number UN1950
UN proper shipping name Aerosols, non-flammable
Transport hazard class(es)
Class 2.2
Subsidiary risk -
Label(s) 2.2
Packing group Not available.
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
Packaging exceptions 306
Packaging non bulk None
Packaging bulk None
Read safety instructions, SDS and emergency procedures before handling.

IATA

UN number UN1950
UN proper shipping name Aerosols, non-flammable
Transport hazard class(es) 2.2
Subsidiary class(es) -
Packaging group Not available.
Labels required 2.2
Environmental hazards No.
ERG Code 2L
Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
Other information
Cargo aircraft only Allowed with restrictions.
Passenger & cargo Allowed with restrictions.
A98,A145,A167

IMDG

UN number UN1950
UN proper shipping name AEROSOLS, asphyxiant

Transport hazard class(es)

Class	2
Subsidiary risk	5A
Label(s)	2.2

Packing group Not available.

Environmental hazards

Marine pollutant No.

EmS Not available.

Special precautions for user Read safety instructions, SDS and emergency procedures before handling.
190, 327, 625

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

DOT

IATA

General information Classifications are for the material when offered for transport as fully regulated. Depending on the specific transport details (Ship-From/Ship To locations, quantities being shipped, type of packaging and mode of transport) it may be possible to ship this material in a manner other than fully regulated. (One example is IATA Limited or Excepted Quantity. There are others.) Be sure to review all regulatory agency packaging instructions and special provisions, referenced in this section, to identify options applicable to the specifics of your shipment.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

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

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No (Exempt)

SARA 313 (TRI reporting)

Not regulated.

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.

US state regulations

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. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
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)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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 05-22-2018

Revision date 12-04-2020

Version # 18

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling. HMIS® is a registered trade and service mark of the NPCA.

HMIS® ratings
Health: 1*
Flammability: 0
Physical hazard: 3

NFPA ratings
Health: 1
Flammability: 0
Instability: 3

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 This document has undergone significant changes and should be reviewed in its entirety.