SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation of the mixture	SEREVENT INHALATION AEROSOL
Registration number	-
Synonyms	SEREVENT INHALATION AEROSOL 25 MCG * SEREVENT INHALER 25 MCG, 120 DOSE * SEREVENT INHALER - HOSPITAL PACK 25 MCG, 60 DOSE * SALMETEROL XINAFOATE (SALMETEROL HYDROXYNAPHTHOATE), FORMULATED PRODUCT
Issue date	15-October-2013
Version number	14
Revision date	15-October-2013
Supersedes date	14-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 is non-flammable.
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
DICHLORODIFLUOROMETHANE	72.06	75-71-8 200-893-9	-	-	
Classification: **DSD:** -					
CLP: -					
FLUOROTRICHLOROMETHANE	27.89	75-69-4 200-892-3	-	-	
Classification: **DSD:** -					
CLP: -					
SALMETEROL XINAFOATE	0.05	94749-08-3 -	-	-	
Classification: **DSD:** Xi;R36/38, N;R51/53					
CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319					

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 Rinse mouth. Call a physician or poison control centre immediately. Only induce vomiting at the instruction of medical personnel. Never give anything by mouth to an unconsious 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 Aerosol containers may violently rupture when exposed to the heat of fire. This product is non-flammable.

5.1. Extinguishing media

Suitable extinguishing media Water. Foam. Dry chemical powder. Carbon dioxide (CO_2).

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 Use standard firefighting procedures and consider the hazards of other involved materials. 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. 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	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. Prevent product from entering drains. 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

7.1. Precautions for safe handling	Avoid prolonged exposure. Provide adequate ventilation. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.
7.2. Conditions for safe storage, including any incompatibilities	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	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

General information	Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if personal protective equipment (PPE) is used in the workplace.
Eye/face protection	Eye wash fountain is recommended. Chemical goggles 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	Aerosol
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

Percent volatile	100 % estimated

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	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. Occupational exposure to the substance or mixture may cause adverse effects.

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.

Components	Species	Test results
SALMETEROL XINAFOATE (CAS 94749-08-3)		
Acute		
Inhalation		
LC50	Rat	> 75 mg/l
Oral		
LD50	Rat	> 1000 mg/kg
Subchronic		
Inhalation		
LOEL	Rat	>= 0.16 mg/kg/day, 26 weeks, adrenergic effects
Oral		
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

Mutagenicity

SALMETEROL XINAFOATE

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
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.

Components		Species	Test results
DICHLORODIFLUOROMETHANE (CAS 75-71-8)			
Aquatic			
Acute			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	67 mg/l, 48 hours, Static renewal test
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

Components		Species	Test results
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

Half-life (Photolysis-atmospheric)

DICHLORODIFLUOROMETHANE > 300 years Measured

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 Kow)

DICHLORODIFLUOROMETHANE 2.16

FLUOROTRICHLOROMETHANE 2.53

SALMETEROL XINAFOATE 2.1 (Measured).

Bioconcentration factor (BCF)

DICHLORODIFLUOROMETHANE 2.3 - 10 Measured, Cyprinus carpio, carp

12.4. Mobility in soil

Adsorption

Soil/sediment sorption - log Koc

DICHLORODIFLUOROMETHANE 2.3 Estimated

SALMETEROL XINAFOATE 3.84 - 4.52

Mobility in general

Volatility

Henry's law

DICHLORODIFLUOROMETHANE 0.343 atm m3/mol Measured, 25 °C

Distribution

Octanol/water distribution coefficient log DOW

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

14.1. UN number	UN1950
14.2. UN proper shipping name	AEROSOLS
14.3. Transport hazard class(es)	2.2
Subsidiary class(es)	-
14.4. Packing group	Not available.
14.5. Environmental hazards	No
Tunnel code	E
Labels required	2.2
Additional information:	
LTD QTY index	LQ2
Special Provisions	190, 327, 601, 625

IATA

14.1. UN number	UN1950
14.2. UN proper shipping name	Aerosols, non-flammable
14.3. Transport hazard class(es)	2.2
Subsidiary class(es)	-
14.4. Packing group	Not available.
Labels required	2
Additional Information:	
Passenger & cargo	Allowed.
Packaging Instruction	203
Pkg Inst cargo only	203
Pkg Inst pasenger & cargo LQ	Y203
SP See 44	A98,A145,A167
Max net qty pkg	75 kg
Max net qty pkg cargo only	150 kg
Max net qty pkg LQ	30 kg G

IMDG

14.1. UN number	UN1950
14.2. UN proper shipping name	AEROSOLS
14.3. Transport hazard class(es)	2
Subsidiary class(es)	5A
14.4. Packing group	Not available.
14.5. Environmental hazards	
Marine pollutant	No
Labels required	2
14.6. Special precautions for user	Not available.

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.

ADR; IATA

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

DICHLORODIFLUOROMETHANE (CAS 75-71-8)
FLUOROTRICHLOROMETHANE (CAS 75-69-4)

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

DICHLORODIFLUOROMETHANE (CAS 75-71-8)
FLUOROTRICHLOROMETHANE (CAS 75-69-4)

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: Business Units Composition / Information on Ingredients: Disclosure Overrides Physical & Chemical Properties: TOXICOLOGICAL INFORMATION: ECOLOGICAL INFORMATION: TRANSPORT INFORMATION: 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.