SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Version 5.6  Revision Date: 09.04.2021  SDS Number: 75387-00016  Date of last issue: 10.10.2020
Date of first issue: 16.03.2015

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone / Formoterol Metered Dose Inhaler Formulation

Manufacturer or supplier’s details
Company name of supplier: Organon & Co.
Address: Avenida 16 de Septiembre No. 301
Xaltocan - Xochimilco Mexico 16090
Telephone: 52 55 57284444
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
Aerosols: Category 3
Reproductive toxicity: Category 1B

GHS label elements
Hazard pictograms:

Signal Word: Danger

Hazard Statements:
H229 Pressurised container: May burst if heated.
H360DF May damage the unborn child. Suspected of damaging fertility.

Precautionary Statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
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.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.
P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F.
Disposal:
P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards
May displace oxygen and cause rapid suffocation.

SECTION 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>Ethanol#</td>
<td>Ethanol</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
</tr>
<tr>
<td>Formoterol</td>
<td>43229-80-7</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.
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:
May damage the unborn child. Suspected of damaging fertility.
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 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 fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

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 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.
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>VLE-CT</td>
<td>1,000 ppm</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>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 4)</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-
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

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

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
- 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 hu-
Carcinogenicity - Assessment: Limited evidence of carcinogenicity in animal studies

Reproductive toxicity
May damage the unborn child. Suspected of damaging fertility.

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.

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

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Embryo-fetal toxicity.: LOAEL: 0.7 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
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 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
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.

**Domestic regulation**

**NOM-002-SCT**
- 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.
SAFETY DATA SHEET
Mometasone / Formoterol Metered Dose Inhaler Formulation

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
NOM-165-SEMARNAT-2013, Norm establishing a list of substances subject to report for the Registry of Emissions and Pollutant Transfer

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>MPU (kg/year)</th>
<th>Transfer/Release (kg/year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,1,1,2,3,3,3-Heptafluoropropane</td>
<td>431-89-0</td>
<td>2500 kg/year</td>
<td>100 kg/year</td>
</tr>
</tbody>
</table>

MPU: Applicable reporting threshold when the substance, pure or in mixture in a composition of more than 1% by weight, is used for industrial activities at facilities that are subject to report or are produced by them

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills: 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

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / STEL: Short-term exposure limit
- NOM-010-STPS-2014 / VLE-CT: Short term exposure limit value

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 con-
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Version: 5.6
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Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 09.04.2021

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8