

1. Identification

Product identifier	VENTOLIN SYRUP
Other means of identification	Not available.
Synonym(s)	AEROLIN ORAL SOLUTION 2 MG/5 ML * VENTILAN ORAL SOLTION 2 MG/5 ML * VENTOLIN SYRUP 2 MG/5 ML * VENTOLINE SIROP 2 MG/5 ML * SULTANOL SIROP 2 MG/5 ML * FORMULA CODE B052 * VENTOLIN ELIXIR * VENTOLIN LIQUID * VENTOLIN ORAL LIQUID * SULTANOL SAFT * SULBUTAN ORAL SOLUTION * VENTILAN SOLUCION * VENTORLIN ORAL SOLUTION * 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
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 Research Triangle Park, NC 27709 USA
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 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	%
HYDROUS CITRIC ACID	2-HYDROXY-1,2,3-PROPANETRICARBOXY ACID, MONOHYDRATE CITRIC ACID, MONOHYDRATE CITRIC ACID MONOHYDRATE C6H10O8 OHS84211 RTECS GE7810000	5949-29-1	< 1

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
HYDROXYPROPYL METHYL CELLULOSE	METHOCEL K4M	9004-65-3	0.45
	GONIOSOL		
	ISOPRO ALKALINE		
	ISOPTO PLAIN		
	ISOPTO TEARS		
	METHOCEL E,F,K		
	METHOCEL HG		
	METHYL CELLULOSE PROPYLENE		
	GLYCOL ETHER		
	HYPROMELLOSE		
	TEARISOL		
	ULTRA TEARS		
	RTECS NF9125000		
	CELLULOSE, 2-HYDROXYPROPYL		
	METHYL ESTER		
	METHYLHYDROXYPROPYLCELLULOSE		
	PHARMACOAT 603		
SODIUM BENZOATE	BENZOIC ACID, SODIUM SALT BENZOATE OF SODA SODIUM BENZOIC ACID C7H6NaO2 OHS20965 RTECS DH6650000 GR 33388B 427 (GW ACN)	532-32-1	< 0.2
ALBUTEROL SULFATE	386 (GW ACN) ALBUTEROL SULPHATE SALBUTAMOL HEMISULPHATE AH 3365F SALBUTAMOL SULPHATE BIS[(TERT-BUTYL)(BETA,3,4-TRIHIDROXY	51022-70-9	0.05
Other components below reportable levels			90 - 100

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	Move container from fire area if it can be done without risk.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. For personal protection, see section 8 of the MSDS.
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Methods and materials 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. 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**

Do not taste or swallow. Avoid breathing mist or vapor. Avoid prolonged exposure. Provide adequate ventilation. 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

HYDROUS CITRIC ACID
(CAS 5949-29-1)

8 HR TWA

5000 mcg/m3

OHC

1

HYDROXYPROPYL
METHYL CELLULOSE
(CAS 9004-65-3)

OHC

1

SODIUM BENZOATE (CAS
532-32-1)

8 HR TWA

5000 mcg/m3

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**

If contact is likely, safety glasses with side shields are recommended.

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**

Liquid.

Form

Liquid.

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.
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Information on toxicological effects

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

Components	Species	Test Results
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
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)		
Acute		
<i>Oral</i>		
LD50	Rat	> 2000 mg/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.	
Maximisation assay (Magnusson and Kligman)		
HYDROXYPROPYL METHYL CELLULOSE		Result: Negative Species: Guinea pig
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			
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
HYDROXYPROPYL METHYL CELLULOSE (CAS 9004-65-3)			
Aquatic			
Acute			
Fish	EC50	Fish	> 100 mg/L, 96 hours
SODIUM BENZOATE (CAS 532-32-1)			
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 100 mg/L, 96 hours, Static test
Fish	EC50	Fathead minnow (Juvenile Pimephales promelas)	484 mg/L, 96 hours, Flow-through test

* 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

Percent degradation (Anaerobic biodegradation)

SODIUM BENZOATE 93 %, 7 days Other degradation test system, Mixed Residential/Industrial

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

HYDROXYPROPYL METHYL CELLULOSE -5
SODIUM BENZOATE 1.89

Bioconcentration factor (BCF)

ALBUTEROL SULFATE 1 Calculated
HYDROXYPROPYL METHYL CELLULOSE 3.2 Estimated

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

ALBUTEROL SULFATE -1.6 - -1.15 Measured
SODIUM BENZOATE 1.16 Calculated

Mobility in general

Volatility

Henry's law

ALBUTEROL SULFATE 0 atm m³/mol Calculated
HYDROXYPROPYL METHYL CELLULOSE 0 atm m³/mol Estimated

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.

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.

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)	No
Canada	Domestic Substances List (DSL)	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)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
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	07-15-2013
Revision date	07-15-2013
Version #	12
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: Multiple Properties Regulatory Information: United States