



SAFETY DATA SHEET

1. Identification

Product identifier SEREVENT INHALATION AEROSOL
Other means of identification Not available.
Synonym(s) 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
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	%
DICHLORODIFLUOROMETHANE	CHLOROFLUOROCARBON 12 DICHLORODIFLUOROMETHANE(R-12) DICHLORODIFLUOROMETHANE (CCI2F2) DIFLUORODICHLOROMETHANE CF 12 FREON 12 CFC 12 RCRA U075 UN 1028 CCI2F2 OHS06880 RTECS PA8200000	75-71-8	72.06

Hazardous components			
Chemical name	Common name and synonyms	CAS number	%
FLUOROTRICHLOROMETHANE	TRICHLOROMONOFUOROMETHANE MONOFUOROTRICHLOROMETHANE TRICHLOROFLUOROMETHANE FLUOROCHLOROFORM FREON 11 F 11 FC 11 CFC 11 RCRA U121 CCI3F OHS09990 RTECS PB6125000 CFC-11 (TRICHLOROFLUOROMETHANE) CFC11 FLUORITRIKLOORIMETAANI FLUOROTRICLOROMETANO HFO-11 METHANE, TRICHLOROFLURO TRICHLOROFLUORMETHANE TRICHLOROMONOFUORO-METHANE TRICLOROFLUORMETANO TRIKLORFLUORMETAN (KFK-11)	75-69-4	27.89
SALMETEROL XINAFOATE	GR 33343G SALMETEROL HYDROXYNAPHTHOATE 4-HYDROXY-ALPHA'-(((6-(4-PHENYLBUTO) 1-HYDROXY-2-NAPHTHALENECARBOXYL 144 (GW ACN)	94749-08-3	0.05

*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. 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 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	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the local poison control information centre.
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.

5. Fire-fighting measures

Suitable extinguishing media	Water. 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	Use standard firefighting procedures and consider the hazards of other involved materials. Move containers from fire area if you can do so without risk.
Specific methods	Move containers from fire area if you can do so without risk.

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. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. 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. Prevent entry into waterways, sewer, basements or confined areas. 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 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.

7. Handling and storage**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.

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).

8. Exposure controls/personal protection**Occupational exposure limits****GSK****Components****Type****Value**

SALMETEROL
XINAFOATE (CAS
94749-08-3)

8 HR TWA

1 mcg/m³

OHC

5

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)**Components****Type****Value**

DICHLORODIFLUOR
OMETHANE (CAS 75-71-8)

PEL

4950 mg/m³

1000 ppm

FLUOROTRICHLORO
METHANE (CAS 75-69-4)

PEL

5600 mg/m³

1000 ppm

US. ACGIH Threshold Limit Values**Components****Type****Value**

DICHLORODIFLUOR
OMETHANE (CAS 75-71-8)

TWA

1000 ppm

FLUOROTRICHLORO
METHANE (CAS 75-69-4)

Ceiling

1000 ppm

US. NIOSH: Pocket Guide to Chemical Hazards**Components****Type****Value**

DICHLORODIFLUOR
OMETHANE (CAS 75-71-8)

TWA

4950 mg/m³

1000 ppm

FLUOROTRICHLORO
METHANE (CAS 75-69-4)

Ceiling

5600 mg/m³

1000 ppm

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**

Eye wash fountain is recommended. Chemical goggles are 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 suitable protective clothing.

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	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	Solid.
Form	Aerosol.
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.
Other information	
Percent volatile	100 % estimated

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	Hazardous polymerization does not occur.
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 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 Health injuries are not known or expected under normal use.

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
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 sensitization None known.

Skin sensitization 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.

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.

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.

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. 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			
<i>Acute</i>			
Fish	EC50	Orange-red killfish (Adult Oryzias latipes)	67 mg/L, 48 hours, Static renewal test
SALMETEROL XINAFOATE (CAS 94749-08-3)			
Aquatic			
<i>Acute</i>			
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
<i>Chronic</i>			
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			
<i>Acute</i>			
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.

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-soil)

SALMETEROL XINAFOATE 29.9 - 49.9 %, 64 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

SALMETEROL XINAFOATE 2.1 (Measured).

DICHLORODIFLUOROMETHANE 2.16

FLUOROTRICHLOROMETHANE 2.53

Bioconcentration factor (BCF)

DICHLORODIFLUOROMETHANE 2.3 - 10 Measured, Cyprinus carpio, carp

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

Other adverse effects Not available.

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.

US RCRA Hazardous Waste U List: Reference

DICHLORODIFLUOROMETHANE (CAS 75-71-8) U075

FLUOROTRICHLOROMETHANE (CAS 75-69-4) U121

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

UN number UN1950
UN proper shipping name Aerosols, non-flammable
Transport hazard class(es) 2.2
Subsidiary class(es) Not available.
Packing group Not available.
Special precautions for user Not available.
Labels required 2.2

Packaging exceptions	306
Packaging non bulk	None
Packaging bulk	None
Qty limits cargo	150 kg
Qty limits passenger	75 kg

IATA

UN number	UN1950
UN proper shipping name	Aerosols, non-flammable
Transport hazard class(es)	2.2
Subsidiary class(es)	-
Packaging group	Not available.
Labels required	2
ERG Code	2L
Passenger & cargo	Allowed.
Additional Information:	
Packaging Instruction	203
Pkg Inst cargo only	203
Pkg Inst passenger & cargo	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

UN number	UN1950
UN proper shipping name	AEROSOLS
Transport hazard class(es)	2
Subsidiary class(es)	5A
Packaging group	Not available.
Environmental hazards	
Marine pollutant	No
Labels required	2
EmS	Not available.
Special precautions for user	Not available.

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.

DOT



IATA



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)

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

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

US. New Jersey Worker and Community Right-to-Know Act

DICHLORODIFLUOROMETHANE (CAS 75-71-8) 500 lbs
 FLUOROTRICHLOROMETHANE (CAS 75-69-4) 500 lbs

US. Pennsylvania RTK - Hazardous Substances

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

US. Rhode Island RTK

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

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

Country(s) or region	Inventory name	On inventory (yes/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 10-15-2013

Revision date 10-15-2013

Version # 14

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: Disclosure Overrides
Physical & Chemical Properties:
Toxicological Information:
Ecological Information:
Transport Information:
Regulatory Information: United States