

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 (CO ₂).
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-TETRAFLUOROET
HANE (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		
<i>Inhalation</i>		
LCL0	Rat	567000 ppm, 4 hour
LOEC	Rat	200000 mg/day CNS depression.
Subchronic		
<i>Inhalation</i>		
NOAEC	Rat	50000 ppm, 13 weeks
ALBUTEROL SULFATE (CAS 51022-70-9)		
Acute		
<i>Oral</i>		
LD50	Rat	660 mg/kg
Chronic		
<i>Oral</i>		
LOEL	Dog	2 mg/kg/day, 1 years
Subacute		
<i>Oral</i>		
LOEL	Rat	30 mg/kg/day, 30 Day

Components	Species	Test Results
Subchronic		
<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
		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

ALBUTEROL SULFATE

In vivo cytogenetics
Result: Negative
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

ALBUTEROL SULFATE

5000 ppm Inhalation
Result: Negative
Species: Rat
Test Duration: 78 weeks
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

1,1,1,2-TETRAFLUOROETHANE	Heart. Species: Dog Organ: Heart
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Specific target organ toxicity - repeated exposure

Aspiration hazard Due to lack of data the classification is not possible.

Further information Caution - Pharmaceutical agent.

1,1,1,2-TETRAFLUOROETHANE	0, Asphyxiant
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12. Ecological information

Ecotoxicity Not expected to be harmful to aquatic organisms.

Components	Species	Test Results
ALBUTEROL SULFATE (CAS 51022-70-9)		
Aquatic		
<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
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Biodegradability

Percent degradation (Aerobic biodegradation-soil)

ALBUTEROL SULFATE	1.3 - 38.7 %, 64 days
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Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

1,1,1,2-TETRAFLUOROETHANE	1.274
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Bioconcentration factor (BCF)

ALBUTEROL SULFATE	1 Calculated
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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 m³/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.