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 of the chemical and restrictions on use

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.

Restrictions on use No other uses are advised.

Details of manufacturer or importer

Manufacturer

GlaxoSmithKline Australia
1061 Mountain Highway
Melbourne, Victoria 3155
Australia
Australia General Information (Normal Business Hours): (03) 9721 6000

TRANSPORTATION EMERGENCY NUMBERS
(available 24hrs/7days: multi-language response)
Australia Toll Free +(61) 2 9037 2994
International Toll Call +(1) 703 527 3887

2. Hazard(s) identification

Classification of the hazardous chemical

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements, including precautionary statements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Other hazards which do not result in classification

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixture

Identity of chemical ingredients	CAS number and other unique identifiers	Concentration of ingredients
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

Description of necessary 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 centre immediately. Do not induce vomiting without advice from poison control center.
Personal protection for first-aid responders	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.
Symptoms caused by exposure	The following adverse effects have been noted with therapeutic use of this material: headache; changes in blood pressure; altered heart rate and pulse.
Medical attention and special treatment	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 centre.

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Pressurised container may explode when exposed to heat or flame. During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for fire fighters	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.
Hazchem Code	Not available.
General fire hazards	Aerosol containers may violently rupture when exposed to the heat of fire.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel	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.
For emergency responders	Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the SDS.
Environmental precautions	Prevent further leakage or spillage if safe to do so. Avoid release to the environment. Avoid discharge into drains, water courses or onto the ground.

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.

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 and personal protection

Control parameters

Follow standard monitoring procedures.

Occupational exposure limits

GSK

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

Australia. OELs. (Adopted National Exposure Standards for Atmospheric Contaminants in the Occupational Environment)

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

UK. EH40 Workplace Exposure Limits (WELs)

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

Germany. DFG MAK List (advisory OELs). Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area (DFG)

Components	Type	Value
1,1,1,2-TETRAFLUOROETHANE (CAS 811-97-2)	TWA	4200 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, for example personal protective equipment (PPE)

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. Avoid exposure - obtain special instructions before use.

Other

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

Respiratory protection

In case of insufficient ventilation, wear suitable respiratory equipment.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

Hygiene measures	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
Colour	Not available.
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	-26 °C (-14.8 °F)
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.
Vapour pressure	Not available.
Vapour 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	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials. Avoid direct sunlight, conditions that might generate heat and sources of ignition.
Incompatible materials	Strong oxidising 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 possible 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 exposure The following adverse effects have been noted with therapeutic use of this material: headache; changes in blood pressure; altered heart rate and pulse.

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
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/irritation Not available.

Respiratory or skin sensitisation

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

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

Mutagenicity

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

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

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.

Other 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-ready)

ALBUTEROL SULFATE	1 %, 28 days Modified Sturm test.

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 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^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 methods 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.

Residual waste 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

IATA

UN number	1950
UN proper shipping name	Aerosols, non-flammable
Transport hazard class(es)	
Class	2.2
Subsidiary risk	-
Label(s)	2.2
Packing group	Not applicable.
Environmental hazards	No.
ERG Code	2L
Special precautions for user	Not available.
Other information	
Passenger and cargo aircraft	Allowed.
Cargo aircraft only	Allowed.

IMDG

UN number	1950
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 Not available.

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

Safety, health and environmental regulations

National regulations This Material Safety Data Sheet was prepared in accordance with the Australia National Code of Practice for the Preparation of Material Safety Data Sheets (NOHSC: 2011.)

Australia Medicines & Poisons Appendix A

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix B

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix C

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix D

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix E

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix F

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix G

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix H

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix I

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix J

Poisons schedule number not allocated.

Australia Medicines & Poisons Appendix K

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 2

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 3

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 4

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 5

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 6

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 7

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 8

Poisons schedule number not allocated.

Australia Medicines & Poisons Schedule 9

Poisons schedule number not allocated.

High Volume Industrial Chemicals (HVIC)

1,1,1,2-TETRAFLUOROETHANE (CAS 811-97-2)	1000 - 9999 TONNES See the regulation for additional information.

Importation of Ozone Deleting Substances (Customs(Prohibited imports) Regulations 1956, Schedule 10)

1,1,1,2-TETRAFLUOROETHANE (CAS 811-97-2)	9

National Pollutant Inventory (NPI) substance reporting list

Not listed.

Prohibited Carcinogenic Substances

Not regulated.

Prohibited Substances (National Model Regulation for the control of Workplace Hazardous Substances, Schedule 2 NOHSC:1005 (1994) as amended)

Not listed.

Resricted Importation of Organochlorine Chemicals (Customs(Prohibited Imports) Regulations 1956, Schedule 9)

Not listed.

Restricted Carcinogenic Substances

Not regulated.

International regulations The product does not need to be labelled in accordance with EC directives or respective national laws.

Stockholm Convention

Not applicable.

Rotterdam Convention

Not applicable.

Kyoto protocol

1,1,1,2-TETRAFLUOROETHANE (CAS 811-97-2)	Listed.

Montreal Protocol

Not applicable.

Basel Convention

Not applicable.

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

Issue date 21-October-2014

Revision date	21-October-2014
References	ACGIH EPA: AQUIRE database NLM: Hazardous Substances Data Base US. IARC Monographs on Occupational Exposures to Chemical Agents 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. This safety data sheet was prepared in accordance with JIS Z 7253:2012.
Revision Information	Product and Company Identification: Product and Company Identification Composition / Information on Ingredients: Disclosure Overrides Physical & Chemical Properties: Toxicological Information: Ecological Information: Mobility Transport Information: Proper Shipping Name/Packing Group Regulatory Information: United States GHS: Classification