SAFETY DATA SHEET
Mometasone / Formoterol Metered Dose Inhaler Formulation

Version 3.8  Revision Date: 05/29/2019  SDS Number: 75385-00012  Date of last issue: 2019/04/24  Date of first issue: 2015/03/16

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone / Formoterol Metered Dose Inhaler Formulation

Manufacturer or supplier’s details
Company name of supplier: MSD
Address: Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone: 048-588-8411
E-mail address: EHSDATASTEWARD@msd.com
Emergency telephone number: 1-908-423-6000

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

2. HAZARDS IDENTIFICATION

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

GHS label elements
Hazard pictograms: 

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

Precautionary statements: Prevention:
P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.
P251 Do not pierce or burn, even after use.
P273 Avoid release to the environment.
Response:
P391 Collect spillage.
Storage:
P410 + P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/ 122 °F.
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

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.

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

Substance / Mixture: Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Ethanol</td>
<td>64-17-5</td>
<td>1.8</td>
<td>2-202</td>
</tr>
<tr>
<td></td>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.087 - &lt;= 0.17</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Formoterol</td>
<td>43229-80-7</td>
<td>&gt;= 0.0009 - &lt;= 0.0087</td>
<td></td>
</tr>
</tbody>
</table>

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.
Get medical attention.

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:
None known.

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.

Notes to physician:
Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Version 3.8 Revision Date: 05/29/2019 SDS Number: 75385-00012 Date of last issue: 2019/04/24 Date of first issue: 2015/03/16

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 and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided.
                           Prevent further leakage or spillage if safe to do so.
                           Prevent spreading over a wide area (e.g. by containment or oil barriers).
                           Retain and dispose of contaminated wash water.
                           Local authorities should be advised if significant spillages cannot be contained.

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

Handling
Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation: Use with local exhaust ventilation.
Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe vapours or spray mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents
Hygiene measures:
- Ensure that eye flushing systems and safety showers are located 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 exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</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></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></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: Use respiratory protection unless adequate local exhaust
ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

Filter type: Self-contained breathing apparatus

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

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>aerosol</td>
<td></td>
</tr>
<tr>
<td>Colour</td>
<td>white to off-white</td>
<td></td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>-16.5 °C</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>3,900 hPa (20 °C)</td>
<td></td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>5.9</td>
<td></td>
</tr>
<tr>
<td>Relative density</td>
<td>5.9</td>
<td></td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
<td></td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
<td></td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Oxidizing properties: The substance or mixture is not classified as oxidizing.
Molecular weight: No data available
Particle size: No data available

10. STABILITY AND REACTIVITY

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

11. TOXICOLOGICAL INFORMATION

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: 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:

Ethanol:
Genotoxicity in vitro
Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
## Mometasone / Formoterol Metered Dose Inhaler Formulation

| 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 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

10 / 21
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 development-toxicity

- Test Type: Embryo-foetal development
  - Species: Rat
  - Application Route: Dermal
  - Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight
  - Result: Embryo-foetal toxicity

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

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

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

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

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

Effects on foetal development:

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

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

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

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

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

**STOT - single exposure**
Not classified based on available information.

**Components:**

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

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

**STOT - repeated exposure**
Not classified based on available information.

**Components:**

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

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

**Repeated dose toxicity**

**Components:**

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

**Mometasone:**
- **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
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Version 3.8  Revision Date: 05/29/2019  SDS Number: 75385-00012  Date of last issue: 2019/04/24  Date of first issue: 2015/03/16

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:**

**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
### 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>3.8</td>
<td>05/29/2019</td>
<td>75385-00012</td>
<td>2019/04/24</td>
<td>2015/03/16</td>
</tr>
</tbody>
</table>

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

#### M-Factor (Chronic aquatic toxicity)
- 100

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

- NOEC: 1,000 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209
  - Remarks: No toxicity at the limit of solubility

#### Formoterol:
- LC50 (Oncorhynchus mykiss (rainbow trout)): > 120 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203

- EC50 (Daphnia magna (Water flea)): > 114 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

- 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

Hazardous to the ozone layer
Not applicable

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
SAFETY DATA SHEET

Mometasone / Formoterol Metered Dose Inhaler Formulation

Version 3.8  Revision Date: 05/29/2019  SDS Number: 75385-00012  Date of last issue: 2019/04/24
Date of first issue: 2015/03/16

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

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

IMDG-Code
UN number : UN 1950
Proper shipping name : AEROSOLS
(Mometasone)
Class : 2.2
Packing group : Not assigned by regulation
Labels : 2.2
EmS Code : F-D, S-U
Marine pollutant : yes

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

National Regulations
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), (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

<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

<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)

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
Not applicable
Specific Narcotic or Psychotropic Raw Material
Not applicable

Waste Disposal and Public Cleansing Law
Not applicable

International Regulations
Montreal Protocol (Ozone Depleting Substances) : 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

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -
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.

JP / EN