

## 1. Identification

<b>Product identifier</b>	<b>VENTOLIN HFA</b>
<b>Other means of identification</b>	Not available.
<b>Synonym(s)</b>	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
<b>Recommended use</b>	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.
<b>Recommended restrictions</b>	No other uses are advised.
<b>Manufacturer/Importer/Supplier/Distributor information</b>	
<b>Manufacturer</b>	

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 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

Hazardous components			
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	386 (GW ACN) ALBUTEROL SULPHATE SALBUTAMOL HEMISULPHATE AH 3365F SALBUTAMOL SULPHATE BIS[(TERT-BUTYL)(BETA,3,4-TRIHIDROXY	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

<b>Inhalation</b>	Move to fresh air. Call a physician if symptoms develop or persist.
<b>Skin contact</b>	Rinse skin with water/shower. Get medical attention if irritation develops and persists.

<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	The following adverse effects have been noted with therapeutic use of this material: headache; changes in blood pressure; altered heart rate and pulse.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically.
<b>General information</b>	If you feel unwell, seek medical advice (show the label where possible).

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO <sub>2</sub> ).
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed. Pressurized container may explode when exposed to heat or flame.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.
<b>Specific methods</b>	Move container from fire area if it can be done without risk. Cool containers exposed to flames with water until well after the fire is out.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. For personal protection, see section 8 of the MSDS.
<b>Methods and materials for containment and cleaning up</b>	<p>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.</p> <p>Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination.</p> <p>Never return spills in original containers for re-use. For waste disposal, see section 13 of the MSDS.</p>
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Avoid prolonged exposure. Observe good industrial hygiene practices.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the MSDS). The recommended temperature for storage is 15 - 25 °C.

## 8. Exposure controls/personal protection

### Occupational exposure limits

<b>GSK Components</b>	<b>Type</b>	<b>Value</b>
ALBUTEROL SULFATE (CAS 51022-70-9)	8 HR TWA	10 mcg/m <sup>3</sup>
	OHC	4
<b>US. AIHA Workplace Environmental Exposure Level (WEEL) Guides</b>		
<b>Components</b>	<b>Type</b>	<b>Value</b>
1,1,1,2-TETRAFLUOROETHANE (CAS 811-97-2)	TWA	4240 mg/m <sup>3</sup>
		1000 ppm

<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	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.
<b>Individual protection measures, such as personal protective equipment</b>	
<b>Eye/face protection</b>	If contact is likely, safety glasses with side shields are recommended.

<b>Hand protection</b>	For prolonged or repeated skin contact use suitable protective gloves. 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. Glove selection must take into account any solvents and other hazards present. Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided.
<b>Other</b>	Wear suitable protective clothing.
<b>Respiratory protection</b>	When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	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.

## 9. Physical and chemical properties

### Appearance

<b>Physical state</b>	Liquid.
<b>Form</b>	Aerosol.
<b>Color</b>	Not available.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	-14.8 °F (-26 °C)
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	Hazardous polymerization does not occur.
<b>Conditions to avoid</b>	Contact with incompatible materials. Avoid direct sunlight, conditions that might generate heat and sources of ignition.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Health injuries are not known or expected under normal use.
<b>Inhalation</b>	Health injuries are not known or expected under normal use.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	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
ALBUTEROL SULFATE (CAS 51022-70-9)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	660 mg/kg
<b>Chronic</b>		
<i>Oral</i>		
LOEL	Dog	2 mg/kg/day, 1 years
<b>Subacute</b>		
<i>Oral</i>		
LOEL	Rat	30 mg/kg/day, 30 Day
<b>Subchronic</b>		
<i>Inhalation</i>		
LOEL	Rat	600 mcg/kg/day, 26 weeks
NOAEL	Dog	1710 mcg/kg/day, 13 weeks
	Rat	512 mcg/kg/day, 6 months
NOEL	Dog	1.9 mg/kg/day, 13 weeks
		220 mcg/kg/day, 26 weeks

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

<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.
<b>Serious eye damage/eye irritation</b>	Not available.
<b>Respiratory sensitization</b>	Due to lack of data the classification is not possible.
<b>Skin sensitization</b>	Not available.
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

ALBUTEROL SULFATE

Ames  
Result: Negative  
Chromosomal Aberration Assay In Vitro  
Result: Negative  
Mouse micronucleus test  
Result: Negative

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

ALBUTEROL SULFATE

Result: Negative  
Species: Mouse  
Result: Negative  
Species: Rat

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

ALBUTEROL SULFATE

2.5 mg/kg/day Embryofetal Development, Species-specific  
Result: Developmental effects including cleft palate  
Species: Mouse  
50 mg/kg/day Embryofetal Development  
Result: Cranial malformations  
Species: Rabbit

ALBUTEROL SULFATE

50 mg/kg/day Fertility  
 Result: Negative  
 Species: Rat  
 Embryofetal Development  
 Result: Negative  
 Species: Rat

**Specific target organ toxicity - single exposure** 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.

## 12. Ecological information

### Ecotoxicity

Components	Species	Test Results
ALBUTEROL SULFATE (CAS 51022-70-9)		
<b>Aquatic</b>		
<i>Acute</i>		
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
<i>Chronic</i>		
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** 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

#### Volatility

##### Henry's law

ALBUTEROL SULFATE 0 atm m<sup>3</sup>/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.

<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	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

<b>DOT</b>	
<b>UN number</b>	UN1950
<b>UN proper shipping name</b>	Aerosols, non-flammable
<b>Transport hazard class(es)</b>	2.2
<b>Subsidiary class(es)</b>	Not available.
<b>Packing group</b>	Not available.
<b>Special precautions for user</b>	May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options.
	Consumer Commodity, ORM-D may apply. or May be exempt from DOT regulations. See 173.307.
<b>Labels required</b>	2.2
<b>Packaging exceptions</b>	306
<b>Packaging non bulk</b>	None
<b>Packaging bulk</b>	None
<b>IATA</b>	
<b>UN number</b>	UN1950
<b>UN proper shipping name</b>	Aerosols, non-flammable
<b>Transport hazard class(es)</b>	2.2
<b>Subsidiary class(es)</b>	-
<b>Packaging group</b>	Not available.
<b>Environmental hazards</b>	No
<b>Labels required</b>	Not available.
<b>ERG Code</b>	2L
<b>Special precautions for user</b>	May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options.
	ID 8000, Consumer Commodity, may apply. See Packing Instruction Y963.
	May not be subject to IATA regulations, see SP A98.
<b>IMDG</b>	
<b>UN number</b>	UN1950
<b>UN proper shipping name</b>	AEROSOLS, asphyxiant
<b>Transport hazard class(es)</b>	2
<b>Subsidiary class(es)</b>	5A
<b>Packaging group</b>	Not available.
<b>Environmental hazards</b>	
<b>Marine pollutant</b>	No
<b>Labels required</b>	Not available.
<b>EmS</b>	Not available.
<b>Special precautions for user</b>	May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options.
	May be exempt from IMDG regulations. See IMDG Special Provision 190.
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	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



## 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.

**US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)**

Not listed.

**SARA 304 Emergency release notification**

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

<b>Hazard categories</b>	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - Yes Reactivity Hazard - No
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<b>SARA 302 Extremely hazardous substance</b>	No
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<b>SARA 311/312 Hazardous chemical</b>	No
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### 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.

<b>Safe Drinking Water Act (SDWA)</b>	Not regulated.
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**DEA Essential Chemical Code Number**

Not regulated.

<b>Food and Drug Administration (FDA)</b>	Not regulated.
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### US state regulations

**US. Massachusetts RTK - Substance List**

Not regulated.

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

Not regulated.

**US. Pennsylvania RTK - Hazardous Substances**

Not regulated.

**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 this product complies 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

<b>Issue date</b>	05-31-2013
<b>Revision date</b>	05-31-2013
<b>Version #</b>	14
<b>Further information</b>	This material has not been assessed for HMIS or NFPA ratings.
<b>References</b>	GSK Hazard Determination
<b>Disclaimer</b>	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.
<b>Revision Information</b>	Product and Company Identification: Business Units Composition / Information on Ingredients: Disclosure Overrides Physical & Chemical Properties: Multiple Properties Toxicological Information: Ecological Information: Transport Information: Proper Shipping Name/Packing Group Regulatory Information: United States GHS: Classification