

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name or designation of the mixture VENTOLIN INHALATION AEROSOL

Registration number -

Synonyms VENTOLIN INHALATION AEROSOL * VENTOLIN INHALATION AEROSOL REFILL * VENTOLIN EASI-BREATHE 100MCG, 200 DOSE * VENTOLIN EASI-BREATHE INHALER * VENTOLIN AEROSOL * VENTOLIN AEROSOL * VENTOLIN AEROSOL BEZFREONOWY ZAWIESINA * VENTOLIN INHALACIOS AEROSOL * VENTOLIN INHALADOR * VENTOLIN INHALATEUR * VENTOLIN INHALATORS * VENTOLIN INHALATSIIONIAEROSOL * VENTOLIN INHALER * VENTOLIN INHALER N * SALBUTAMOL, FORMULATED PRODUCT

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1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified uses 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.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK
980 Great West Road
Brentford, Middlesex TW8 9GS UK
UK General Information (normal business hours): +44-20-8047-5000
Email Address: msds@gsk.com
Website: www.gsk.com

1.4. Emergency telephone number

TRANSPORT EMERGENCIES:
UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC as amended

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

Classification according to Regulation (EC) No 1272/2008 as amended

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

2.2. Label elements

Label according to Regulation (EC) No. 1272/2008 as amended

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

Supplemental label information Not applicable.

2.3. Other hazards Caution - Pharmaceutical agent.
Aerosol containers may violently rupture when exposed to the heat of fire.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

General information

Chemical name	%	CAS-No. / EC No.	REACH Registration No.	INDEX No.	Notes
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DICHLORODIFLUOROMETHANE	70 - < 80	75-71-8 200-893-9	-	-	
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Classification: **DSD:** -

CLP: -

FLUOROTRICHLOROMETHANE	20 - < 30	75-69-4 200-892-3	-	-	
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Classification: **DSD:** -

CLP: -

SALBUTAMOL	< 0.2	18559-94-9 242-424-0	-	-	
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Classification: **DSD:** Xn;R20/22

CLP: Acute Tox. 4;H302, Acute Tox. 4;H332

Other components below reportable levels < 0.1

SECTION 4: First aid measures

General information If you feel unwell, seek medical advice (show the label where possible). Show this safety data sheet to the doctor in attendance.

4.1. Description of first aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. Get medical attention if symptoms occur.

4.2. Most important symptoms and effects, both 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.

4.3. Indication of any immediate medical attention and special treatment needed Treat symptomatically.

SECTION 5: Firefighting measures

General fire hazards Aerosol containers may violently rupture when exposed to the heat of fire. This product is non-flammable.

5.1. Extinguishing media

Suitable extinguishing media Water fog. Foam. Dry chemical powder. Carbon dioxide (CO₂).

Unsuitable extinguishing media None known.

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed. Pressurised container may explode when exposed to heat or flame.

5.3. Advice for firefighters

Special protective equipment for firefighters Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

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

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Keep unnecessary personnel away. For personal protection, see section 8.

For emergency responders Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.

6.2. Environmental precautions Avoid discharge into drains, water courses or onto the ground.

6.3. Methods and material 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 in original containers for re-use.

6.4. Reference to other sections

For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid prolonged exposure. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

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.

7.3. Specific end use(s)

Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

GSK

Components

Type

Value

SALBUTAMOL (CAS
18559-94-9)

8 HR TWA

10 mcg/m³

OHC

4

Biological limit values

No biological exposure limits noted for the ingredient(s).

Recommended monitoring procedures

Follow standard monitoring procedures.

Derived No Effect Level (DNEL)

Not available.

Predicted no effect concentrations (PNECs)

Not available.

8.2. Exposure controls

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

General information

Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment.

Eye/face protection

If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- Hand protection

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. Select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other

Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)

Respiratory protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Where breathable aerosols/dust are formed, use suitable combination filter for gases/vapours of organic, inorganic, acid inorganic, alkaline compounds and toxic particles (eg. EN 14387).

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.

Environmental exposure controls

Hazard guidance and control recommendations

Not available.

SECTION 9: Physical and chemical properties

9.1. Information on basic 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.
Vapour pressure	Not available.
Vapour density	Not available.
Relative density	Not available.
Solubility(ies)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidizing properties	Not available.

9.2. Other information

Percent volatile	99.9 % estimated
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SECTION 10: Stability and reactivity

10.1. Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability	Material is stable under normal conditions.
10.3. Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid	Contact with incompatible materials. Avoid direct sunlight, conditions that might generate heat and sources of ignition.
10.5. Incompatible materials	Strong oxidising agents.
10.6. Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.
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Information on likely routes of exposure

Ingestion	Health injuries are not known or expected under normal use.
Inhalation	Health injuries are not known or expected under normal use.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.

Symptoms The following adverse effects have been noted with therapeutic use of this material: headache; changes in blood pressure; altered heart rate and pulse.

11.1. Information on toxicological effects

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

Components	Species	Test results
DICHLORODIFLUOROMETHANE (CAS 75-71-8)		
Acute		
<i>Inhalation</i>		
LC50	Rat	> 800000 mg/l, 30 Minutes
LOEL	Human	27000 ppm, Effects on heart and respiratory parameters. 10000 ppm, Impaired psychomotor performance.
NOEL	Human	1000 ppm
<i>Oral</i>		
LD50	Rat	> 1 g/kg
Chronic		
<i>Oral</i>		
NOAEL	Rat	15 mg/kg/day, dietary study - Decrease in bodyweight.
FLUOROTRICHLOROMETHANE (CAS 75-69-4)		
Acute		
<i>Oral</i>		
LD50	Rat	> 15000 mg/day
SALBUTAMOL (CAS 18559-94-9)		
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
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.

Corrosivity

FLUOROTRICHLOROMETHANE

OECD 404
Result: Non-irritant
Species: Rabbit

Irritation Corrosion - Skin

DICHLORODIFLUOROMETHANE

Result: Slightly irritating
Species: Rabbit
Test Duration: 1 months

Serious eye damage/eye irritation

Eye

FLUOROTRICHLOROMETHANE

Acute ocular irritation; OECD 405
Result: Non-Irritating
Species: Rabbit

Carcinogenicity

FLUOROTRICHLOROMETHANE

488 - 1077 mg/kg/day oral

Result: negative

Species: Rat

Test Duration: 78 weeks

DICHLORODIFLUOROMETHANE

8 - 80 mg/kg/day

Result: No tumourigenic effect.

Species: Dog

SALBUTAMOL

Result: negative

Species: Mouse

Notes: Data from albuterol sulfate

Result: negative

Species: Rat

Notes: Data from albuterol sulfate

Reproductive toxicity

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

Reproductive toxicity**Reproductivity**

DICHLORODIFLUOROMETHANE

15 - 150 mg/kg/day 3-generation study

Result: No adverse effects on fertility, or development.

Species: Rat

SALBUTAMOL

2.5 mg/kg/day Embryofetal Development, Species-specific

Result: Developmental effects including cleft palate

Species: Mouse

FLUOROTRICHLOROMETHANE

Notes: Data from albuterol sulfate

200000 ppm Foetal development - inhalation

Result: NOAEL

Species: Rabbit

200000 ppm Foetal development - inhalation

Result: NOAEL

Species: Rat

DICHLORODIFLUOROMETHANE

200000 ppm, Inhalation

Result: No adverse foetal effects observed

Species: Rabbit

200000 ppm, Inhalation

Result: No adverse foetal effects observed

Species: Rat

SALBUTAMOL

50 mg/kg/day Embryofetal Development

Result: Cranial malformations

Species: Rabbit

Notes: Data from albuterol sulfate

50 mg/kg/day Fertility

Result: negative

Species: Rat

Notes: Data from albuterol sulfate

Embryofetal Development

Result: negative

Species: Rat

Notes: Data from albuterol sulfate

Specific target organ toxicity - single exposure

Heart.

FLUOROTRICHLOROMETHANE

Organ: Heart

Specific target organ toxicity - repeated exposure

Heart.

Aspiration hazard

Due to lack of data the classification is not possible.

Mixture versus substance information

Not available.

Other information

Caution - Pharmaceutical agent.

FLUOROTRICHLOROMETHANE

Asphyxiant

SECTION 12: Ecological information**12.1. Toxicity**

Components		Species	Test results
DICHLORODIFLUOROMETHANE (CAS 75-71-8)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	67 mg/l, 48 hours, Static renewal test

Components		Species	Test results
SALBUTAMOL (CAS 18559-94-9)			
Aquatic			
<i>Acute</i>			
Activated Sludge Respiration	IC50	Residential sludge	> 830 mg/l, 3 hours
Crustacea	EC50	Water flea (Daphnia magna)	243 mg/l, 48 hours, Static , TAD 4.08
	NOEC	Water flea (Daphnia magna)	83.2 mg/l, 48 hours, Static test
<i>Chronic</i>			
Crustacea	EC50	Water flea (Ceriodaphnia dubia)	> 100 mg/l, 8 days, Static renewal, EPA 1002
	LOEC	Water flea (Ceriodaphnia dubia)	> 100 mg/l, 8 days, Static renewal test
	NOEC	Water flea (Ceriodaphnia dubia)	100 mg/l, 8 days, 7 day static renewal

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

12.2. Persistence and degradability

Persistence and degradability

Photolysis

Half-life (Photolysis-atmospheric)

DICHLORODIFLUOROMETHANE > 300 years Measured

UV/visible spectrum wavelength

SALBUTAMOL 225 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

SALBUTAMOL > 1 years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-ready)

SALBUTAMOL 1 %, 28 days Modified Sturm test.

Percent degradation (Aerobic biodegradation-soil)

SALBUTAMOL 1.3 - 38.7 %, 64 days

12.3. Bioaccumulative potential

Not available.

Partition coefficient

n-octanol/water (log Kow)

DICHLORODIFLUOROMETHANE 2.16
 FLUOROTRICHLOROMETHANE 2.53
 SALBUTAMOL 0.061 (Calculated).

Bioconcentration factor (BCF)

DICHLORODIFLUOROMETHANE 2.3 - 10 Measured, Cyprinus carpio, carp

12.4. Mobility in soil

No data available.

Adsorption

Soil/sediment sorption - log Koc

DICHLORODIFLUOROMETHANE 2.3 Estimated
 SALBUTAMOL -1.6 - -1.15 Measured

Mobility in general

Volatility

Henry's law

DICHLORODIFLUOROMETHANE 0.343 atm m³/mol Measured, 25 °C
 SALBUTAMOL 0 atm m³/mol Calculated, 20 C

12.5. Results of PBT

Not available.

and vPvB

assessment

12.6. Other adverse effects

Not available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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).

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.

EU waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Disposal methods/information	Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

SECTION 14: Transport information

ADR

14.1. UN number	UN1950
14.2. UN proper shipping name	AEROSOLS, asphyxiant
14.3. Transport hazard class(es)	2.2
Subsidiary class(es)	-
14.4. Packing group	Not available.
14.5. Environmental hazards	No
Tunnel code	E
Labels required	2.2
Additional information:	
LTD QTY index	LQ2
Special Provisions	190, 327, 625

IATA

14.1. UN number	UN1950
14.2. UN proper shipping name	Aerosols, non-flammable
14.3. Transport hazard class(es)	2.2
Subsidiary class(es)	-
14.4. Packing group	Not available.
Labels required	2.2

Additional Information:

Passenger & cargo	Allowed.
Packaging Instruction	203
Pkg Inst cargo only	203
Pkg Inst pasenger & cargo	Y203

LQ

SP See 44	A98,A145,A167
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Max net qty pkg	75 kg
Max net qty pkg cargo only	150 kg
Max net qty pkg LQ	30 kg G

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.

IMDG

14.1. UN number	UN1950
14.2. UN proper shipping name	AEROSOLS, asphyxiant
14.3. Transport hazard class(es)	2
Subsidiary class(es)	5A
14.4. Packing group	Not available.
14.5. Environmental hazards	

Marine pollutant	No
Labels required	2.2

14.6. Special precautions for user	May be able to ship as an Excepted or Limited Quantity. Review all HazMat Table packaging exceptions and instructions to identify options.
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May be exempt from IMDG regulations. See IMDG Special Provision 190.

14.7. Transport in bulk according to Annex II of MARPOL73/78 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.
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SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

EU regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

DICHLORODIFLUOROMETHANE (CAS 75-71-8)

FLUOROTRICHLOROMETHANE (CAS 75-69-4)

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended

Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended

Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

DICHLORODIFLUOROMETHANE (CAS 75-71-8)

FLUOROTRICHLOROMETHANE (CAS 75-69-4)

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

Authorisations

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended

Not listed.

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Not listed.

Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations

The product is classified and labelled in accordance with EC directives or respective national laws.
This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations

Follow national regulation for work with chemical agents.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out.

SECTION 16: Other information

List of abbreviations

Not available.

References	GSK Hazard Determination
Information on evaluation method leading to the classification of mixture	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
Full text of any statements or R-phrases and H-statements under Sections 2 to 15	R20/22 Harmful by inhalation and if swallowed. H302 Harmful if swallowed. H332 Harmful if inhaled.
Revision information	Product and Company Identification: Material Processes SECTION 1: Identification of the substance/mixture and of the company/undertaking: Product use SECTION 2: Hazards identification: Classification of the substance or mixture Composition / Information on Ingredients: Ingredients Transport Information: Material Transportation Information Regulatory Information: United States
Training information	Follow training instructions when handling this material.
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.