



SAFETY DATA SHEET

1. Identification

Product identifier	VENTODISK
Other means of identification	Not available.
Synonym(s)	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
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 (by country / geographic region):
Africa / EU / Israel / Middle East +44 (0) 1235 239 670
(English / European languages): +65 3158 1074
Asia Pacific (except China): +86 10 5100 3039
China: +44 (0) 1235 239 671
Middle East / Africa (Arabic-speaking countries): +1 703 527 3887
US:
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

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
LACTOSE	D-LACTOSE 4-O-BETA-D-GLACTOPYRANOSYL-D-GLUC MILK SUGAR SACCHARUM LACTIS LACTOBIOSE LACTIN 4-(BETA-D-GALACTOSIDO)-D-GLUCOSE L-5 BP-680 D-(+)-LACTOSE C12H22O11 OHS12415 RTECS OD9625000	63-42-3	98 - 99.04
ALBUTEROL SULFATE	386 (GW ACN) ALBUTEROL SULPHATE SALBUTAMOL HEMISULPHATE AH 3365F SALBUTAMOL SULPHATE BIS[(TERT-BUTYL)(BETA,3,4-TRIHIDROXY	51022-70-9	0.96 - < 2

*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. 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.
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	Provide general supportive measures and treat symptomatically.
General information	If you feel unwell, seek medical advice (show the label where possible).

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	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	Cool containers exposed to flames with water until well after the fire is out.

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 personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ventilate closed spaces before entering them. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.
Methods and materials for containment and cleaning up	Stop the flow of material, if this is without risk. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water. For waste disposal, see section 13 of the MSDS.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Minimize 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.
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).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components

Components	Type	Value
ALBUTEROL SULFATE (CAS 51022-70-9)	8 HR TWA	10 mcg/m3
	OHC	4
LACTOSE (CAS 63-42-3)	OHC	1

Biological limit values

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

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

Wear safety glasses with side shields (or goggles).

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.

Other

Wear suitable protective clothing.

Respiratory protection

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators.

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.

9. Physical and chemical properties

Appearance

Physical state

Solid.

Form

Solid.

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

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.

Explosive limit - lower (%)

Not available.

Explosive limit - upper (%)

Not available.

Vapor pressure

Not available.

Vapor 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.

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.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. Toxicological information

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 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
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 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.

ALBUTEROL SULFATE

Ames
 Result: Negative
 Chromosomal Aberration Assay In Vitro
 Result: Negative
 Mouse micronucleus test
 Result: Negative

Carcinogenicity

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

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.

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.

Further information Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity

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

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

ALBUTEROL SULFATE 1.3 - 38.7 %, 64 days

Bioaccumulative potential Not available.

Bioconcentration factor (BCF)

ALBUTEROL SULFATE 1 Calculated

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

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions	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.
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).
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	Not regulated as a dangerous good.
IATA	Not regulated as a dangerous good.
IMDG	Not regulated as a dangerous good.
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.

15. Regulatory information

US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)	Not regulated.
CERCLA Hazardous Substance List (40 CFR 302.4)	Not listed.
US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)	Not listed.
SARA 304 Emergency release notification	Not regulated.
Superfund Amendments and Reauthorization Act of 1986 (SARA)	
Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No
SARA 302 Extremely hazardous substance	No

SARA 311/312 Hazardous chemical No

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.

DEA Essential Chemical Code Number

Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

US. Pennsylvania RTK - Hazardous Substances

Not regulated.

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 this product complies 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 05-30-2013

Revision date 05-30-2013

Version # 09

Further information This material has not been assessed for HMIS or NFPA ratings.

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