

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

1.1. Product identifier

Trade name or designation of the mixture	VENTODISK
Registration number	-
Synonyms	VENTODISK 200 MCG * VENTODISK 400 MCG * VENTODISK 200 MCG - REFILL * VENTODISK 400 MCG - REFILL * VENTODISK - HOSPITAL PACK 200 MCG * VENTODISK - HOSPITAL PACK 400 MCG * VENTOLIN VENTODISK * VENTOLIN ROTADISK * SULTANOL ROTADISKS * VENTOLINE ROTADISKS * ALBUTEROL SULFATE (SALBUTAMOL SULPHATE), FORMULATED PRODUCT
Issue date	30-May-2013
Version number	09
Revision date	30-May-2013

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 (by country / geographic region):
Africa / EU / Israel / Middle East
(English / European languages): +44 (0) 1235 239 670
Asia Pacific (except China): +65 3158 1074
China: +86 10 5100 3039
Middle East / Africa (Arabic-speaking countries): +44 (0) 1235 239 671
US: +1 703 527 3887
available 24 hrs/7 days; multi-language response

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

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.
This material will support combustion.

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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LACTOSE	98 - 99.04	63-42-3 200-559-2	-	-	
Classification:	DSD: -				
	CLP: -				
ALBUTEROL SULFATE	0.96 - < 2	51022-70-9 256-916-8	-	-	
Classification:	DSD: Xn;R20/22				
	CLP: Acute Tox. 4;H302, Acute Tox. 4;H332				

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

SECTION 4: First aid measures

General information If you feel unwell, seek medical advice (show the label where possible).

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 This material will support combustion.

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.

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. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Ventilate closed spaces before entering them. 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 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 Stop the flow of material, if this is without risk. Following product recovery, flush area with water.

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

Minimise dust generation and accumulation. Do not taste or swallow. Avoid breathing dust. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the MSDS).

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

ALBUTEROL SULFATE
(CAS 51022-70-9)

8 HR TWA

10 mcg/m³

LACTOSE (CAS 63-42-3)

OHC

4

OHC

1

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

Solid.

Form	Solid.
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	Not available.
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	No relevant additional information available.

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.
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.
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
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
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
LACTOSE (CAS 63-42-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 10 g/kg
* 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 sensitisation	Due to lack of data the classification is not possible.	
Skin sensitisation	Not available.	
Germ cell mutagenicity	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
Germ cell mutagenicity		
Mutagenicity		
ALBUTEROL SULFATE	Ames	Result: negative
	Chromosomal Aberration Assay In Vitro	Result: negative
	Mouse micronucleus test	Result: negative
Carcinogenicity		
ALBUTEROL SULFATE	This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA. Not classifiable as to carcinogenicity to humans.	
	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.	
Reproductive toxicity		
Reproductivity		
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	
	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.
Mixture versus substance information	Not available.
Other information	Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity

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.

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential Not available.

Partition coefficient n-octanol/water (log Kow) Not available.

Bioconcentration factor (BCF)

ALBUTEROL SULFATE 1 Calculated

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

ALBUTEROL SULFATE -1.6 - -1.15 Measured

LACTOSE 1 Calculated

Mobility in general

Volatility

Henry's law

ALBUTEROL SULFATE 0 atm m³/mol Calculated

LACTOSE < 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

12.5. Results of PBT and vPvB assessment Not available.

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. This material and its container must be disposed of as hazardous waste. Do not allow this material to drain into sewers/water supplies. Do not contaminate ponds, waterways or ditches with chemical or used container. Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

ADR	Not regulated as dangerous goods.
IATA	Not regulated as dangerous goods.
IMDG	Not regulated as dangerous goods.
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.

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**
Not listed.
- 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**
Not listed.
- 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.

Always applicable.

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

Not regulated.

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: Business Units
Composition / Information on Ingredients: Ingredients
Physical & Chemical Properties:
Regulatory Information: United States
GHS: Classification

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.