SAFETY DATA SHEET

1. Identification

Product identifier **ADVAIR DISKUS**

Other means of identification Not available.

Synonym(s) ADVAIR DISKUS 50/100 MCG * ADVAIR DISKUS 50/250 MCG * ADVAIR DISKUS 50/500 MCG * SERETIDE ACCUHALER 100, 60 DOSE * SERETIDE ACCUHALER 250, 60 DOSE * SERETIDE ACCUHALER 500, 60 DOSE * SERETIDE DISKUS * SERETAIDE DISKUS * VIANI MITE 50 MCG/100 MCG DISKUS * VIANI 50 MCG/250 MCG DISKUS * VIANI FORTE 50 MCG/500 MCG DISKUS * SALMETEROL XINAFOATE (SALMETEROL HYDROXYNAPHTHOATE) AND FLUTICASONE PROPIONATE, 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	%
FLUTICASONE PROPIONATE	CCI18781 FLUTICASONE THIOACID PROPIONATE ANDROSTA-1,4-DIENE-17-CARBOTHIOIC ACID, 6,9-DIFLUORO-11-HYDROXY-16-METHYL-3 S-(FLUOROMETHYL)ESTER, (6ALPHA,11BETA, 16 ALPHA, 17ALPHA)- FLUTICASONE 17-PROPIONATE (6ALPHA,11BETA,16ALPHA, 17ALPHA)-6,9-DIFLUORO-11-HYDROXY-16 -DIENE-17-CARBOTHIOIC ACID S-(FLUOROMETHYL) ESTER S-FLUOROMETHYL 6ALPHA,9ALPHA-DIFLUORO-11BETA-HYDI S-FLUOROMETHYL 6 ALPHA, 9 ALPHA-DIFLUORO-11 BETA-HYDROXY-16 ALPHA-METHYL-3-OXO-17 ALPHA-PROIONYLOXYANDRIOSTA-1,4-DI(BETA-CARBOTHIOATE 151 (GW ACN) RTECS BV7980000 (6ALPHA,11BETA,16ALPHA, 17ALPHA)-6,9-DIFLUORO-17-{[(FLUOROME PROPANOATE	80474-14-2	0.8 - 4.0
SALMETEROL XINAFOATE	GR 33343G SALMETEROL HYDROXYNAPHTHOATE 4-HYDROXY-ALPHA'-(((6-(4-PHENYLBUTO) 1-HYDROXY-2-NAPHTHALENECARBOXYL) 144 (GW ACN)	94749-08-3	0.6
Other components below reportable levels			>95.0

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation If dust from the material is inhaled, remove the affected person immediately 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 thoroughly with plenty of water for at least 15 minutes and consult a physician.

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: increased susceptibility to infection; headache; inflamed nasal cavity; back pain; joint pain; coughing; nausea; vomiting.

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. Foam. Dry chemical powder.

Unsuitable extinguishing media Carbon dioxide (CO2).

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. In the event of fire, cool tanks with water spray. Move containers from fire area if you can do so without risk.

Specific methods Cool containers exposed to flames with water until well after the fire is out.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the MSDS.

Methods and materials for containment and cleaning up

Minimize dust generation and accumulation. Collect spillage. If sweeping of a contaminated area is necessary use a dust suppressant agent which does not react with the product. Sweep up or vacuum up spillage and collect in suitable container for disposal. Collect dust using a vacuum cleaner equipped with HEPA filter. Prevent product from entering drains. Following product recovery, flush area with water. 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

Minimize dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with skin and eyes. Avoid prolonged exposure. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Practice good housekeeping. Avoid release to the environment. Do not empty into drains.

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 in a well-ventilated place. Guard against dust accumulation of this material. Store away from incompatible materials (see Section 10 of the MSDS).

8. Exposure controls/personal protection

Occupational exposure limits

GSK

Components	Type	Value	Note
FLUTICASONE PROPIONATE (CAS 80474-14-2)	8 HR TWA	3 mcg/m3	
	OHC	4	SKIN
		4	REPRODUCTIVE HAZARD
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).

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. 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

Use tight fitting goggles if dust is generated.

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

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. 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

Powder.

Color

White.

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	Avoid heat, sparks, open flames and other ignition sources. 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. Inhalation of dusts may cause respiratory irritation.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Dust in the eyes will cause irritation. 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: increased susceptibility to infection; headache; inflamed nasal cavity; back pain; joint pain; coughing; nausea; vomiting.

Information on toxicological effects

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

Components	Species	Test Results
FLUTICASONE PROPIONATE (CAS 80474-14-2)		
Acute		
Oral		
LD50	Rat	> 1000 mg/kg
Subacute		
Inhalation		
NOAEL	Rat	0.2 mcg/L/day, 28 Day

Components	Species	Test Results
Subchronic		
Inhalation		
LOEL	Rat	3 mcg/kg/day, 26 weeks
NOAEL	Dog	68 mcg/kg/day, 26 weeks
	Rat	14 mcg/kg/day, 26 weeks
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

FLUTICASONE PROPIONATE	OECD 404 Result: Negative
SALMETEROL XINAFOATE	Result: Irritant Species: Human

Irritation Corrosion - Skin: P.I.I. value

FLUTICASONE PROPIONATE	0

Serious eye damage/eye irritation Dust in the eyes will cause irritation.

Eye

FLUTICASONE PROPIONATE	OECD 405 Result: Negative Species: Rabbit
SALMETEROL XINAFOATE	OECD 405 Result: Severe Species: Rabbit

Respiratory sensitization Due to lack of data the classification is not possible.

Skin sensitization Not available.

Maximisation assay (Magnusson and Kligman)

SALMETEROL XINAFOATE	Result: Negative Species: Guinea pig

Sensitization

FLUTICASONE PROPIONATE	0 % OECD 406 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.

FLUTICASONE PROPIONATE	Ames Result: Negative
SALMETEROL XINAFOATE	Ames - Screen Result: Negative
FLUTICASONE PROPIONATE	Bacterial High Throughput Fluctuation Test Result: Negative Chinese Hamster Ovarian Cell Test Result: Negative
SALMETEROL XINAFOATE	Chromosomal aberration assay Result: Negative GreenScreen Assay Result: Negative HPRT gene mutation in human lymphocytes Result: Negative

SALMETEROL XINAFOATE	High throughput fluctuation test (HTFT) Result: Negative In vitro cytogenetic Assay Result: Negative L5178Y mouse lymphoma thymidine kinase locus assay Result: Negative
FLUTICASONE PROPIONATE	Micronucleus Assay Result: Negative Species: Mouse Micronucleus Test Result: Negative Species: Mouse
SALMETEROL XINAFOATE	Rat Micronucleus Assay Result: Negative
FLUTICASONE PROPIONATE	SOS/umu Assay Result: Negative Yeast 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.

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
FLUTICASONE PROPIONATE	Inhalation Result: Negative Species: Rat dermal Result: Negative Species: Mouse oral Result: Negative Species: Mouse

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
FLUTICASONE PROPIONATE	100 mcg/kg/day Embryofetal Development Result: reduced foetal bodyweight, minor skeletal variations Species: Rat 100 mcg/kg/day Female fertility (Segment I) Result: reduced foetal bodyweight, minor skeletal variations Species: Rat
SALMETEROL XINAFOATE	2 mg/kg/day Reproductive performance and development of two untreated generations, NOAEL Species: Rat Notes: GR33343G
FLUTICASONE PROPIONATE	50 mcg/kg/day Pre- and Post-natal development Result: maternal toxicity Species: Rat
SALMETEROL XINAFOATE	>= 1 mg/kg/day Embryo-foetal development- Oral, Species-specific Species: Rabbit Organ: Skeletal effects, open eye, cleft palate Notes: GR33343G
FLUTICASONE PROPIONATE	>= 25.7 mcg/kg/day Embryofetal Development Result: maternal toxicity, reduced foetal body weight; no malformations or other variations Species: Rat

FLUTICASONE PROPIONATE	>= 45 mcg/kg/day Embryofetal Development Result: cleft palate Species: Mouse >= 50 mcg/kg/day Embryofetal Development Result: maternal toxicity; reduced foetal weight; foetal resorptions Species: Rabbit SAR / QSAR, Glucocorticoid

Specific target organ toxicity - single exposure Heart.

Specific target organ toxicity - repeated exposure May cause damage to organs through prolonged or repeated exposure. Adrenal glands. Bone tissue. Immune system.

Aspiration hazard Due to lack of data the classification is not possible.

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
FLUTICASONE PROPIONATE (CAS 80474-14-2)			
Acute			
	IC50	Activated sludge	> 1000 mg/l, 3 hours
Aquatic			
Acute			
Crustacea	EC50	Water flea (Daphnia magna)	> 0.55 mg/l, 48 hours, Static test
Terrestrial			
Acute			
Earthworm	EC50	Manure worm (Eisenia foetida)	> 1000 mg/kg, 28 days
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

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

Persistence and degradability

Photolysis

UV/visible spectrum wavelength

SALMETEROL XINAFOATE	338 nm

Hydrolysis

Half-life (Hydrolysis-neutral)

FLUTICASONE PROPIONATE	> 1 Years Measured
SALMETEROL XINAFOATE	> 1 Years Measured

Biodegradability

Percent degradation (Aerobic biodegradation-soil)

FLUTICASONE PROPIONATE	9 - 50 %, 64 days
SALMETEROL XINAFOATE	29.9 - 49.9 %, 64 days

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

SALMETEROL XINAFOATE	2.1 (Measured).
FLUTICASONE PROPIONATE	2.78

Mobility in soil

Adsorption

Sludge/biomass distribution coefficient - log Kd

FLUTICASONE PROPIONATE	3.13 - 3.55 Estimated

Soil/sediment sorption - log Koc

FLUTICASONE PROPIONATE	3.41 - 3.83 Measured
SALMETEROL XINAFOATE	3.84 - 4.52

Mobility in general

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.

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
NFPA ratings	Health: Flammability: Instability:

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

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

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

US - California Proposition 65 - CRT: Listed date/Developmental toxin

FLUTICASONE PROPIONATE (CAS 80474-14-2) Listed: May 15, 1998

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 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	12-03-2013
Revision date	12-03-2013

Version #	18
Further information	This material has not been assessed for HMIS or NFPA ratings.
NFPA ratings	Health: Flammability: Instability:
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: Reports Ecological Information: Reports Transport Information: Agency Name, Packaging Type, and Transport Mode Selection Regulatory Information: United States