SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Product name: Mometasone / Formoterol Metered Dose Inhaler Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil  B-2220
Telephone: 551-430-6000
Emergency telephone: 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 in accordance with ABNT NBR 14725 Standard
Aerosols: Category 3
Long-term (chronic) aquatic hazard: Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard
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.
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 tempera-
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>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol#</td>
<td>64-17-5</td>
<td>Flammable liquids, Category 2</td>
<td>1,8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye irritation, Category 2A</td>
<td></td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>Reproductive toxicity, Category 1B</td>
<td>&gt;= 0,087 &lt;= 0,17</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specific target organ toxicity - repeated exposure (Inhalation) (Immune system, Liver, Kidney, Skin), Category 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Long-term (chronic) aquatic hazard, Category 1</td>
<td></td>
</tr>
<tr>
<td>Formoterol</td>
<td>43229-80-7</td>
<td>Acute toxicity (Inhalation), Category 4</td>
<td>&gt;= 0,0009 &lt;= 0,0087</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carcinogenicity, Category 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reproductive toxicity, Category 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specific target organ toxicity - single exposure (Cardio-vascular system, Central nervous system), Category 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specific target organ toxicity - repeated exposure (Heart), Category 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Short-term (acute) aquatic hazard, Category 3</td>
<td></td>
</tr>
</tbody>
</table>

# Voluntarily-disclosed non-hazardous substance

SECTION 4. FIRST AID MEASURES
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Version 5.2  Revision Date: 09.04.2021  SDS Number: 75375-00016  Date of last issue: 10.10.2020
Date of first issue: 16.03.2015

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.

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. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media:
None known.

Specific hazards during fire fighting:
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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES
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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 diking or other appropriate containment to keep material from spreading. If diked 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 vapors 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:
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Oxidizing agents
  - Flammable solids
  - Pyrophoric liquids
  - Pyrophoric solids
  - Self-heating substances and mixtures
  - Substances and mixtures which in contact with water emit flammable gases
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients 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>LT</td>
<td>780 ppm 1.480 mg/m³</td>
<td>BR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STEL 1.000 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 10 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Formoterol</td>
<td>43229-80-7</td>
<td>TWA</td>
<td>0.05 µg/m³ (OEB 5)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 0.5 µg/100 cm²</td>
<td>Internal</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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: aerosol

**Color**: white to off-white

**Odor**: No data available

**Odor 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
Vapor pressure: 3.900 hPa (20 °C)
Relative vapor 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
Autoignition 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.
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**SECTION 11. TOXICOLOGICAL INFORMATION**

**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.

**Information on likely routes of exposure:**
- 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: vapor

**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 sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Ethanol:
Test Type: Local lymph node assay (LLNA)
Routes of exposure: Skin contact
Species: Mouse
Result: negative

Mometasone:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Assessment: Does not cause skin sensitization.
Result: negative
Remarks: The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.

Formoterol:
Test Type: Maximization Test
Routes of exposure: 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

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

Mometasone:
Genotoxicity in vitro: Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal
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:
Species: Mouse
Application Route: Oral
Result: negative

Genotoxicity in vivo:
Species: Rat
Cell type: Bone marrow
Result: negative

Genotoxicity in vivo:
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:
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:
Species: Rat
Application Route: Oral
Exposure time: 2 Years
LOAEL: 0.5 mg/kg body weight
Target Organs: Ovary
Remarks: The mechanism or mode of action may not be relevant in humans.

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:
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 fetal weight.
Result: No effects on fertility., Effect on reproduction capacity.

Effects on fetal development:
- Test Type: Embryo-fetal development
  - Species: Mouse
  - Application Route: Subcutaneous
  - Embryo-fetal toxicity: LOAEL: 0,06 mg/kg body weight
  - Result: Embryotoxic effects., Teratogenicity and developmental toxicity

- Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Dermal
  - Embryo-fetal toxicity: LOAEL: 0,3 mg/kg body weight
  - Result: Embryo-fetal toxicity.

- Test Type: Embryo-fetal development
  - Species: Rabbit
  - Application Route: Dermal
  - Embryo-fetal toxicity: LOAEL: 0,15 mg/kg body weight
  - Result: Embryo-fetal 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 fetal development:
- Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Oral
  - Developmental Toxicity: LOAEL: 0,2 mg/kg body weight
  - Result: Embryo-fetal toxicity., No malformations were observed.

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

Test Type: Embryo-fetal development
Species: Rat
Application Route: inhalation (dust/mist/fume)
Developmental Toxicity: NOAEL: 1,2 mg/kg body weight
Result: No embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: LOAEL: 60 mg/kg body weight
Result: Embryo-fetal 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:**
Routes of exposure : 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:**
Routes of exposure : inhalation (dust/mist/fume)
Target Organs : Immune system, Liver, Kidney, Skin
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Formoterol:**
Routes of exposure : 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
- LOAEL: 0.3 mg/kg
- Application Route: Oral
- Exposure time: 30 d
- Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species: Dog
- NOAEL: 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
- NOAEL: >= 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
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Species: Dog
LOAEL: 0,003 mg/kg
Application Route: Oral
Exposure time: 1 y
Target Organs: Heart

Species: Rat
LOAEL: 0,3 mg/kg
Application Route: Oral
Exposure time: 1 y
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

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: EC50 (Ceriodaphnia (water flea)): > 1.000 mg/l
### aquatic invertebrates

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Concentration</th>
<th>Exposure Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>ErC50</td>
<td>275 mg/l</td>
<td>48 h</td>
</tr>
<tr>
<td>EC10</td>
<td>11.5 mg/l</td>
<td>72 h</td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Concentration</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50</td>
<td>0.11 mg/l</td>
<td>96 h</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>LC50</td>
<td>&gt; 5 mg/l</td>
<td>7 d</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Concentration</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>&gt; 5 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>EC50</td>
<td>&gt; 5 mg/l</td>
<td>96 h</td>
<td>US-EPA OPPTS 850.1035</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Concentration</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>&gt; 3.2 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

Toxicity to fish (Chronic toxicity):

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Concentration</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
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<tbody>
<tr>
<td>NOEC</td>
<td>0.00014 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
<td></td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Concentration</th>
<th>Exposure Time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOEC</td>
<td>0.34 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
<td>No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

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- log Pow: -0.35
octanol/water

**Mometasone:**
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioccentration 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 (passen...: 203
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

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.

Domestic regulation

ANTT
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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable
Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
BR OEL: Brazil. NR 15 - Unhealthy activities and operations
ACGIH / STEL: Short-term exposure limit
BR OEL / LT: Up to 48 hours /week

Acronyms: 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 Civil Aviation Organization; 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 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.

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