SAFETY DATA SHEET

GlaxoSmithKline

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Material **ADVAIR DISKUS**

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 * SERETAIDE DISKUS * VIANI MITE 50 MCG/100 MCG DISKUS * VIANI 50 MCG/250 MCG DISKUS * VIANI FORTE 50 MCG/500 MCG DISKUS * NDC NO 0173-0695-00 * NDC NO 0173-0695-02 * NDC NO 0173-0696-00 * NDC NO 0173-0696-02 * NDC NO 0173-0697-00 * NDC NO 0173-0697-02 * SALMETEROL XINAFOATE (SALMETEROL HYDROXYNAPHTHOATE) AND FLUTICASONE PROPIONATE, FORMULATED PRODUCT

Company Name

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Multi-language response

2. HAZARDS IDENTIFICATION

Fire and Explosion Assume that this product is capable of sustaining combustion.

Health Caution - Potent pharmaceutical agent.
Health effects information is based on hazards of components.
May cause steroid withdrawal rash.

Environment No information is available about the potential of this product to produce adverse environmental effects.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS #	Percent	EC-No.
FLUTICASONE PROPIONATE	80474-14-2	0.8 to 4	
NON-HAZARDOUS INGREDIENTS	Unassigned	95.4 to 98.6	
SALMETEROL XINAFOATE	94749-08-3	0.6	

4. FIRST-AID MEASURES

Ingestion Never attempt to induce vomiting. Do not attempt to give any solid or liquid by mouth if the exposed subject is unconscious or semi-conscious. Wash out the mouth with water. If the exposed subject is fully conscious, give plenty of water to drink. Obtain medical attention.

Inhalation Physical form suggests that risk of inhalation exposure is negligible.

Skin Contact Using appropriate personal protective equipment, remove contaminated clothing and flush exposed area with large amounts of water. Obtain medical attention if skin reaction occurs, which may be immediate or delayed.

Eye Contact Wash immediately with clean and gently flowing water. Continue for at least 15 minutes. Obtain medical attention.

NOTES TO HEALTH PROFESSIONALS

Medical Treatment Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information centre. Medical treatment in cases of overexposure should be treated as an overdose of glucocorticosteroid.

Medical Conditions Caused or Aggravated by Exposure Refer to prescribing information for detailed description of medical conditions caused by or aggravated by overexposure to this product.

Antidotes No specific antidotes are recommended.

5. FIRE-FIGHTING MEASURES

Fire and Explosion Hazards Not expected for the product, although the packaging is combustible.

Extinguishing Media Water, dry powder or foam extinguishers are recommended. Carbon dioxide extinguishers may be ineffective.

Special Firefighting Procedures For single units (packages): No special requirements needed. For larger amounts (multiple packages/pallets) of product: Since toxic, corrosive or flammable vapours might be evolved from fires involving this product and associated packaging, self contained breathing apparatus and full protective equipment are recommended for firefighters. If possible, contain and collect firefighting water for later disposal.

Hazardous Combustion Products Toxic, corrosive or flammable thermal decomposition products are expected when the product is exposed to fire.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Wear protective clothing and equipment consistent with the degree of hazard.

Environmental Precautions For large spills, take precautions to prevent entry into waterways, sewers, or surface drainage systems.

Clean-up Methods Collect and place it in a suitable, properly labelled container for recovery or disposal.

Decontamination Procedures No specific decontamination or detoxification procedures have been identified for this product.

7. HANDLING AND STORAGE

HANDLING

General Requirements No special control measures required for the normal handling of this product. Normal room ventilation is expected to be adequate for routine handling of this product.

STORAGE No storage requirements necessary for occupational hazards. Follow product information storage instructions to maintain efficacy.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

INGREDIENT	FLUTICASONE PROPIONATE	
GSK Occupational Hazard Category	4	
GSK Occupational Exposure Limit	3 mcg/m3 (8 HR TWA)	SKIN
INGREDIENT	SALMETEROL XINAFOATE	
GSK Occupational Hazard Category	5	
GSK Occupational Exposure Limit	1 mcg/m3 (8 HR TWA)	

ENGINEERING CONTROLS

Exposure Controls	The active ingredient was formerly assigned to OHC 4 with the Highly Potent notation. 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. Refer to the Exposure Control Matrix for more information about how ECA's are assigned and how to interpret them. Special considerations apply in the planning, design, review and implementation of controls - seek specialist assistance from local occupational hygienist or safety department.
Containment	Open handling may result in overexposure. It is strongly advised that dedicated areas and containment, such as glove boxes, isolators, and enclosed material transfer systems be used to prevent personnel exposure and spread of contamination.
Ventilation	Local exhaust ventilation (LEV) is not appropriate at this level, since total containment should usually be used.
Administrative	Strict control of access to the working area is essential. Only trained personnel should enter the area during operations. Adopt procedures to prevent contamination of working materials and adjacent areas.

PERSONAL PROTECTIVE EQUIPMENT

Eye Protection	When isolation is not possible, chemical splash goggles or equivalent eye protection must be used with other applicable protective equipment.
Gloves	Care must be exercised if insufficient data are available and further guidance should be sought from your local EHS department. Glove selection must take into account any solvents and other hazards present. The selection of gloves for a specific activity must be based on the material's properties and on possible permeation and degradation that may occur under the circumstances of use. Potential allergic reactions can occur with certain glove materials (e.g. Latex) and therefore these should be avoided.
Respirators	When isolation is not possible, respiratory protective equipment (RPE) should be combined with applicable protective equipment.
Other Equipment or Procedures	Follow all local regulations if personal protective equipment (PPE) is used in the workplace. When isolation is not possible in production areas, applicable protective equipment must be used. Consider additional control procedures for maintenance, cleaning and emergencies.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Physical Form	Powder.

10. STABILITY AND REACTIVITY

Stability	This product is expected to be stable.
Conditions to Avoid	None for normal handling of this product.

11. TOXICOLOGY INFORMATION

Pharmacological Effects This material is a selective glucocorticoid receptor agonist.
Adverse effects of overexposure might include: suppression of adrenal glands; temporary decrease in white blood cell counts; symptoms of hypersensitivity (such as skin rash, hives, itching, and difficulty breathing); increased susceptibility to infection.

Target Organ Effects Adverse effects might occur in the following organ(s) following overexposure: adrenal glands; immune system.

Routes of Exposure

Oral Toxicity Not expected to be toxic following ingestion.

Skin Effects Irritation is not expected following direct contact. Pharmacological effects may occur following skin absorption.

Eye Effects Minor irritation might occur following direct contact with eyes.

Sensitisation Allergic skin reactions might occur following dermal exposure. Assessment based upon information from human exposure.

Genetic Toxicity Not expected to be genotoxic under occupational exposure conditions.

Carcinogenicity Not expected to produce cancer in humans under occupational exposure conditions. No components are listed as carcinogens by GSK, IARC, NTP or US OSHA.

Reproductive Effects Not expected to produce adverse effects on fertility or development under occupational exposure conditions.

Other Adverse Effects None known for occupational exposure.

12. ECOLOGICAL INFORMATION

Summary This material contains two or more active pharmaceutical ingredients that have been tested, one of which may be harmful if released directly to the environment. Specific information on that active pharmaceutical ingredient is provided below. Consult the MSDS of the active ingredient for specific information about potential environmental effects. Appropriate precautions should be taken to limit release of this material to the environment. Local regulations and procedures should be consulted prior to environmental release.

ECOTOXICITY

Aquatic

Activated Sludge Respiration This material contains an active pharmaceutical ingredient that is not toxic to activated sludge microorganisms.

IC50:	> 998 mg/l, 3 Hours, Activated sludge

Algal This material contains an active pharmaceutical ingredient that is toxic to algae.

IC50:	4 mg/l, 72 Hours, Scenedesmus subspicatus, green algae, Measured
NOEC:	1.9 mg/l

Daphnid This material contains an active pharmaceutical ingredient that is harmful to daphnids. This material contains an active pharmaceutical ingredient that is harmful to daphnids in chronic toxicity studies.

EC50:	20 mg/l, 48 Hours, Daphnia pulex
NOEC:	6.7 mg/l, 48 Hours, Daphnia pulex
Chronic LOEC:	5 mg/l, 8 Days, Ceriodaphnia dubia, Static renewal test
Chronic NOEC:	1.6 mg/l, 8 Days, Ceriodaphnia dubia

Fish This material contains an active pharmaceutical ingredient that is harmful to fish.

Juvenile Oncorhyncus mykiss, rainbow trout

EC50:	35 mg/l, 96 Hours, Static renewal test
NOEC:	7.5 mg/l

Terrestrial

Earthworm This mixture contains an active pharmaceutical ingredient that is not toxic to earthworms.

	EC50:	334 mg/kg, 28 Days, Eisenia foetida, manure worm,
	NOEC:	209 mg/kg, 28 Days, Eisenia foetida, manure worm,

MOBILITY

Solubility This material contains an active pharmaceutical ingredient that for environmental fate predictions has limited solubility in water.

Mobility

Volatility This material contains an active pharmaceutical ingredient that will not readily enter into the air from hard surfaces or from a container of the pure substance.

MOBILITY

Adsorption This material contains an active pharmaceutical ingredient that is likely to adsorb to soil or sediment. This material contains an active pharmaceutical ingredient that is likely to adsorb to sludges and other biomass.

Soil Sediment Sorption (log Koc): 3.84 to 4.52

Partitioning This material contains an active pharmaceutical ingredient with octanol/water partition coefficient data that suggests that for environmental fate predictions the active pharmaceutical ingredient may have the tendency to distribute into fats.

Persistence/Degradation

Hydrolysis This material contains an active pharmaceutical ingredient that has been shown to be chemically stable in water. Hydrolysis is unlikely to be a significant depletion mechanism.

Half-Life, Neutral: > 1 Years, Measured

PERSISTENCE/DEGRADATION

Photolysis This material contains an active pharmaceutical ingredient that is likely to undergo photodegradation.

UV/Visible Spectrum: 338 nm

Persistence/Degradation

Biodegradation This material contains an active pharmaceutical ingredient that has been tested and is expected to be biodegradable.

Aerobic - Ready

Percent Degradation: 50 %, 12.8 days, Sturm test

Aerobic - Soil

Percent Degradation: 29.9 to 49.9 %, 64 days

13. DISPOSAL CONSIDERATIONS

Disposal Recommendations Collect for recycling or recovery if possible. The disposal method for rejected products/returned goods must ensure that they cannot be re-sold or re-used.

Regulatory Requirements Observe all local and national regulations when disposing of this material.

14. TRANSPORT INFORMATION

The SDS should accompany all shipments for reference in the event of spillage or accidental release. Only authorised persons trained and competent in accordance with appropriate national and international regulatory requirements may prepare dangerous goods for transport.

UN Classification and Labelling

Transport Information Transportation and shipping of this product is not restricted. It has no known, significant hazards requiring special packaging or labelling for air, maritime, US or European ground transport purposes.

15. REGULATORY INFORMATION

EU Classification and Labelling

Exempt from requirements of EU Dangerous Preparations directive - product regulated as a medicinal product, cosmetic product or medical device.

US OSHA Standard (29 CFR Part 1910.1200)

Classification	This product is not classified as hazardous according to the OSHA Hazard Communication Standard.

Other US Regulations

TSCA Status	Exempt
Australian Classification according to Hazardous Substance and Dangerous Goods Regulatory Framework	This product is not classified as hazardous according to the NOHSC Approved Criteria for Classifying Hazardous Substances.

16. OTHER INFORMATION

References	GSK Hazard Determination
SDS Version Number	16

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.