1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Mometasone / Formoterol Metered Dose Inhaler Formulation

Supplier’s company name, address and phone number
Company name of supplier : Organon & Co.
Address : 30 Hudson Street, 33nd floor
           Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
E-mail address : EHSSTEWARD@organon.com
Emergency telephone number : 215-631-6999

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Aerosols : Category 3
Long-term (chronic) aquatic hazard : Category 2
Hazardous to the ozone layer : Category 1

GHS label elements
Hazard pictograms : ![Warning]![Ozone]

Signal word : Warning

Hazard statements : H229 Pressurised container: May burst if heated.
                   H411 Toxic to aquatic life with long lasting effects.
                   H420 Harms public health and the environment by destroying ozone in the upper atmosphere.

Precautionary statements : Prevention:
                          P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
                          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 40 °C/ 104 °F.

Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.
P502 Refer to manufacturer or supplier for information on recovery or recycling.

Other hazards which do not result in classification
Important symptoms and outlines of the emergency assumed
May displace oxygen and cause rapid suffocation.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>1,1,1,2,3,3-Heptafluoropropane</td>
</tr>
<tr>
<td></td>
<td>Ethanol#</td>
</tr>
<tr>
<td></td>
<td>Mometasone</td>
</tr>
<tr>
<td></td>
<td>Formoterol</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.
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.

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.

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 absor-
bent. 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.

Avoid contact with eyes.

Avoid breathing vapours or spray mist.

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

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.

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:

Oxidizing solids

Oxidizing liquids

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of)</th>
<th>Control parameters / Permissible</th>
<th>Basis</th>
</tr>
</thead>
</table>

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SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

<table>
<thead>
<tr>
<th>Exposure</th>
<th>Concentration</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>STEL 1,000 ppm</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA 1 µg/m³ (OEB 4) Internal</td>
</tr>
<tr>
<td>Formoterol</td>
<td>43229-80-7</td>
<td>TWA 0.05 µg/m³ (OEB 5) Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

Wipe limit: 10 µg/100 cm² Internal

Wipe limit: 0.5 µg/100 cm² Internal

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: aerosol

Colour: white to off-white

Odour: No data available

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: -16.5 °C

Flammability (solid, gas): Not applicable

Flammability (liquids): No data available

Lower explosion limit and upper explosion limit / flammability limit: No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Flash point: No data available

Decomposition temperature: No data available

pH: No data available

Evaporation rate: No data available

Auto-ignition temperature: No data available

Viscosity:
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>3,900 hPa (20 °C)</td>
</tr>
<tr>
<td>Density and / or relative density</td>
<td></td>
</tr>
<tr>
<td>Relative density</td>
<td>5.9</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>5.9</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**10. STABILITY AND REACTIVITY**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>If the temperature rises there is danger of the vessels bursting due to the high vapor pressure. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

**11. TOXICOLOGICAL INFORMATION**

<table>
<thead>
<tr>
<th>Route of exposure</th>
<th>Information on likely routes of exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Information on likely routes of exposure</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Inhalation</td>
</tr>
<tr>
<td>Ingestion</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Ingestion</td>
</tr>
</tbody>
</table>

**Acute toxicity**

Not classified based on available information.

**Components:**

1,1,1,2,3,3,3-Heptafluoropropane:
Acute inhalation toxicity : LC50 (Rat): > 788696 ppm
Exposure time: 4 h
Test atmosphere: gas
Method: OECD Test Guideline 403

**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 sensitiser.

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:

1,1,1,2,3,3,3-Heptafluoropropane:
Genotoxicity in vitro:
Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: inhalation (gas)
Result: negative

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
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
### 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>5.2</td>
<td>2021/04/09</td>
<td>75385-00016</td>
<td>2020/10/10</td>
<td>2015/03/16</td>
</tr>
</tbody>
</table>

#### Exposure

<table>
<thead>
<tr>
<th></th>
<th>2 Years</th>
<th>0.067 mg/kg body weight</th>
<th>negative</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species</strong></td>
<td>Mouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Inhalation</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>19 Months</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td>0.160 mg/kg body weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>negative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Formoterol:

<table>
<thead>
<tr>
<th></th>
<th>Rat</th>
<th>0.5 mg/kg body weight</th>
<th>Ovary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Species</strong></td>
<td>Mouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Application Route</strong></td>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Exposure time</strong></td>
<td>2 Years</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>LOAEL</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Target Organs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td></td>
<td></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:

**1,1,1,2,3,3,3-Heptafluoropropane:**

**Effects on fertility**

- **Test Type:** One-generation reproduction toxicity study
- **Species:** Rat
- **Application Route:** inhalation (vapour)
- **Result:** negative
- **Remarks:** Based on data from similar materials

**Effects on foetal development**

- **Test Type:** Embryo-foetal development
- **Species:** Rat
- **Application Route:** inhalation (gas)
- **Method:** OECD Test Guideline 414
- **Result:** negative

**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: Embryofetal development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 0.2 mg/kg body weight
  - Result: Embryofetal toxicity, No malformations were observed.

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

- Test Type: Embryofetal development
  - Species: Rat
  - Application Route: Inhalation (dust/mist/fume)
  - Developmental Toxicity: NOAEL: 1.2 mg/kg body weight
  - Result: No embryofetal toxicity

- Test Type: Embryofetal development
  - Species: Rabbit
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 60 mg/kg body weight
  - Result: Embryofetal 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:

1,1,1,2,3,3,3-Heptafluoropropane:
Species: Rat
NOAEL: 731.69 mg/l
Application Route: inhalation (gas)
Exposure time: 13 Weeks
Method: OECD Test Guideline 413

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

Formoterol:
Species: Dog
LOAEL: >= 1.5 mg/kg
Application Route: Inhalation
Exposure time: 13 Weeks
Target Organs: Heart

Species: Rat
NOAEL: 0.14 mg/kg
Application Route: Inhalation
Exposure time: 13 Weeks
Target Organs: Heart

Species: Dog
LOAEL: 0.003 mg/kg
Application Route: Oral
Exposure time: 1 yr
Target Organs: Heart

Species: Rat
LOAEL: 0.3 mg/kg
Application Route: Oral
Exposure time: 1 yr
Target Organs: Heart

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:

1,1,1,2,3,3,3-Heptafluoropropane:
Toxicity to fish: LC50 (Danio rerio (zebra fish)): > 200 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 200 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 114 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 1.2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Toxicity to microorganisms: EC50: > 173.1 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

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: EC10 (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

#### 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

#### 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
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<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>5.2</td>
<td>2021/04/09</td>
<td>75385-00016</td>
<td>2020/10/10</td>
<td>2015/03/16</td>
</tr>
</tbody>
</table>

**Formoterol:**

**Toxicity to fish**: LC50 (Oncorhynchus mykiss (rainbow trout)): > 120 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Remark: No toxicity at the limit of solubility

**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:**

1,1,1,2,3,3,3-Heptafluoropropane:

**Biodegradability**: Result: Not readily biodegradable.
Biodegradation: 1 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

**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

**Ethanol**:

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

**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

**Hazardous to the ozone layer**

**Components:**

1,1,1,2,3,3,3-Heptafluoropropane:

Ozone-Depletion Potential: Regulation: Japan. Enforcement Ordinance of the Law concerning the Protection of the Ozone Layer through the Control of Specified Substances and other measures (Update: 2018-08-10)
Number: 6
Group: Annex F - Group I

**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
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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
Refer to section 15 for specific national regulation.

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

Related Regulations

Fire Service Law
Group 4, Alcohols, (400 litre), Hazardous rank II, (Remained chemical in a spray can after degassing falls under this group)

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable
Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>61</td>
<td>&gt;=1 - &lt;10</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>61</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
According to MITI Notice No. 139 in 1997, the High Pressure Gas Safety Act isn't applied to this product.

Explosive Control Law
Not applicable

Vessel Safety Law
Gases (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Gases (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)
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Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation: Noxious liquid substance (Category Z)
Pack transportation: Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Not applicable

International 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

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

AIIC - 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 Or-
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JP / EN