SAFETY DATA SHEET

1. Identification

Product identifier **SEREVENT DISKHALER**

Other means of identification

Synonyms SEREVENT DISKHALER 50 MCG * BETAMICAN ACCUHALER * SEREVENT 50 ROTADISK * セレベント50ロタディスク * SEREVENT ROTADISK ΣΚΌΝΗ ΓΙΑ ΕΙΣΠΝΟΉ * BEGLAN ACCUHALER * BEGLAN ACCUHALER 50 MICROGRAMOS, POLVO PARA INHALACIÓN * SEREVENT DISKHALER - HOSPITAL PACK 50 MCG * SALMETEROL XINAFOATE, FORMULATED PRODUCT

Recommended use Medicinal Product.

This safety data sheet (SDS) has been prepared in accordance with workplace safety standards which require identification of all known hazards of the material regardless of potential risk. The information is intended for people handling the material in the workplace. Warnings included may not apply in all cases. Needs may vary depending upon the potential for exposure in the workplace. The SDS is not intended to provide information relevant to final use of the material for the purpose intended. Consumers/Patients should consult prescribing information/package insert/product label or consult their chemist or physician.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

COMPANY NAME GlaxoSmithKline US

Address: 5 Moore Drive
Research Triangle Park, NC 27709 USA

Telephone: +1-888-825-5249 (General Inquiries)

Email: msds@gsk.com

Website: www.gsk.com

EMERGENCY CONTACTS

VERISK 3E GLOBAL INCIDENT RESPONSE

Telephone: +(1) 760 476 3971 (In country)
+(1) 760 476 3962 or +(1) 866 519 4752 (International)
24/7; multi-language response

Contract Number: 334878

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Not classified.

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements

Hazard symbol None.

Signal word None.

Hazard statement The mixture does not meet the criteria for classification.

Precautionary statement

Prevention Not available.

Response Not available.

Storage Not available.

Disposal Not available.

Hazard(s) not otherwise classified (HNOC) Caution - Pharmaceutical agent. See section 11 of the SDS for additional information on health hazards.

Supplemental information 99.7% of the mixture consists of component(s) of unknown acute dermal toxicity. 99.7% of the mixture consists of component(s) of unknown acute inhalation toxicity. 99.7% of the mixture consists of component(s) of unknown acute hazards to the aquatic environment. 99.7% of the mixture consists of component(s) of unknown long-term hazards to the aquatic environment.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
SALMETEROL XINAFOATE	GR 33343G SALMETEROL HYDROXYNAPHTHOATE 4-HYDROXY- ALPHA'- (((6- (4-PHENYLBUTOXY)HEXYL)AMINO)METHYL)-1,3 -BENZENEDIMETHANOL, 1-HYDROXY-2-NAPHTHALENECARBOXYLATE	94749-08-3	0.3
Other components below reportable levels			99.7

4. First-aid measures

Inhalation If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop. Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist.

Skin contact Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if irritation develops and persists.

Eye contact Do not rub eyes. Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician. Rinse with water. Get medical attention if irritation develops and persists.

Ingestion If swallowed: Immediately call a poison center or doctor/physician. Rinse mouth. Do not induce vomiting without advice from poison control center.

Most important symptoms/effects, acute and delayed The following adverse effects have been noted with therapeutic use of this material: tremor; palpitations; muscle cramps; increased heart rate; increased blood pressure. Headache.

Indication of immediate medical attention and special treatment needed Treat symptomatically. No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.

General information IF exposed or concerned: Get medical advice/attention. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

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 Move containers from fire area if you can do so without risk. Use water spray to cool unopened containers.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Wear appropriate protective equipment and clothing during clean-up. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Avoid the generation of dusts during clean-up. Collect dust using a vacuum cleaner equipped with HEPA filter. Stop the flow of material, if this is without risk.

Large Spills: Wet down with water and dike for later disposal. Shovel the material into waste container. Following product recovery, flush area with water.

Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal. For waste disposal, see section 13 of the SDS.

Environmental precautions Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid prolonged exposure. Practice good housekeeping.

Conditions for safe storage, including any incompatibilities Store in tightly closed container. Store in a well-ventilated place. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known 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).

Exposure guidelines

Appropriate engineering controls Ventilate as needed to control airborne dust. Use explosion-proof ventilation equipment if airborne dust levels are high. Good general ventilation 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. If engineering measures are not sufficient to maintain concentrations of dust particulates below the Occupational Exposure Limit (OEL), suitable respiratory protection must be worn. 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 Not normally needed. If contact is likely, safety glasses with side shields are recommended.

Skin protection

Hand protection Not normally needed. For prolonged or repeated skin contact use suitable protective gloves.

Other Not normally needed. Wear suitable protective clothing as protection against splashing or contamination.

Respiratory protection No personal respiratory protective equipment normally required. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. 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. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance

Physical state Solid.

Form Powder.Inhaler.

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

Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Oxidizing properties	Not oxidizing.

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 product's decomposition. No hazardous decomposition products are known.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Health injuries are not known or expected under normal use.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	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: tremor; muscle cramps; increased heart rate; increased blood pressure; palpitations. Headache.

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

Skin corrosion/irritation No adverse effects due to skin contact are expected.

Irritation Corrosion - Skin

SALMETEROL XINAFOATE	Acute dermal irritation; OECD 404 Result: Slightly irritating. Species: Rabbit

Irritation Corrosion - Skin

SALMETEROL XINAFOATE	Occupational exposure. Result: Irritating to skin. Species: Human

Serious eye damage/eye irritation Direct contact with eyes may cause temporary irritation.

Eye

SALMETEROL XINAFOATE	OECD 405 Result: Severe Species: Rabbit

Respiratory or skin sensitization

Respiratory sensitization Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin sensitization This product is not expected to cause skin sensitization.

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

Mutagenicity

SALMETEROL XINAFOATE	Ames - Screen Result: Negative Chromosomal aberration assay Result: Negative GreenScreen Assay Result: Negative High throughput fluctuation test (HTFT) Result: Negative HPRT gene mutation in human lymphocytes Result: Negative In vitro cytogenetic Assay Result: Negative L5178Y mouse lymphoma thymidine kinase locus assay Result: Negative Rat Micronucleus Assay Result: Negative

Carcinogenicity No data available to indicate product or any components present at greater than 0.1% are carcinogenic. Carcinogenic effects are not expected as a result of occupational exposure.

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

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Reproductivity

SALMETEROL XINAFOATE	>= 1 mg/kg/day Embryo-foetal development- Oral, Species-specific Species: Rabbit Organ: Skeletal effects, open eye, cleft palate Notes: GR33343G 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

Specific target organ toxicity - single exposure Not assigned. Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure Not assigned. Based on available data, the classification criteria are not met.

Aspiration hazard Not an aspiration hazard.

Chronic effects Prolonged inhalation may be harmful.

Further information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity Contains a substance which causes risk of hazardous effects to the environment.

Components		Species	Test Results
SALMETEROL XINAFOATE (CAS 94749-08-3)			
Aquatic			
Acute			
Activated Sludge Respiration	IC50	Residential sludge	> 998 mg/l, 3 hours OECD 209
Algae	EC50	Green algae (Scenedesmus subspicatus)	4 mg/l, 72 hours Measured, OECD 201
	NOEC	Green algae (Scenedesmus subspicatus)	1.9 mg/l
Crustacea	EC50	Water flea (Daphnia pulex)	20 mg/l, 48 hours OECD 202
	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, OECD 203
	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, EPA Method 1002
	NOEC	Water flea (Ceriodaphnia dubia)	1.6 mg/l, 8 days
Terrestrial			
Acute			
Earthworm	EC50	Manure worm (Eisenia foetida)	334 mg/kg, 28 days OECD 222
	NOEC	Manure worm (Eisenia foetida)	209 mg/kg, 28 days

Persistence and degradability No data is available on the degradability of this product.

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

Bioaccumulative potential Not available.

Partition coefficient n-octanol / water (log Kow)

SALMETEROL XINAFOATE	2.1 (Measured).

Mobility in soil No data available.

Adsorption

Soil/sediment sorption - log Koc

SALMETEROL XINAFOATE	3.84 - 4.52

Mobility in general Not available.

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. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable 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.

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 Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

14. Transport information

DOT

Not regulated as a dangerous good.

Read safety instructions, SDS and emergency procedures before handling.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical No

SARA 313 (TRI reporting)

Not regulated.

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.

US state regulations

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. For more information go to www.P65Warnings.ca.gov.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Industrial Chemicals (AICIS)	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
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
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 05-21-2018

Revision date 05-11-2022

Version # 11

HMIS® ratings Health: 2*
Flammability: 0
Physical hazard: 0

NFPA ratings Health: 2
Flammability: 0
Instability: 0

List of abbreviations AICIS: Australian Inventory of Industrial Chemicals.

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 This document has undergone significant changes and should be reviewed in its entirety.