

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

1.1. Product identifier

Trade name or designation of the mixture	SEREVENT DISKUS
Registration number	-
Synonyms	SEREVENT DISKUS 50 MCG, 60 DOSE * SEREVENT ACCUHALER 50 MCG, 60 DOSE * AEROMAX DISKUS * SALMETEROL XINAFOATE (SALMETEROL HYDROXYNAPHTHOATE), FORMULATED PRODUCT
Issue date	08-October-2013
Version number	10
Revision date	08-October-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

This product will support combustion.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.

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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SALMETEROL XINAFOATE	0.58	94749-08-3	-	-	
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Classification: **DSD:** Xi;R36/38, N;R51/53
 CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319

Other components below reportable levels 99.42

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 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.

4.1. Description of 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. If breathing is difficult, trained personnel should give oxygen. 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 centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both 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.

4.3. Indication of any immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.

SECTION 5: Firefighting measures

General fire hazards This product will support combustion.

5.1. Extinguishing media

Suitable extinguishing media	Water. Foam. Dry chemical powder.
Unsuitable extinguishing media	Carbon dioxide (CO2).

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	Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk. In the event of fire, cool tanks with water spray.

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. Ensure adequate ventilation. 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 release to the environment. Contact local authorities in case of spillage to drain/aquatic environment. Prevent further leakage or spillage if safe to do so. Do not contaminate water. 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. Collect spillage. Prevent product from entering drains. 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

Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from heat and sources of ignition. Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. 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

SALMETEROL
XINAFOATE (CAS
94749-08-3)

8 HR TWA

1 mcg/m3

OHC

5

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

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

General information

Follow all local regulations if personal protective equipment (PPE) is used in the workplace.

Eye/face protection

If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

Skin protection

- 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. With respect to the above precautions 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

No personal respiratory protective equipment normally required. 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

Contain spills and prevent releases and observe national regulations on emissions. Environmental manager must be informed of all major releases.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance

Physical state

Solid.

Form

Powder.

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	Avoid heat, sparks, open flames and other ignition sources. 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.
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	Direct contact with eyes may cause temporary irritation.
Symptoms	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.

11.1. Information on toxicological effects

Acute toxicity	Health injuries are not known or expected under normal use.
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Components	Species	Test results
SALMETEROL XINAFOATE (CAS 94749-08-3)		
Acute		
<i>Inhalation</i>		
LC50	Rat	> 75 mg/l
<i>Oral</i>		
LD50	Rat	> 1000 mg/kg

Components	Species	Test results
Subchronic		
<i>Inhalation</i>		
LOEL	Rat	>= 0.16 mg/kg/day, 26 weeks, adrenergic effects
<i>Oral</i>		
NOAEL	Rat	0.2 mg/kg/day, 26 weeks, adrenergic effects
* 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.	
Corrosivity		
SALMETEROL XINAFOATE		Result: Irritant Species: Human
Serious eye damage/eye irritation	Avoid contact with eyes.	
Eye		
SALMETEROL XINAFOATE		OECD 405 Result: Severe Species: Rabbit
Respiratory sensitisation	Not available.	
Skin sensitisation	Health injuries are not known or expected under normal use.	
Maximisation assay (Magnusson and Kligman)		
SALMETEROL XINAFOATE		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.	
Germ cell mutagenicity		
Mutagenicity		
SALMETEROL XINAFOATE		Ames - Screen Result: negative Chromosomal aberration assay Result: negative GreenScreen Assay Result: negative HPRT gene mutation in human lymphocytes Result: negative High throughput fluctuation test (HTFT) Result: negative In vitro cytogenetic Assay Result: negative L5178Y mouse lymphoma thymidine kinase locus assay Result: negative Rat Micronucleus Assay Result: negative
Carcinogenicity	Not classifiable as to carcinogenicity to humans.	
SALMETEROL XINAFOATE		>= 0.15 mg/kg/day, Species-specific Result: positive Species: Rat Organ: Pituitary/ Uterus >= 1.4 mg/kg/day, Species-specific Result: positive Species: Mouse Organ: uterus
Reproductive toxicity	Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.	
Reproductive toxicity		
Reproductivity		
SALMETEROL XINAFOATE		0.1 mg/kg/day Reproductive performance and development of two untreated generations, NOEL Species: Rat Notes: GR33343X

Reproductivity
SALMETEROL XINAFOATE

1 mg/kg/day Reproductive performance and development of two untreated generations
Species: Rat
Organ: Skeletal effects
Notes: GR33343X
2 mg/kg/day Reproductive performance and development of two untreated generations, NOAEL
Species: Rat
Notes: GR33343G
≥ 1 mg/kg/day Embryo-foetal development- Oral,
Species-specific
Species: Rabbit
Organ: Skeletal effects, open eye, cleft palate
Notes: GR33343G

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.
Mixture versus substance information	No information available.
Other information	Caution - Pharmaceutical agent.

SECTION 12: Ecological information

12.1. Toxicity	No information is available about the potential of this product to produce adverse environmental effects. The product contains a substance which may cause long-term adverse effects in the environment.
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Components		Species	Test results
SALMETEROL XINAFOATE (CAS 94749-08-3)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 998 mg/l, 3 hours
Algae	EC50	Green algae (Scenedesmus subspicatus)	4 mg/l, 72 hours, Measured
	NOEC	Green algae (Scenedesmus subspicatus)	1.9 mg/l
Crustacea	EC50	Water flea (Daphnia pulex)	20 mg/l, 48 hours
	NOEC	Water flea (Daphnia pulex)	6.7 mg/l, 48 hours
Fish	EC50	Rainbow trout (Juvenile Oncorhyncus mykiss)	35 mg/l, 96 hours, Static renewal test
	NOEC	Rainbow trout (Juvenile Oncorhyncus mykiss)	7.5 mg/l
Chronic			
Crustacea	LOEC	Water flea (Ceriodaphnia dubia)	5 mg/l, 8 days, Static renewal test
	NOEC	Water flea (Ceriodaphnia dubia)	1.6 mg/l, 8 days
Terrestrial			
Acute			
Earthworm	EC50	Manure worm (Eisenia foetida)	334 mg/kg, 28 days
	NOEC	Manure worm (Eisenia foetida)	209 mg/kg, 28 days

* Estimates for product may be based on additional component data not shown.

12.2. Persistence and degradability

Persistence and degradability

Photolysis

UV/visible spectrum wavelength

SALMETEROL XINAFOATE 338 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

SALMETEROL XINAFOATE

> 1 years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

SALMETEROL XINAFOATE

50 %, 12.8 days Modified Zahn-Wellens, primary biodegradation, loss of parent.

Percent degradation (Aerobic biodegradation-soil)

SALMETEROL XINAFOATE

29.9 - 49.9 %, 64 days

12.3. Bioaccumulative potential

Partition coefficient

n-octanol/water (log K_{ow})

SALMETEROL XINAFOATE

2.1 (Measured).

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log K_{oc}

SALMETEROL XINAFOATE

3.84 - 4.52

Mobility in general

Distribution

Octanol/water distribution coefficient log D_{OW}

SALMETEROL XINAFOATE

1.32, pH 9

1.71, pH 7

2.06, pH 5

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.

Special precautions

Dispose in accordance with all applicable 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

Not listed.

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

Not listed.

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

R36/38 Irritating to eyes and skin.

R51/53 Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

R52/53 Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Revision information

Product and Company Identification: Product and Company Identification

Composition / Information on Ingredients: Ingredients

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.