SAFETY DATA SHEET

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

1.1. Product identifier

Trade name or designation of the mixture

ADVAIR HFA

Registration number

-

Synonyms

ADVAIR HFA INHALATION AEROSOL * SERETIDE INHALER HFA * SERETIDE EVOHALER * BREXOTIDE INHALER HFA 134A * FLIXOVENT INHALER HFA 134A * SERETAIDE INHALER HFA 134A * VIANI EVOHALER * VIANI INHALER HFA * VIANI MITE 25 MCG/50 MCG DOSIER-AEROSOL FCKW-FREI * VIANI 25 MCG/125 MCG DOSIER-AEROSOL FCKW-FREI * VIANI FORTE 25 MCG/250 MCG DOSIER-AEROSOL FCKW-FREI * SALMETEROL/FLUTICASONE PROPIONATE INHALATION AEROSOL * SALMETEROL/FLUTICASONE PROPIONATE INHALER 25/50 MCG 120 ACTN * SALMETEROL/FLUTICASONE PROPIONATE INHALER 25/125 MCG 120 ACTN * SALMETEROL/FLUTICASONE PROPIONATE INHALER 25/250 MCG 120 ACTN * SALMETEROL/FLUTICASONE PROPIONATE 134A 120 ACTN * SALMETEROL XINAFOATE AND FLUTICASONE PROPIONATE, FORMULATED PRODUCT

Issue date

14-October-2013

Version number

20

Revision date

14-October-2013

Supersedes date

03-October-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
Not applicable.

2.3. Other hazards

This product is non-flammable. Aerosol containers may violently rupture when exposed to the heat of fire.
Caution - Pharmaceutical agent. See section 11 for additional information on health hazards.
SECTION 3: Composition/information on ingredients

3.2. Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>%</th>
<th>CAS-No. / EC No.</th>
<th>REACH Registration No.</th>
<th>INDEX No.</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,1,1,2-TETRAFLUOROETHANE</td>
<td>99.6 - 99.87</td>
<td>811-97-2</td>
<td>212-377-0</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Classification:</td>
<td>DSD:</td>
<td></td>
<td>CLP:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FLUTICASONE PROPIONATE</td>
<td>0.08 - 0.34</td>
<td>80474-14-2</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Classification:</td>
<td>DSD:</td>
<td>Repr. Cat. 2;R61, Repr. Cat. 3;R62, Xn:R48/20/21, R53</td>
<td>CLP: Repr. 1B;H360D, Repr. 2;H361f, STOT RE 2;H373</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SALMETEROL XINAFOATE</td>
<td>0.05</td>
<td>94749-08-3</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Classification:</td>
<td>DSD:</td>
<td>Xi;R36/38, N;R51/53</td>
<td>CLP: Skin Irrit. 2;H315, Eye Irrit. 2;H319</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Classification:</td>
<td>DSD:</td>
<td></td>
<td>CLP:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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: Move to fresh air. Call a physician if symptoms develop or persist.
- 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
This product is non-flammable. Aerosol containers may violently rupture when exposed to the heat of fire.

5.1. Extinguishing media
- Unsuitable extinguishing media: None known.

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. 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.

6.2. 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.

6.3. Methods and material for containment and cleaning up
- Stop the flow of material, if this is without risk. Collect spillage. Dike far ahead of spill for later disposal. Prevent product from entering drains. Following product recovery, flush area with water.
- Never return spills in original containers for re-use.

6.4. Reference to other sections
- For personal protection, see section 8. For waste disposal, see section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
- Avoid prolonged exposure. Provide adequate ventilation. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. Avoid release to the environment. Do not empty into drains.

7.2. Conditions for safe storage, including any incompatibilities
- Store in original tightly closed container. Store in a cool, dry place out of direct sunlight. Store away from incompatible materials (see Section 10 of the MSDS). The recommended temperature for storage is 15-25 °C.

7.3. Specific end use(s)
- Medicinal Product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits

<table>
<thead>
<tr>
<th>GSK Components</th>
<th>Value</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLUTICASONE PROPIONATE (CAS 80474-14-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 HR TWA</td>
<td>3 mcg/m³</td>
<td></td>
</tr>
<tr>
<td>OHC</td>
<td>4</td>
<td>Skin</td>
</tr>
<tr>
<td>SALMETEROL XINAFOATE (CAS 94749-08-3)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8 HR TWA</td>
<td>1 mcg/m³</td>
<td>Reproductive hazard</td>
</tr>
<tr>
<td>OHC</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

UK. EH40 Workplace Exposure Limits (WELs)

<table>
<thead>
<tr>
<th>Components</th>
<th>Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,1,1,2-TETRAFLUOROE THANE (CAS 811-97-2)</td>
<td>TWA</td>
<td>4240 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1000 ppm</td>
</tr>
</tbody>
</table>

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
- Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk assessment.

Individual protection measures, such as personal protective equipment

General information
- 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.

Eye/face protection
- If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)
Skin protection
- 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. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

- Other
  Respiratory protection
  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).

  Thermal hazards
  Wear appropriate thermal protective clothing, when necessary.

Hygiene measures
  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.

Environmental exposure controls
  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

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

9.2. Other information
  No relevant additional information available.

SECTION 10: Stability and reactivity
10.1. Reactivity
  The product is stable and non-reactive under normal conditions of use, storage and transport.
10.2. Chemical stability
  Material is stable under normal conditions.
10.3. Possibility of hazardous reactions
  No dangerous reaction known under conditions of normal use.
10.4. Conditions to avoid
  Contact with incompatible materials.
10.5. Incompatible materials

Strong oxidising agents.

10.6. Hazardous decomposition products

Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

SECTION 11: Toxicological information

General information

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

Information on likely routes of exposure

- **Ingestion**: Health injuries are not known or expected under normal use.
- **Inhalation**: Prolonged inhalation may be harmful. Health injuries are not known or expected under normal use.
- **Skin contact**: Health injuries are not known or expected under normal use.
- **Eye contact**: Health injuries are not known or expected under normal use.

Symptoms

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.

<table>
<thead>
<tr>
<th>Components</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLUTICASONE PROPIONATE (CAS 80474-14-2)</td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
</tr>
<tr>
<td><strong>Subacute</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>Rat</td>
</tr>
<tr>
<td><strong>Subchronic</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td></td>
</tr>
<tr>
<td>LOEL</td>
<td>Rat</td>
</tr>
<tr>
<td>NOAEL</td>
<td>Dog</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
</tr>
<tr>
<td>SALMETEROL XINAFOATE (CAS 94749-08-3)</td>
<td></td>
</tr>
<tr>
<td><strong>Acute</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td></td>
</tr>
<tr>
<td>LC50</td>
<td>Rat</td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Rat</td>
</tr>
<tr>
<td><strong>Subchronic</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Inhalation</strong></td>
<td></td>
</tr>
<tr>
<td>LOEL</td>
<td>Rat</td>
</tr>
<tr>
<td><strong>Oral</strong></td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>Rat</td>
</tr>
</tbody>
</table>

* 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**

Direct contact with eyes may cause temporary irritation.
Eye
SALMETEROL XINAFOATE
Result: Severe
Species: Rabbit

FLUTICASONE PROPIONATE
Result: negative
Species: Rabbit

Respiratory sensitisation
Based on available data, the classification criteria are not met.

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

Maximisation assay (Magnusson and Kligman)
SALMETEROL XINAFOATE
Result: negative
Species: Guinea pig

Skin sensitisation
Based on available data, the classification criteria are not met.

Germin cell mutagenicity
Based on available data, the classification criteria are not met.

Mutagenicity

FLUTICASONE PROPIONATE
Result: negative
Species: Mouse

SALMETEROL XINAFOATE
Result: negative
Species: Mouse

FLUTICASONE PROPIONATE
Result: negative
Species: Mouse

SALMETEROL XINAFOATE
Result: negative
Species: Mouse

SALMETEROL XINAFOATE
Result: negative
Species: Mouse

Germ cell mutagenicity

Mutagenicity

FLUTICASONE PROPIONATE
Result: negative
Species: Mouse

SALMETEROL XINAFOATE
Result: negative
Species: Mouse

FLUTICASONE PROPIONATE
Result: negative
Species: Mouse

SALMETEROL XINAFOATE
Result: negative
Species: Mouse

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
Result: positive
Species: Rat
Organ: Pituitary/ Uterus
>= 0.15 mg/kg/day, Species-specific

FLUTICASONE PROPIONATE
Result: negative
Species: Rat
Organ: uterine
>= 1.4 mg/kg/day, Species-specific

SALMETEROL XINAFOATE
Result: positive
Species: Mouse
Organ: uterus

FLUTICASONE PROPIONATE
Result: negative
Species: Rat
Organ: uterine

SALMETEROL XINAFOATE
Result: negative
Species: Mouse

FLUTICASONE PROPIONATE
Result: negative
Species: Mouse

Material name: ADVAIR HFA
SDS UK
126599 Version No.: 20 Revision date: 14-October-2013 Issue date: 14-October-2013
Reproductive toxicity Components in this product have been shown to cause birth defects and reproductive disorders in laboratory animals.

### Reproductive toxicity

#### 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

- **Species:** Rat

<table>
<thead>
<tr>
<th>Dose Level</th>
<th>Effect Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mcg/kg/day</td>
<td>Embryofetal Development (Segment I) reduced foetal bodyweight, minor skeletal variations</td>
</tr>
<tr>
<td>100 mcg/kg/day</td>
<td>Female fertility (Segment I) reduced foetal bodyweight, minor skeletal variations</td>
</tr>
</tbody>
</table>

#### FLUTICASONE PROPIONATE

- **Species:** Rat

<table>
<thead>
<tr>
<th>Dose Level</th>
<th>Effect Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mcg/kg/day</td>
<td>Pre- and Post-natal development maternal toxicity</td>
</tr>
</tbody>
</table>

#### SALMETEROL XINAFOATE

- **Species:** Rabbit

<table>
<thead>
<tr>
<th>Dose Level</th>
<th>Effect Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;= 1 mg/kg/day</td>
<td>Embryo-foetal development- Oral, species-specific skeletal effects, open eye, cleft palate</td>
</tr>
</tbody>
</table>

#### FLUTICASONE PROPIONATE

- **Species:** Rabbit

<table>
<thead>
<tr>
<th>Dose Level</th>
<th>Effect Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;= 25.7 mcg/kg/day</td>
<td>Embryofetal Development maternal toxicity, reduced foetal body weight; no malformations or other variations</td>
</tr>
<tr>
<td>&gt;= 45 mcg/kg/day</td>
<td>Embryofetal Development reduced foetal weight; foetal resorptions</td>
</tr>
<tr>
<td>&gt;= 50 mcg/kg/day</td>
<td>Embryofetal Development maternal toxicity; reduced foetal weight; foetal resorptions</td>
</tr>
</tbody>
</table>

#### Specific target organ toxicity - single exposure

- Heart. Based on available data, the classification criteria are not met.

#### Specific target organ toxicity - repeated exposure

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

#### Aspiration hazard

- Not likely, due to the form of the product.

#### Mixture versus substance information

- No information available.

#### Other information

- Caution - Pharmaceutical agent.

### SECTION 12: Ecological information

#### 12.1. Toxicity

The product contains a substance which may cause long-term adverse effects in the environment. No information is available about the potential of this product to produce adverse environmental effects.

<table>
<thead>
<tr>
<th>Components</th>
<th>Species</th>
<th>Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLUTICASONE PROPIONATE (CAS 80474-14-2)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>IC50</td>
<td>Activated sludge</td>
</tr>
<tr>
<td>Aquatic</td>
<td>EC50</td>
<td>Water flea (Daphnia magna)</td>
</tr>
<tr>
<td>Terrestrial</td>
<td>EC50</td>
<td>Manure worm (Eisenia fetida)</td>
</tr>
<tr>
<td>Components</td>
<td>Species</td>
<td>Test results</td>
</tr>
<tr>
<td>------------</td>
<td>---------</td>
<td>--------------</td>
</tr>
<tr>
<td><strong>Aquatic</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>IC50</td>
<td>Residential sludge</td>
</tr>
<tr>
<td></td>
<td>EC50</td>
<td>Green algae (Scenedesmus subspicatus)</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>Green algae (Scenedesmus subspicatus)</td>
</tr>
<tr>
<td></td>
<td>EC50</td>
<td>Water flea (Daphnia pulex)</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>Water flea (Daphnia pulex)</td>
</tr>
<tr>
<td></td>
<td>EC50</td>
<td>Rainbow trout (Juvenile Oncorhyncus mykiss)</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>Rainbow trout (Juvenile Oncorhyncus mykiss)</td>
</tr>
<tr>
<td><strong>Chronic</strong></td>
<td>LOEC</td>
<td>Water flea (Ceriodaphnia dubia)</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>Water flea (Ceriodaphnia dubia)</td>
</tr>
<tr>
<td><strong>Terrestrial</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute</td>
<td>EC50</td>
<td>Manure worm (Eisenia foetida)</td>
</tr>
<tr>
<td></td>
<td>NOEC</td>
<td>Manure worm (Eisenia foetida)</td>
</tr>
</tbody>
</table>

* 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**

<table>
<thead>
<tr>
<th>Component</th>
<th>Half-life (Hydrolysis-neutral)</th>
<th>Biodegradability</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FLUTICASONE PROPIONATE</td>
<td>Percent degradation</td>
</tr>
<tr>
<td></td>
<td>SALMETEROL XINAFOATE</td>
<td>(Aerobic biodegradation-inherent)</td>
</tr>
<tr>
<td></td>
<td>&gt; 1 years Measured</td>
<td>50 %, 12.8 days Modified Zahn-Wellens, primary biodegradation, loss of parent.</td>
</tr>
<tr>
<td></td>
<td>&gt; 1 years Measured</td>
<td>Percent degradation (Aerobic biodegradation-ready)</td>
</tr>
<tr>
<td></td>
<td>FLUTICASONE PROPIONATE</td>
<td>&lt; 44 %, 28 days</td>
</tr>
<tr>
<td></td>
<td>SALMETEROL XINAFOATE</td>
<td>Percent degradation (Aerobic biodegradation-soil)</td>
</tr>
<tr>
<td></td>
<td>&gt; 1 years Measured</td>
<td>FLUTICASONE PROPIONATE</td>
</tr>
<tr>
<td></td>
<td>FLUTICASONE PROPIONATE</td>
<td>9 - 50 %, 64 days</td>
</tr>
<tr>
<td></td>
<td>SALMETEROL XINAFOATE</td>
<td>29.9 - 49.9 %, 64 days</td>
</tr>
</tbody>
</table>

**12.3. Bioaccumulative potential**

**Partition coefficient**

<table>
<thead>
<tr>
<th>Component</th>
<th>n-octanol/water (log Kow)</th>
<th>12.4. Mobility in soil</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1,1,1,2-TETRAFLUOROETHANE</td>
<td>1.274</td>
</tr>
<tr>
<td></td>
<td>FLUTICASONE PROPIONATE</td>
<td>2.78</td>
</tr>
<tr>
<td></td>
<td>SALMETEROL XINAFOATE</td>
<td>2.1 (Measured).</td>
</tr>
</tbody>
</table>

**Adsorption**

<table>
<thead>
<tr>
<th>Component</th>
<th>Sludge/biomass distribution coefficient - log Kd</th>
<th>Soil/sediment sorption - log Koc</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>FLUTICASONE PROPIONATE</td>
<td>3.13 - 3.55 Estimated</td>
</tr>
<tr>
<td></td>
<td>FLUTICASONE PROPIONATE</td>
<td>3.41 - 3.83 Measured</td>
</tr>
<tr>
<td></td>
<td>SALMETEROL XINAFOATE</td>
<td>3.84 - 4.52</td>
</tr>
</tbody>
</table>
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

Residual waste
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.

EU waste code
The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Disposal methods/information
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.

Special precautions
Dispose in accordance with all applicable regulations.

SECTION 14: Transport information

ADR
14.1. UN number
UN1950
14.2. UN proper shipping name
AEROSOLS
14.3. Transport hazard class(es)
2.2
14.4. Packing group
Not available.
14.5. Environmental hazards
No
Tunnel code
E
Labels required
2.2
LTD QTY index
LQ2
Special Provisions
190, 327, 601, 625

IATA
14.1. UN number
UN1950
14.2. UN proper shipping name
Aerosols, non-flammable
14.3. Transport hazard class(es)
2.2
14.4. Packing group
Not available.
Labels required
2
Additional Information:
Passenger & cargo
Allowed.
Packaging Instruction
203
Pkg Inst cargo only
203
Pkg Inst passenger & cargo LQ
Y203
SP See 44
A98,A145,A167
Max net qty pkg
75 kg
Max net qty pkg cargo only
150 kg
Max net qty pkg LQ
30 kg G

IMDG
14.1. UN number
UN1950
14.2. UN proper shipping name
AEROSOLS
14.3. Transport hazard class(es)  2
Subsidiary class(es)  5A
14.4. Packing group  Not available.
14.5. Environmental hazards
Marine pollutant  No
Labels required  2
14.6. Special precautions for user  Not available.
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.

ADR; IATA

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.
  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.
Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work
Not listed.

Directive 94/33/EC on the protection of young people at work
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:
Ecological Information: Mobility
Transport Information: Product Shipping Name/Packing Group
Regulatory Information: United States
GHS: Classification

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.