

1. Identification

Product identifier VENTOLIN ACCUHALER

Other means of identification Not available.

Synonym(s) VENTOLIN ACCUHALER 200 MCG, 60 DOSE * AEROLIN DISKUS * SULTANOL DISKUS * VENTILAN DISKUS * VENTOLIN DISKUS * VENTOLINE DISKUS * 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

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
ALBUTEROL SULFATE	386 (GW ACN) ALBUTEROL SULPHATE SALBUTAMOL HEMISULPHATE AH 3365F SALBUTAMOL SULPHATE BIS[(TERT-BUTYL)(BETA,3,4-TRIHYDROXY	51022-70-9	1.9
Other components below reportable levels			98.1

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation

In case of accident by inhalation: remove casualty to fresh air and keep at rest. If not breathing, give artificial respiration. Oxygen or artificial respiration if needed. Do not use mouth-to-mouth method if victim inhaled the substance. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Get medical attention immediately.

Skin contact

Immediately flush with plenty of water for at least 15 minutes while removing contaminated clothing and shoes. Get medical attention immediately.

Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	Call a physician or poison control center immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.
Most important symptoms/effects, acute and delayed	The following adverse effects have been noted with therapeutic use of this material: tremor; headache; palpitations; muscle cramps; increased heart rate; increased blood pressure; changes in clinical chemistry parameters.
Indication of immediate medical attention and special treatment needed	In case of shortness of breath, give oxygen. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Pre-placement and periodic health surveillance is not usually indicated. The final determination of the need for health surveillance should be determined by local risk assessment.

5. Fire-fighting measures

Suitable extinguishing media	Water fog. Foam. Dry chemical powder.
Unsuitable extinguishing media	Carbon dioxide (CO2).
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	In the event of fire, cool tanks with water spray.
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. Keep out of low areas. Wear appropriate personal protective equipment. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust. 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. Use only outdoors or in a well-ventilated area. 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

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

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. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Chemical goggles are recommended. Wear a full-face respirator, if needed. Eye wash fountain is recommended.
Hand protection	The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present.

Other	Wear chemical protective equipment that is specifically recommended by the manufacturer. It may provide little or no thermal protection.
Respiratory protection	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	Wash hands after handling and before eating.

9. Physical and chemical properties

Appearance

Physical state	Solid.
Form	Powder.
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. Avoid heat, sparks, open flames and other ignition sources.
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	Harmful if swallowed. Health injuries are not known or expected under normal use.
Inhalation	Harmful if inhaled. Health injuries are not known or expected under normal use.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Direct contact with eyes may cause temporary irritation.

Symptoms related to the physical, chemical and toxicological characteristics

The following adverse effects have been noted with therapeutic use of this material: tremor; headache; muscle cramps; increased heart rate; increased blood pressure; palpitations; changes in clinical chemistry parameters.

Information on toxicological effects**Acute toxicity**

Harmful if inhaled. Harmful if swallowed. Health injuries are not known or expected under normal use.

Components**Species****Test Results**

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/eye irritation

Avoid contact with eyes.

Respiratory sensitization

None known.

Skin sensitization

Health injuries are not known or expected under normal use.

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

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

None known.

Specific target organ toxicity - repeated exposure	None known.
Aspiration hazard	Not likely, due to the form of the product.
Chronic effects	Prolonged inhalation may be harmful.
Further information	Caution - Pharmaceutical agent.

12. Ecological information

Ecotoxicity	No information is available about the potential of this product to produce adverse environmental effects.
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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
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Biodegradability

Percent degradation (Aerobic biodegradation-soil)

ALBUTEROL SULFATE	1.3 - 38.7 %, 64 days
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Bioaccumulative potential

Bioconcentration factor (BCF)

ALBUTEROL SULFATE	1 Calculated
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Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

ALBUTEROL SULFATE	-1.6 - -1.15 Measured
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Mobility in general

Volatility

Henry's law

ALBUTEROL SULFATE	0 atm m ³ /mol Calculated
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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.
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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.
Local disposal regulations	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).

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****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 - Yes
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.

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

Country(s) or region	Inventory name	On inventory (yes/no)*
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, including date of preparation or last revision

Issue date	10-11-2013
Revision date	10-11-2013
Version #	08
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