

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

### 1.1. Product identifier

**Trade name or designation of the mixture** VENTOLIN INJECTION

**Registration number** -

**Synonyms** VENTOLIN INJECTION 50 MCG/ML \* VENTOLIN INJECTION 500 MCG/ML \* VENTOLIN AMPUL \* VENTOLIN AMPULES \* VENTOLIN BOLUS INJECTION \* VENTOLIN INJECTIE INJECTIEVLOEISTOF \* VENTOLIN INJECTABLE \* VENTOLIN SOLUCION INYECTABLE \* AEROLIN INJECTION \* SALBUMOL INJECTION \* SULTANOL AMPULLE \* VENTILAN INJECTION \* VENTOLINE INJECTION \* ALBUTEROL SULFATE (SALBUTAMOL SULPHATE), FORMULATED PRODUCT

**Issue date** 11-July-2013

**Version number** 11

**Revision date** 11-July-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::  
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

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.

## 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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Sodium chloride	0.89	7647-14-5 231-598-3	-	-	
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**Classification:** **DSD:** -

**CLP:** -

ALBUTEROL SULFATE	0.06	51022-70-9 256-916-8	-	-	
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**Classification:** **DSD:** Xn;R20/22

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

Other components below reportable levels 99.05

## 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 product is expected to be non-combustible.

### 5.1. Extinguishing media

**Suitable extinguishing media** Water fog. Foam. Dry chemical powder. Carbon dioxide (CO<sub>2</sub>).

**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. 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

<b>7.1. Precautions for safe handling</b>	Do not taste or swallow. Avoid breathing vapour. Avoid contact with skin. Avoid contact with eyes. Avoid prolonged exposure. Avoid contact with clothing. 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. Wash contaminated clothing before reuse.
<b>7.2. Conditions for safe storage, including any incompatibilities</b>	Store locked up. 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).
<b>7.3. Specific end use(s)</b>	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

OHC

4

Sodium chloride (CAS  
7647-14-5)

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

Liquid.

<b>Form</b>	Liquid.
<b>Colour</b>	Not available.
<b>Odour</b>	Not available.
<b>Odour threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Vapour pressure</b>	Not available.
<b>Vapour density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not available.
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Explosive properties</b>	Not available.
<b>Oxidizing properties</b>	Not available.
<b>9.2. Other information</b>	No relevant additional information available.

## SECTION 10: Stability and reactivity

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

## SECTION 11: Toxicological information

<b>General information</b>	Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.
<b>Information on likely routes of exposure</b>	
<b>Ingestion</b>	Health injuries are not known or expected under normal use.
<b>Inhalation</b>	Health injuries are not known or expected under normal use.
<b>Skin contact</b>	Health injuries are not known or expected under normal use.
<b>Eye contact</b>	Health injuries are not known or expected under normal use.
<b>Symptoms</b>	The following adverse effects have been noted with therapeutic use of this material: headache; changes in blood pressure; altered heart rate and pulse.
<b>11.1. Information on toxicological effects</b>	
<b>Acute toxicity</b>	Health injuries are not known or expected under normal use.

Components	Species	Test results
ALBUTEROL SULFATE (CAS 51022-70-9)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	660 mg/kg
<b>Chronic</b>		
<i>Oral</i>		
LOEL	Dog	2 mg/kg/day, 1 years
<b>Subacute</b>		
<i>Oral</i>		
LOEL	Rat	30 mg/kg/day, 30 Day
<b>Subchronic</b>		
<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
Sodium chloride (CAS 7647-14-5)		
<b>Acute</b>		
<i>Oral</i>		
LD50	Rat	3000 mg/kg
* Estimates for product may be based on additional component data not shown.		
<b>Skin corrosion/irritation</b>	Health injuries are not known or expected under normal use.	
<b>Serious eye damage/eye irritation</b>	Not available.	
<b>Respiratory sensitisation</b>	Due to lack of data the classification is not possible.	
<b>Skin sensitisation</b>	Not available.	
<b>Germ cell mutagenicity</b>	No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.	
<b>Germ cell mutagenicity</b>		
<b>Mutagenicity</b>		
ALBUTEROL SULFATE	Ames Result: negative Chromosomal Aberration Assay In Vitro Result: negative Mouse micronucleus test Result: negative	
<b>Carcinogenicity</b>	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	
<b>Reproductive toxicity</b>	Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.	
<b>Reproductive toxicity</b>		
<b>Reproductivity</b>		
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	

<b>Specific target organ toxicity - single exposure</b>	Heart.
<b>Specific target organ toxicity - repeated exposure</b>	Heart.
<b>Aspiration hazard</b>	Due to lack of data the classification is not possible.
<b>Mixture versus substance information</b>	Not available.
<b>Other information</b>	Caution - Pharmaceutical agent.

## SECTION 12: Ecological information

### 12.1. Toxicity

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
Sodium chloride (CAS 7647-14-5)			
Aquatic			
Acute			
Algae	EC50	Algae (Nitscheria linearis)	2430 mg/l, 5 days
Crustacea	EC50	Water flea (Daphnia magna)	3310 mg/l, 48 hours, Static test
Fish	EC50	Bluegill sunfish (Juvenile Lepomis macrochirus)	1295 mg/l, 96 hours, Static test
		Fathead minnow (Juvenile Pimephales promelas)	6390 mg/l, 96 hours, Static test
		Goldfish (Adult Carassius auratus)	7000 mg/l, 96 hours
		Mosquito fish (Adult Gambusia affinis)	17550 mg/l, 96 hours, Static test

\* 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

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<sup>3</sup>/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** 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

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

#### **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.