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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,1,2-TETRAFLUOROETHANE</td>
<td>1,2,2,2-TETRAFLUOROETHANE * C2H2F4 * OHS76816</td>
<td>811-97-2</td>
<td>99.7 - 99.83</td>
</tr>
<tr>
<td>ALBUTEROL SULFATE</td>
<td>ALBUTEROL SULPHATE * SALBUTAMOL HEMISULPHATE * AH 3365F * SALBUTAMOL SULPHATE * BIS[TERT-BUTYL]BETA,3,4-TRIHYDROXY YPHENETHYL]AMMONIUM J[SULFATE</td>
<td>51022-70-9</td>
<td>0.17&lt; 0.3</td>
</tr>
</tbody>
</table>

*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

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.

Environmental precautions
Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.

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

<table>
<thead>
<tr>
<th>GSK Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALBUTEROL SULFATE</td>
<td>8 HR TWA</td>
<td>10 mcg/m3</td>
</tr>
<tr>
<td>(CAS 51022-70-9)</td>
<td>OHC</td>
<td>4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>US. AIHA Workplace Environmental Exposure Level (WEEL) Guides Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,1,1,2-TETRAFLUOROETHANE (CAS 811-97-2)</td>
<td>TWA</td>
<td>4240 mg/m3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1000 ppm</td>
</tr>
</tbody>
</table>

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.

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

* 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**

<table>
<thead>
<tr>
<th>Component</th>
<th>Result</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,1,1,2-TETRAFLUOROETHANE</td>
<td>Negative</td>
<td>Ames</td>
</tr>
<tr>
<td>ALBUTEROL SULFATE</td>
<td>Negative</td>
<td>Ames, Chromosomal Aberration Assay In Vitro</td>
</tr>
<tr>
<td>1,1,1,2-TETRAFLUOROETHANE</td>
<td>Negative</td>
<td>Chromosomal Aberration Assay In Vivo, Dominant lethal assay, Inhalation study.</td>
</tr>
<tr>
<td>ALBUTEROL SULFATE</td>
<td>Negative</td>
<td>Mouse micronucleus test</td>
</tr>
<tr>
<td>1,1,1,2-TETRAFLUOROETHANE</td>
<td>Negative</td>
<td>Unscheduled DNA Synthesis in vivo, Inhalation study.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Result</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,1,1,2-TETRAFLUOROETHANE</td>
<td>Negative</td>
<td>2500 - 5000 ppm Inhalation, Test Duration: 2 years</td>
</tr>
<tr>
<td>ALBUTEROL SULFATE</td>
<td>Negative</td>
<td>Species: Mouse, Result: Developmental effects including cleft palate</td>
</tr>
</tbody>
</table>

Not listed.

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

<table>
<thead>
<tr>
<th>Reproductivity</th>
<th>Result</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALBUTEROL SULFATE</td>
<td>Developmental effects including cleft palate</td>
<td>2.5 mg/kg/day Embryofetal Development, Species-specific</td>
</tr>
</tbody>
</table>

Material name: VENTOLIN HFA  
126598  Version #: 15  Revision date: 10-21-2014  Issue date: 10-21-2014  
SDS US  
5 / 10
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 Species: Dog
Heart. 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 IC50 Residential sludge > 1000 mg/l, 3 days OECD 209
Respiration

Crustacea EC50 Water flea (Daphnia magna) 292 mg/l, 48 hours Static test, OECD 201

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

Volutility
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) Class 2.2
Subsidiary class(es) -
Packing 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.

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.
  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

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>Yes</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>Yes</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*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