

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

### 1.1. Product identifier

**Trade name or designation of the mixture** ADVAIR DISKUS

**Registration number** -

**Synonyms** 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

**Issue date** 03-December-2013

**Version number** 18

**Revision date** 03-December-2013

**Supersedes date** 03-December-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

#### 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** 97.6 % of the mixture consists of component(s) of unknown acute oral toxicity.

**2.3. Other hazards** Assume that this product is capable of sustaining combustion.  
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 |
|---------------|---|------------------|------------------------|-----------|-------|
|---------------|---|------------------|------------------------|-----------|-------|

|                        |           |            |   |   |  |
|------------------------|-----------|------------|---|---|--|
| FLUTICASONE PROPIONATE | 0.8 - 4.0 | 80474-14-2 | - | - |  |
|------------------------|-----------|------------|---|---|--|

**Classification:** **DSD:** Repr. Cat. 2;R61, Repr. Cat. 3;R62, Xn;R48/20/21, R53

**CLP:** Repr. 1B;H360D, Repr. 2;H361f, STOT RE 2;H373

|                      |     |            |   |   |  |
|----------------------|-----|------------|---|---|--|
| SALMETEROL XINAFOATE | 0.6 | 94749-08-3 | - | - |  |
|----------------------|-----|------------|---|---|--|

**Classification:** **DSD:** Xi;R36/38, N;R51/53

**CLP:** Skin Irrit. 2;H315, Eye Irrit. 2;H319

Other components below reportable levels >95.0

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** If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 4.1. Description of first aid measures

**Inhalation** If dust from the material is inhaled, remove the affected person immediately to fresh air.

**Skin contact** Wash off with soap and water. 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.

**4.2. Most important symptoms and effects, both 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.

**4.3. Indication of any immediate medical attention and special treatment needed** Provide general supportive measures and treat symptomatically.

## SECTION 5: Firefighting measures

**General fire hazards** Assume that this product is capable of sustaining combustion.

### 5.1. Extinguishing media

**Suitable extinguishing media** Water. Foam. Dry chemical powder.

**Unsuitable extinguishing media** Carbon dioxide (CO<sub>2</sub>).

**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. In the event of fire, cool tanks with water spray. 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. Wear a dust mask if dust is generated above 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.

**For emergency responders** Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the MSDS.

|                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>6.2. Environmental precautions</b>                            | 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.                                                                                                                                                            |
| <b>6.3. Methods and material for containment and cleaning up</b> | Minimise 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. |
| <b>6.4. Reference to other sections</b>                          | For personal protection, see section 8. For waste disposal, see section 13.                                                                                                                                                                                                                                                                                                                                             |

## SECTION 7: Handling and storage

|                                                                          |                                                                                                                                                                                                                                                                                                                                                               |
|--------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>7.1. Precautions for safe handling</b>                                | Minimise dust generation and accumulation. Provide appropriate exhaust ventilation at places where dust is formed. Avoid breathing dust. Avoid contact with skin and eyes. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Practice good housekeeping. Avoid release to the environment. Do not empty into drains. |
| <b>7.2. Conditions for safe storage, including any incompatibilities</b> | 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).                                                          |
| <b>7.3. Specific end use(s)</b>                                          | Medicinal Product                                                                                                                                                                                                                                                                                                                                             |

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### Occupational exposure limits

| GSK Components                          | Type     | Value    | Note                |
|-----------------------------------------|----------|----------|---------------------|
| FLUTICASONE PROPIONATE (CAS 80474-14-2) | 8 HR TWA | 3 mcg/m3 |                     |
|                                         | OHC      | 4        | Skin                |
| SALMETEROL XINAFOATE (CAS 94749-08-3)   | 8 HR TWA | 1 mcg/m3 | Reproductive hazard |
|                                         | 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** 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

|                               |                                                                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>General information</b>    | 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.                                                                                                                                               |
| <b>Eye/face protection</b>    | Use tight fitting goggles if dust is generated. (eg. EN 166)                                                                                                                                                                                                                                                                                                                                        |
| <b>Skin protection</b>        |                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>- Hand protection</b>      | 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). |
| <b>- Other</b>                | Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust)                                                                                                                                                                                                                                                                                                                   |
| <b>Respiratory protection</b> | When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. 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).                                                                                         |

|                                                    |                                                                                                                                                                                                                       |
|----------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Thermal hazards</b>                             | Wear appropriate thermal protective clothing, when necessary.                                                                                                                                                         |
| <b>Hygiene measures</b>                            | 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. |
| <b>Environmental exposure controls</b>             |                                                                                                                                                                                                                       |
| <b>Hazard guidance and control recommendations</b> | 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

|                                                     |                |
|-----------------------------------------------------|----------------|
| <b>Physical state</b>                               | Solid.         |
| <b>Form</b>                                         | Powder.        |
| <b>Colour</b>                                       | White.         |
| <b>Odour</b>                                        | Not available. |
| <b>Odour threshold</b>                              | Not available. |
| <b>pH</b>                                           | Not available. |
| <b>Melting point/freezing point</b>                 | Not available. |
| <b>Initial boiling point and boiling range</b>      | Not available. |
| <b>Flash point</b>                                  | Not available. |
| <b>Evaporation rate</b>                             | Not available. |
| <b>Flammability (solid, gas)</b>                    | Not available. |
| <b>Upper/lower flammability or explosive limits</b> |                |
| <b>Flammability limit - lower (%)</b>               | Not available. |
| <b>Flammability limit - upper (%)</b>               | Not available. |
| <b>Vapour pressure</b>                              | Not available. |
| <b>Vapour density</b>                               | Not available. |
| <b>Relative density</b>                             | Not available. |
| <b>Solubility(ies)</b>                              | Not available. |
| <b>Partition coefficient (n-octanol/water)</b>      | Not available. |
| <b>Auto-ignition temperature</b>                    | Not available. |
| <b>Decomposition temperature</b>                    | Not available. |
| <b>Viscosity</b>                                    | Not available. |
| <b>Explosive properties</b>                         | Not available. |
| <b>Oxidizing properties</b>                         | Not available. |

**9.2. Other information** Not relevant additional information available.

## SECTION 10: Stability and reactivity

|                                                 |                                                                                                  |
|-------------------------------------------------|--------------------------------------------------------------------------------------------------|
| <b>10.1. Reactivity</b>                         | The product is stable and non-reactive under normal conditions of use, storage and transport.    |
| <b>10.2. Chemical stability</b>                 | Material is stable under normal conditions.                                                      |
| <b>10.3. Possibility of hazardous reactions</b> | No dangerous reaction known under conditions of normal use.                                      |
| <b>10.4. Conditions to avoid</b>                | Avoid heat, sparks, open flames and other ignition sources. Contact with incompatible materials. |
| <b>10.5. Incompatible materials</b>             | Strong oxidising agents.                                                                         |
| <b>10.6. Hazardous decomposition products</b>   | Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.          |

## SECTION 11: Toxicological information

|                                                 |                                                             |
|-------------------------------------------------|-------------------------------------------------------------|
| <b>General information</b>                      | Caution - Pharmaceutical agent.                             |
| <b>Information on likely routes of exposure</b> |                                                             |
| <b>Ingestion</b>                                | Health injuries are not known or expected under normal use. |

|                     |                                                                                                                                                                                                                 |
|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Inhalation</b>   | Health injuries are not known or expected under normal use. Inhalation of dusts may cause respiratory irritation.                                                                                               |
| <b>Skin contact</b> | Health injuries are not known or expected under normal use.                                                                                                                                                     |
| <b>Eye contact</b>  | Dust in the eyes will cause irritation. Health injuries are not known or expected under normal use.                                                                                                             |
| <b>Symptoms</b>     | 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. |

#### 11.1. 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) |         |                                                 |
| <b>Acute</b>                            |         |                                                 |
| <i>Oral</i>                             |         |                                                 |
| LD50                                    | Rat     | > 1000 mg/kg                                    |
| <b>Subacute</b>                         |         |                                                 |
| <i>Inhalation</i>                       |         |                                                 |
| NOAEL                                   | Rat     | 0.2 mcg/L/day, 28 Day                           |
| <b>Subchronic</b>                       |         |                                                 |
| <i>Inhalation</i>                       |         |                                                 |
| 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)   |         |                                                 |
| <b>Acute</b>                            |         |                                                 |
| <i>Inhalation</i>                       |         |                                                 |
| LC50                                    | Rat     | > 75 mg/l                                       |
| <i>Oral</i>                             |         |                                                 |
| LD50                                    | Rat     | > 1000 mg/kg                                    |
| <b>Subchronic</b>                       |         |                                                 |
| <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. Due to partial or complete lack of data the classification is not possible.

#### Corrosivity

|                        |                                    |
|------------------------|------------------------------------|
| FLUTICASONE PROPIONATE | OECD 404<br>Result: negative       |
| SALMETEROL XINAFOATE   | Result: Irritant<br>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

|                        |                                                 |
|------------------------|-------------------------------------------------|
| SALMETEROL XINAFOATE   | OECD 405<br>Result: Severe<br>Species: Rabbit   |
| FLUTICASONE PROPIONATE | OECD 405<br>Result: negative<br>Species: Rabbit |

**Respiratory sensitisation** Due to partial or complete lack of data the classification is not possible.

**Skin sensitisation** Due to partial or complete lack of data the classification is not possible.

#### Maximisation assay (Magnusson and Kligman)

|                      |                                         |
|----------------------|-----------------------------------------|
| SALMETEROL XINAFOATE | Result: negative<br>Species: Guinea pig |
|----------------------|-----------------------------------------|

|                               |                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                     |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Sensitisation</b>          |                                                                                                                                   | 0 % OECD 406<br>Result: negative<br>Species: Guinea pig                                                                                                                                                                                                                                                                                             |
| <b>Germ cell mutagenicity</b> | Due to partial or complete lack of data the classification is not possible.                                                       |                                                                                                                                                                                                                                                                                                                                                     |
| <b>Germ cell mutagenicity</b> |                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                     |
| <b>Mutagenicity</b>           |                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                     |
| FLUTICASONE PROPIONATE        |                                                                                                                                   | Ames<br>Result: negative                                                                                                                                                                                                                                                                                                                            |
| SALMETEROL XINAFOATE          |                                                                                                                                   | Ames - Screen<br>Result: negative                                                                                                                                                                                                                                                                                                                   |
| FLUTICASONE PROPIONATE        |                                                                                                                                   | Bacterial High Throughput Fluctuation Test<br>Result: negative<br>Chinese Hamster Ovarian Cell Test<br>Result: negative                                                                                                                                                                                                                             |
| SALMETEROL XINAFOATE          |                                                                                                                                   | Chromosomal aberration assay<br>Result: negative<br>GreenScreen Assay<br>Result: negative<br>HPRT gene mutation in human lymphocytes<br>Result: negative<br>High throughput fluctuation test (HTFT)<br>Result: negative<br>In vitro cytogenetic Assay<br>Result: negative<br>L5178Y mouse lymphoma thymidine kinase locus assay<br>Result: negative |
| FLUTICASONE PROPIONATE        |                                                                                                                                   | Micronucleus Assay<br>Result: negative<br>Species: Mouse<br>Micronucleus Test<br>Result: negative<br>Species: Mouse                                                                                                                                                                                                                                 |
| SALMETEROL XINAFOATE          |                                                                                                                                   | Rat Micronucleus Assay<br>Result: negative                                                                                                                                                                                                                                                                                                          |
| FLUTICASONE PROPIONATE        |                                                                                                                                   | SOS/umu Assay<br>Result: negative<br>Yeast<br>Result: negative                                                                                                                                                                                                                                                                                      |
| <b>Carcinogenicity</b>        | 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<br>Result: positive<br>Species: Rat<br>Organ: Pituitary/ Uterus<br>>= 1.4 mg/kg/day, Species-specific<br>Result: positive<br>Species: Mouse<br>Organ: uterus                                                                                                                                                    |
| FLUTICASONE PROPIONATE        |                                                                                                                                   | Inhalation<br>Result: negative<br>Species: Rat<br>dermal<br>Result: negative<br>Species: Mouse<br>oral<br>Result: negative<br>Species: Mouse                                                                                                                                                                                                        |
| <b>Reproductive toxicity</b>  | Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.               |                                                                                                                                                                                                                                                                                                                                                     |
| <b>Reproductive toxicity</b>  |                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                     |
| <b>Reproductivity</b>         |                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                     |
| SALMETEROL XINAFOATE          |                                                                                                                                   | 0.1 mg/kg/day Reproductive performance and development of two untreated generations, NOEL<br>Species: Rat<br>Notes: GR33343X<br>1 mg/kg/day Reproductive performance and development of two untreated generations<br>Species: Rat<br>Organ: Skeletal effects<br>Notes: GR33343X                                                                     |

## Reproductivity

### 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  
>= 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 partial or complete lack of data the classification is not possible.

**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                         |
|-----------------------------------------|------|---------------------------------------|--------------------------------------|
| FLUTICASONE PROPIONATE (CAS 80474-14-2) |      |                                       |                                      |
| Acute                                   |      |                                       |                                      |
|                                         | IC50 | Activated sludge                      | > 1000 mg/l, 3 hours                 |
| <b>Aquatic</b>                          |      |                                       |                                      |
| Acute                                   |      |                                       |                                      |
| Crustacea                               | EC50 | Water flea (Daphnia magna)            | > 0.55 mg/l, 48 hours, Static test   |
| <b>Terrestrial</b>                      |      |                                       |                                      |
| Acute                                   |      |                                       |                                      |
| Earthworm                               | EC50 | Manure worm (Eisenia foetida)         | > 1000 mg/kg, 28 days                |
| SALMETEROL XINAFOATE (CAS 94749-08-3)   |      |                                       |                                      |
| <b>Aquatic</b>                          |      |                                       |                                      |
| 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                             |

| Components         |      | Species                                              | Test results                                         |
|--------------------|------|------------------------------------------------------|------------------------------------------------------|
| Crustacea          | EC50 | Water flea ( <i>Daphnia pulex</i> )                  | 20 mg/l, 48 hours, OECD 202                          |
|                    | NOEC | Water flea ( <i>Daphnia pulex</i> )                  | 6.7 mg/l, 48 hours                                   |
| Fish               | EC50 | Rainbow trout (Juvenile <i>Oncorhynchus mykiss</i> ) | 35 mg/l, 96 hours, Static renewal test, OECD 203     |
|                    | NOEC | Rainbow trout (Juvenile <i>Oncorhynchus mykiss</i> ) | 7.5 mg/l                                             |
| <i>Chronic</i>     |      |                                                      |                                                      |
| Crustacea          | LOEC | Water flea ( <i>Ceriodaphnia dubia</i> )             | 5 mg/l, 8 days, Static renewal test, EPA Method 1002 |
|                    | NOEC | Water flea ( <i>Ceriodaphnia dubia</i> )             | 1.6 mg/l, 8 days                                     |
| <b>Terrestrial</b> |      |                                                      |                                                      |
| <i>Acute</i>       |      |                                                      |                                                      |
| Earthworm          | EC50 | Manure worm ( <i>Eisenia foetida</i> )               | 334 mg/kg, 28 days, OECD 222                         |
|                    | NOEC | Manure worm ( <i>Eisenia foetida</i> )               | 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

##### 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-inherent)

SALMETEROL XINAFOATE 50 %, 12.8 days Modified Zahn-Wellens, primary biodegradation, loss of parent.

##### Percent degradation (Aerobic biodegradation-ready)

FLUTICASONE PROPIONATE < 44 %, 28 days

##### Percent degradation (Aerobic biodegradation-soil)

FLUTICASONE PROPIONATE 9 - 50 %, 64 days

SALMETEROL XINAFOATE 29.9 - 49.9 %, 64 days

## 12.3. Bioaccumulative potential

### Partition coefficient

#### n-octanol/water (log Kow)

FLUTICASONE PROPIONATE 2.78

SALMETEROL XINAFOATE 2.1 (Measured).

## 12.4. 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

**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

|                                     |                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Residual waste</b>               | 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).                                                                                                                                                                                                 |
| <b>Contaminated packaging</b>       | 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.                                                                                                                                                                                                       |
| <b>EU waste code</b>                | The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.                                                                                                                                                                                                                                                                                                   |
| <b>Disposal methods/information</b> | 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. |
| <b>Special precautions</b>          | Dispose in accordance with all applicable regulations.                                                                                                                                                                                                                                                                                                                                                           |

## SECTION 14: Transport information

### ADR

Not regulated as dangerous goods.

### IATA

Not regulated as dangerous goods.

### IMDG

Not regulated as dangerous goods.

**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.

## 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**

Not listed.

**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**

Not listed.

**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.

Not listed.

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.

R48/20/21 Harmful: danger of serious damage to health by prolonged exposure through inhalation and in contact with 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.

R53 May cause long term adverse effects in the aquatic environment.

R61 May cause harm to the unborn child.

R62 Possible risk of impaired fertility.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H360D May damage the unborn child.

H361f Suspected of damaging fertility.

**Revision information**

Product and Company Identification: Business Units

Composition / Information on Ingredients: Ingredients

Physical & Chemical Properties: Reports

Ecological Information: Reports

Transport Information: Agency Name and Packaging Type/Transport Mode Selection

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.