1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone / Formoterol Metered Dose Inhaler Formulation

Manufacturer or supplier’s details

Company: Organon & Co.
Address: 30 Hudson Street, 33rd floor, Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
Emergency telephone number: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview

Appearance: aerosol
Colour: white to off-white
Odour: No data available
Pressurised container: May burst if heated. Toxic to aquatic life with long lasting effects.

GHS Classification

Aerosols: Category 3
Long-term (chronic) aquatic hazard: Category 2

GHS label elements

Hazard pictograms: 

Signal word: Warning

Hazard statements: H229 Pressurised container: May burst if heated. H411 Toxic to aquatic life with long lasting effects.

Precautionary statements: Prevention:
  P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Mometasone / Formoterol Metered Dose Inhaler Formulation

Version 3.3
Revision Date: 2021/04/09
SDS Number: 75379-00016
Date of last issue: 2020/10/10
Date of first issue: 2015/03/16

P251 Do not pierce or burn, even after use.
P273 Avoid release to the environment.

Response:
P391 Collect spillage.

Storage:
P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Physical and chemical hazards
Pressurised container: May burst if heated.

Health hazards
Not classified based on available information.

Environmental hazards
Toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
May displace oxygen and cause rapid suffocation.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol#</td>
<td>64-17-5</td>
<td>1.8</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.087 -&lt;= 0.17</td>
</tr>
<tr>
<td>Formoterol</td>
<td>43229-80-7</td>
<td>&gt;= 0.0009 -&lt;= 0.0087</td>
</tr>
</tbody>
</table>

# Voluntarily-disclosed non-hazardous substance

4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention immediately.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
### 5. FIREFIGHTING MEASURES

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
</tbody>
</table>

**Specific hazards during firefighting**

- Exposure to combustion products may be a hazard to health.
- If the temperature rises there is danger of the vessels bursting due to the high vapor pressure.

### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Evacuate personnel to safe areas.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ventilate the area.</td>
</tr>
<tr>
<td></td>
<td>Use personal protective equipment.</td>
</tr>
<tr>
<td></td>
<td>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental precautions</th>
<th>Avoid release to the environment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Prevent further leakage or spillage if safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Prevent spreading over a wide area (e.g. by containment or oil barriers).</td>
</tr>
<tr>
<td></td>
<td>Retain and dispose of contaminated wash water.</td>
</tr>
<tr>
<td></td>
<td>Local authorities should be advised if significant spills...</td>
</tr>
</tbody>
</table>
cannot be contained.

Methods and materials for containment and cleaning up:
Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe vapours or spray mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:
Oxidizing agents

Storage
Conditions for safe storage:
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.
- Do not pierce or burn, even after use.
- Keep cool. Protect from sunlight.

Materials to avoid:
Do not store with the following product types:
- Strong oxidizing agents

Packaging material:
Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
</table>

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Mometasone / Formoterol Metered Dose Inhaler Formulation

<table>
<thead>
<tr>
<th>(Form of exposure)</th>
<th>Ethanol: 64-17-5</th>
<th>STEL 1,000 ppm</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone: 83919-23-7</td>
<td>TWA 1 µg/m³ (OEB 4)</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>Formoterol: 43229-80-7</td>
<td>TWA 0.05 µg/m³ (OEB 5)</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
<td></td>
</tr>
<tr>
<td>Wipe limit</td>
<td>0.5 µg/100 cm²</td>
<td>Internal</td>
<td></td>
</tr>
</tbody>
</table>

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Self-contained breathing apparatus

Skin and body protection: Skin should be washed after contact.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: aerosol
Colour: white to off-white
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: -16.5 °C
Flash point: No data available
Evaporation rate: No data available
Flammability (solid, gas): Not applicable
Flammability (liquids): No data available
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapour pressure : 3,900 hPa (20 °C)
Relative vapour density : 5.9
Relative density : 5.9
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
 Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
If the temperature rises there is danger of the vessels bursting due to the high vapor pressure. Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION
Exposure routes
Inhalation
Skin contact
Ingestion
Eye contact
Acute toxicity
Not classified based on available information.
Mometasone / Formoterol Metered Dose Inhaler Formulation

Components:

Ethanol:

Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
   Method: OECD Test Guideline 401

Acute inhalation toxicity:
   LC50 (Rat): 124.7 mg/l
   Exposure time: 4 h
   Test atmosphere: vapour

Mometasone:

Acute oral toxicity:
   LD50 (Rat): > 2,000 mg/kg
   LD50 (Mouse): > 2,000 mg/kg

Acute inhalation toxicity:
   LC50 (Rat): > 3.3 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Remarks: No mortality observed at this dose.

   LC50 (Mouse): > 3.2 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist

Acute toxicity (other routes of administration):
   LD50 (Rat): 300 mg/kg
   Application Route: Subcutaneous
   Symptoms: Breathing difficulties

Formoterol:

Acute oral toxicity:
   LD50 (Rat): 3,130 mg/kg
   LD50 (Mouse): 6,700 mg/kg

Acute inhalation toxicity:
   LC50 (Rat): 1.5 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist

Acute dermal toxicity:
   Remarks: No data available

Acute toxicity (other routes of administration):
   LD50 (Rat): 1,000 mg/kg
   Application Route: Subcutaneous

   LD50 (Mouse): 640 mg/kg
   Application Route: Subcutaneous

Skin corrosion/irritation:
Not classified based on available information.

Components:

Ethanol:
Mometasone / Formoterol Metered Dose Inhaler Formulation

Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

**Mometasone:**
Species: Rabbit
Result: No skin irritation

**Formoterol:**
Species: Rabbit
Result: No skin irritation
Remarks: slight irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components:**

**Ethanol:**
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

**Mometasone:**
Species: Rabbit
Result: No eye irritation

**Formoterol:**
Species: Rabbit
Result: No eye irritation

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Ethanol:**
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

**Mometasone:**
Test Type: Maximisation Test
### Mometasone / Formoterol Metered Dose Inhaler Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.3</td>
<td>2021/04/09</td>
<td>75379-00016</td>
<td>2020/10/10</td>
<td>2015/03/16</td>
</tr>
</tbody>
</table>

#### Exposure routes
- **Species**: Dermal
- **Assessment**: Does not cause skin sensitisation.
- **Result**: negative
- **Remarks**: The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.

### Formoterol:
- **Test Type**: Maximisation Test
- **Exposure routes**: Dermal
- **Species**: Guinea pig
- **Result**: Not a skin sensitizer.

#### Germ cell mutagenicity
Not classified based on available information.

### Components:

#### Ethanol:
- **Genotoxicity in vitro**
  - Test Type: In vitro mammalian cell gene mutation test
  - Result: negative
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- **Genotoxicity in vivo**
  - Test Type: Rodent dominant lethal test (germ cell) (in vivo)
  - Species: Mouse
  - Application Route: Ingestion
  - Result: equivocal

#### Mometasone:
- **Genotoxicity in vitro**
  - Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
  - Test Type: Chromosomal aberration
  - Test system: Chinese hamster lung cells
  - Result: negative
  - Test Type: Chromosomal aberration
  - Test system: Chinese hamster ovary cells
  - Result: positive
  - Test Type: Mouse Lymphoma
  - Result: negative
- **Genotoxicity in vivo**
  - Test Type: Micronucleus test
  - Species: Mouse
  - Application Route: Oral
  - Result: negative
  - Test Type: Chromosomal aberration
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Mometasone / Formoterol Metered Dose Inhaler Formulation

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Formoterol:
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative
Test Type: Chromosomal aberration
Result: negative
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Mouse
Application Route: Oral
Result: negative
Test Type: Micronucleus test
Species: Rat
Application Route: Oral
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Mometasone:
Species: Rat
Application Route: Inhalation
Exposure time: 2 Years
Dose: 0.067 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Inhalation
Exposure time: 19 Months
Dose: 0.160 mg/kg body weight
Result: negative
### Formoterol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>LOAEL</td>
<td>0.5 mg/kg body weight</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Ovary</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>18 month(s)</td>
</tr>
<tr>
<td>LOAEL</td>
<td>2 mg/kg body weight</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Adrenal gland, Liver, Uterus (including cervix)</td>
</tr>
<tr>
<td>Remarks</td>
<td>The mechanism or mode of action may not be relevant in humans.</td>
</tr>
</tbody>
</table>

### Carcinogenicity - Assessment

Limited evidence of carcinogenicity in animal studies

### Reproductive toxicity

Not classified based on available information.

### Components:

#### Ethanol:

Effects on fertility:
- Test Type: Two-generation reproduction toxicity study
- Species: Mouse
- Application Route: Ingestion
- Result: negative

#### Mometasone:

**Effects on fertility**
- Test Type: Fertility
- Species: Rat
- Application Route: Subcutaneous
- Fertility: NOAEL: 0.015 mg/kg body weight
- Symptoms: Reduced embryonic survival, Reduced foetal weight
- Result: No effects on fertility, Effect on reproduction capacity

**Effects on foetal development**
- Test Type: Embryo-foetal development
  - Species: Mouse
  - Application Route: Subcutaneous
  - Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight
  - Result: Embryotoxic effects, Teratogenicity and developmental toxicity

- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Dermal
  - Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight
  - Result: Embryo-foetal toxicity
Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Dermal
Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
Result: Embryo-foetal toxicity, Malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Subcutaneous
Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
Result: Effects on newborn

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight
Result: Embryo-foetal toxicity, Malformations were observed.

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

**Formoterol:**

**Effects on fertility:**
Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Fertility: NOAEL: 3 mg/kg body weight
Result: No effects on fertility

**Effects on foetal development:**
Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 0.2 mg/kg body weight
Result: Embryo-foetal toxicity, No malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 3 mg/kg body weight
Result: Malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: inhalation (dust/mist/fume)
Developmental Toxicity: NOAEL: 1.2 mg/kg body weight
Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 60 mg/kg body weight
Result: Embryo-foetal toxicity, No malformations were observed.

Reproductive toxicity - Assessment :
Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

Components:
Mometasone:
Remarks : Based on available data, the classification criteria are not met.

Formoterol:
Exposure routes : Ingestion, inhalation (dust/mist/fume)
Target Organs : Cardio-vascular system, Central nervous system
Assessment : Causes damage to organs.

STOT - repeated exposure
Not classified based on available information.

Components:
Mometasone:
Exposure routes : inhalation (dust/mist/fume)
Target Organs : Immune system, Liver, Kidney, Skin
Assessment : May cause damage to organs through prolonged or repeated exposure.

Formoterol:
Exposure routes : Ingestion, inhalation (dust/mist/fume)
Target Organs : Heart
Assessment : Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
Ethanol:
Species : Rat
NOAEL : 1,280 mg/kg
LOAEL : 3,156 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Mometasone:
## Mometasone / Formoterol Metered Dose Inhaler Formulation

<table>
<thead>
<tr>
<th></th>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td></td>
<td>0.005 mg/kg</td>
<td>0.3 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td></td>
<td>0.5 mg/kg</td>
<td></td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Rat</td>
<td></td>
<td>0.00013 mg/l</td>
<td></td>
<td>inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td></td>
<td>0.0005 mg/l</td>
<td></td>
<td>inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland</td>
</tr>
</tbody>
</table>

### Formoterol:

<table>
<thead>
<tr>
<th></th>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td></td>
<td>&gt;= 1.5 mg/kg</td>
<td>Inhalation</td>
<td>13 Weeks</td>
<td>Heart</td>
</tr>
<tr>
<td>Dog</td>
<td></td>
<td>0.14 mg/kg</td>
<td>Inhalation</td>
<td>13 Weeks</td>
<td>Heart</td>
</tr>
<tr>
<td>Dog</td>
<td></td>
<td>0.003 mg/kg</td>
<td>Oral</td>
<td>1 yr</td>
<td>Heart</td>
</tr>
<tr>
<td>Rat</td>
<td></td>
<td>0.3 mg/kg</td>
<td>Oral</td>
<td>1 yr</td>
<td>Heart</td>
</tr>
</tbody>
</table>

---
Mometasone / Formoterol Metered Dose Inhaler Formulation

Aspiration toxicity
Not classified based on available information.

Components:
Mometasone: Not applicable

Experience with human exposure

Components:
Mometasone:
Inhalation: Symptoms: allergic rhinitis, Headache, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion
Skin contact: Symptoms: Dermatitis, Itching
Formoterol:
Inhalation: Target Organs: Heart
Symptoms: Palpitation, Tremors, Dizziness, Headache, dry mouth, Nausea, Fatigue

Further information

Components:
Mometasone:
Remarks: Dermal absorption possible

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
Ethanol:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): > 1,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia (water flea)): > 1,000 mg/l Exposure time: 48 h
Toxicity to algae/aquatic plants: ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l Exposure time: 72 h
EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l Exposure time: 72 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 9.6 mg/l Exposure time: 9 d
Mometasone / Formoterol Metered Dose Inhaler Formulation

Toxicity to microorganisms: EC50 (Pseudomonas putida): 6,500 mg/l Exposure time: 16 h

Mometasone:
Toxicity to fish: LC50 (Menidia beryllina (Silverside)): 0.11 mg/l Exposure time: 96 h Remarks: No toxicity at the limit of solubility

LC50 (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l Exposure time: 7 d Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 5 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility

EC50 (Americamysis): > 5 mg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035 Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l Exposure time: 32 d Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0.34 mg/l Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity): 100

Toxicity to microorganisms: EC50: > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility

NOEC: 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition Method: OECD Test Guideline 209 Remarks: No toxicity at the limit of solubility
Formoterol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 120 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 114 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): 94 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
NOEC (Pseudokirchneriella subcapitata (green algae)): 30 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Persistence and degradability

Components:

Ethanol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Mometasone:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Stability in water: Hydrolysis: 50 %(12 d)
Method: OECD Test Guideline 111

Bioaccumulative potential

Components:

Ethanol:
Partition coefficient: n-octanol/water: log Pow: -0.35

Mometasone:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107.1
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water: log Pow: 4.68
Formoterol:
Partition coefficient: n-octanol/water: log Pow: 0.41

Mobility in soil

Components:

Mometasone:
Distribution among environmental compartments: log Koc: 4.02

Other adverse effects:
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. Please ensure aerosol cans are sprayed completely empty (including propellant)

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 1950
Proper shipping name: AEROSOLS
Class: 2.2
Packing group: Not assigned by regulation
Labels: 2.2

IATA-DGR
UN/ID No.: UN 1950
Proper shipping name: Aerosols, non-flammable
Class: 2.2
Packing group: Not assigned by regulation
Labels: Non-flammable, non-toxic Gas
Packing instruction (cargo aircraft): 203
Packing instruction (passenger aircraft): 203

IMDG-Code
UN number: UN 1950
Proper shipping name: AEROSOLS (Mometasone)
Class: 2.2
Packing group: Not assigned by regulation
Labels: 2.2
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Mometasone / Formoterol Metered Dose Inhaler Formulation

Version 3.3  Revision Date: 2021/04/09  SDS Number: 75379-00016  Date of last issue: 2020/10/10
Date of first issue: 2015/03/16

EmS Code : F-D, S-U
Marine pollutant : yes

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

National Regulations

GB 6944/12268
UN number : UN 1950
Proper shipping name : AEROSOLS
Class : 2.2
Packing group : Not assigned by regulation
Labels : 2.2

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

Montreal Protocol : 1,1,1,2,3,3,3-Heptafluoropropane

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / STEL : Short-term exposure limit
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.