SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

SECTION 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, 33nd 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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

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

SECTION 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

SECTION 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.
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. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: Gas reduces oxygen available for breathing.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

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.

Hazardous combustion products: Fluorine compounds
Carbon oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Hazchem Code: 2YE

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions

Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages 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.

SECTION 7. HANDLING AND STORAGE

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.

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.

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
SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>TWA</td>
<td>1,000 ppm</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1,880 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information: Skin

- Wipe limit: 10 µg/100 cm² Internal

Formoterol

- TWA: 0.05 µg/m³ (OEB 5) Internal

- Wipe limit: 0.5 µg/100 cm² Internal

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.

SECTION 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

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes: Inhalation
  Skin contact
  Ingestion
  Eye contact
Acute toxicity
Not classified based on available information.

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:
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
Exposure routes: Dermal
Species: Guinea pig
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.

Chronic toxicity
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

Genotoxicity in vivo: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

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
Species: Rat
Cell type: Bone marrow
Result: negative

Test Type: unscheduled DNA synthesis assay
Species: Rat
Cell type: Liver cells
Result: negative

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>

### Species:

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

### Carcinogenicity - Assessment:

Limited evidence of carcinogenicity in animal studies

### Reproductive toxicity:

Not classified based on available information.

### Components:

#### Ethanol:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Two-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

#### Mometasone:

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Fertility</td>
<td>NOAEL: 0.015 mg/kg body weight</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Reduced embryonic survival, Reduced foetal weight</td>
</tr>
<tr>
<td>Result</td>
<td>No effects on fertility, Effect on reproduction capacity</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Application Route</td>
<td>Subcutaneous</td>
</tr>
<tr>
<td>Embryo-foetal toxicity</td>
<td>LOAEL: 0.06 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>Embryotoxic effects, Teratogenicity and developmental toxicity</td>
</tr>
</tbody>
</table>

| 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:**
Species: Rat
NOAEL: 0.005 mg/kg
### SAFETY DATA SHEET

#### 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>4.4</td>
<td>09.04.2021</td>
<td>75373-00016</td>
<td>10.10.2020</td>
<td>16.03.2015</td>
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</tbody>
</table>

### LOAEL

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOAEL</td>
<td></td>
<td>0.3 mg/kg</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>

### Species

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td></td>
<td>0.5 mg/kg</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>

### Application Route

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>

### Exposure time

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>

### Target Organs

<table>
<thead>
<tr>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>

### Species

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td></td>
<td>0.0013 mg/l</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
</tbody>
</table>

### NOAEL

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<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>
</tbody>
</table>

### Application Route

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<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>
</tbody>
</table>

### Exposure time

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
</tbody>
</table>

### Target Organs

<table>
<thead>
<tr>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
</tbody>
</table>

### Formoterol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td></td>
<td>0.14 mg/kg</td>
<td>Heart</td>
</tr>
</tbody>
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### Application Route

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>13 Weeks</td>
<td>Heart</td>
</tr>
</tbody>
</table>

### Exposure time

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>13 Weeks</td>
<td>Heart</td>
</tr>
</tbody>
</table>

### Target Organs

<table>
<thead>
<tr>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
</tr>
</tbody>
</table>

### Species

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td></td>
<td>0.003 mg/kg</td>
<td>Heart</td>
</tr>
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### Application Route

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>1 yr</td>
<td>Heart</td>
</tr>
</tbody>
</table>

### Exposure time

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 yr</td>
<td>Heart</td>
</tr>
</tbody>
</table>

### Target Organs

<table>
<thead>
<tr>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
</tr>
</tbody>
</table>

### Species

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td></td>
<td>0.3 mg/kg</td>
<td>Heart</td>
</tr>
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</table>

### Application Route

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>1 yr</td>
<td>Heart</td>
</tr>
</tbody>
</table>

### Exposure time

<table>
<thead>
<tr>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 yr</td>
<td>Heart</td>
</tr>
</tbody>
</table>

### Target Organs

<table>
<thead>
<tr>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
</tr>
</tbody>
</table>

### 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

SECTION 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
- 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

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

SECTION 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)

SECTION 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
- 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

ADG
- UN number: UN 1950
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Proper shipping name: AEROSOLS
Class: 2.2
Packing group: Not assigned by regulation
Labels: 2.2
Hazchem Code: 2YE

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Prohibition/Licensing Requirements: There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

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

SECTION 16. OTHER INFORMATION

Further information
Revision Date: 09.04.2021
Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA, ACGIH Threshold Limit Values (TLV)
AU OEL: Australia, Workplace Exposure Standards for Airborne Contaminants.

ACGIH / STEL: Short-term exposure limit
AU OEL / TWA: Exposure standard - time weighted average
AlIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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.

AU / EN