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 * NDC NO 0173-0682-20 * 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 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

Chemical name	Common name and synonyms	CAS number	%
1,1,1,2-TETRAFLUOROETHANE	1,2,2,2-TETRAFLUOROETHANE * C2H2F4 * OHS76816	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

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

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
Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.

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. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed
The following adverse effects have been noted with therapeutic use of this material: headache; changes in blood pressure; 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). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

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

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

General fire hazards
Aerosol containers may violently rupture when exposed to the heat of fire.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.

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. 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 to original containers for re-use. For waste disposal, see section 13 of the SDS.

Environmental precautions
Avoid release to the environment. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
Avoid prolonged exposure. Do not taste or swallow. When using, do not eat, drink or smoke. Provide adequate ventilation. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.

Conditions for safe storage, including any incompatibilities
The pressure in sealed containers can increase under the influence of heat. Keep away from heat, sparks and open flame. Store in a cool, dry place out of direct sunlight. Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS). The recommended temperature for storage is 15 - 25 °C.

8. Exposure controls/personal protection

Occupational exposure limits

GSK

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

US. AIHA 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 (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.

Individual protection measures, such as personal protective equipment

Eye/face protection Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective 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 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 Aerosol.

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.

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. Avoid direct sunlight, conditions that might generate heat and sources of ignition.
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	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	Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use.
Symptoms related to the physical, chemical and toxicological characteristics	The following adverse effects have been noted with therapeutic use of this material: headache; changes in blood pressure; altered heart rate and pulse.

Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

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

Components	Species	Test Results
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 Health injuries are not known or expected under normal use.

Serious eye damage/eye irritation Not available.

Respiratory or skin sensitization

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

Skin sensitization Not available.

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 This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Not classifiable as to carcinogenicity to humans.

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: Negative Species: Mouse Result: Negative Species: Rat

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

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 Due to lack of data the classification is not possible.

Further information Caution - Pharmaceutical agent.

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

Hydrolysis

Half-life (Hydrolysis-neutral)

ALBUTEROL SULFATE	> 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

ALBUTEROL SULFATE	1.3 - 38.7 %, 64 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

1,1,1,2-TETRAFLUOROETHANE	1.274

Bioconcentration factor (BCF)

ALBUTEROL SULFATE	1 Calculated

Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

ALBUTEROL SULFATE	-1.6 - -1.15 Measured

Mobility in general

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. Do not discharge into drains, water courses or onto the ground. 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 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

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 applicable.
Special precautions for user	Not available.
Packaging exceptions	306
Packaging non bulk	None
Packaging bulk	None

IATA

UN number	UN1950
UN proper shipping name	Aerosols, non-flammable
Transport hazard class(es)	2.2
Subsidiary class(es)	-
Packaging group	Not available.
Environmental hazards	No.
Labels required	2.2
ERG Code	2L
Special precautions for user	Not available.
Other information	
Cargo aircraft only	Allowed.
Passenger & cargo	Allowed.

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 applicable.
Environmental hazards	
Marine pollutant	No.
EmS	Not available.
Special precautions for user	Not available.
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.

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

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 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	No

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

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

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

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

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)	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
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 10-21-2014

Revision date 10-21-2014

Version # 15

Further information HMIS® is a registered trade and service mark of the NPCA. 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® 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.