SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Mometasone Metered Dose Inhaler Formulation

Version 1.13  Revision Date: 09/13/2019  SDS Number: 25990-00014  Date of last issue: 31.05.2019  Date of first issue: 28.10.2014

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Mometasone Metered Dose Inhaler Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company : MSD
Innishannon
County Cork - Ireland

Telephone : 353 214329300
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Aerosols, Category 3
Long-term (chronic) aquatic hazard, Category 2
H229: Pressurised container: May burst if heated.
H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)

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, hot surfaces, sparks, open
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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.

Additional Labelling
Contains fluorinated greenhouse gases. (HFC-227ea)

2.5 % by mass of the contents are flammable.

2.3 Other hazards
May displace oxygen and cause rapid suffocation.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>603-002-00-5</td>
<td></td>
<td>Flam. Liq. 2; H225 Eye Irrit. 2; H319</td>
<td>&gt;= 1.8 - &lt;= 2.5</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td></td>
<td></td>
<td></td>
<td>Repr. 1B; H360Df STOT RE 2; H373 Aquatic Chronic 1; H410</td>
<td>&gt;= 0.08 - &lt;= 0.18</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed
None known.

4.3 Indication of any immediate medical attention and special treatment needed
Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

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

Unsuitable extinguishing media : None known.

5.2 Special hazards arising from the substance or mixture
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 : Carbon oxides
Fluorine compounds

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions:
- Evacuate personnel to safe areas.
- Ventilate the area.
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions
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.

6.3 Methods and material for containment and cleaning up
Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling
Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSOHAL PROTECTION section.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling  
Do not get on skin or clothing.  
Do not breathe vapours or spray mist.  
Do not swallow.  
Avoid contact with eyes.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Keep container tightly closed.  
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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers  
Keep tightly closed. Keep in a cool, well-ventilated place.  
Store in accordance with the particular national regulations.  
Do not piercing or burn, even after use. Keep cool. Protect from sunlight.

Advice on common storage  
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

7.3 Specific end use(s)

Specific use(s)  
No data available

No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5</td>
<td>OELV - 15 min (STEL)</td>
<td>1,000 ppm</td>
<td>IE OEL</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>Further information</td>
<td>Skin</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>1900 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td></td>
<td>Long-term systemic effects</td>
<td>343 mg/kg bw/day</td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td></td>
<td>Long-term systemic effects</td>
<td>950 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td></td>
<td>Acute local effects</td>
<td>950 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td></td>
<td>Long-term systemic effects</td>
<td>206 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td></td>
<td>Long-term systemic effects</td>
<td>114 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td></td>
<td>Long-term systemic effects</td>
<td>87 mg/kg bw/day</td>
</tr>
<tr>
<td>1,1,1,2,3,3,3-Heptafluoropropane</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>61279 mg/m³</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td></td>
<td>Long-term systemic effects</td>
<td>6533 mg/m³</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>Fresh water</td>
<td>0.96 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.79 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>2.75 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>580 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>3.6 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>2.9 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>0.63 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>720 mg/kg food</td>
</tr>
<tr>
<td>1,1,1,2,3,3,3-Heptafluoropropane</td>
<td>Fresh water</td>
<td>0.1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>1 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1.73 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>1.3 mg/kg</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Personal protective equipment

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

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: Aerosol containing a dissolved gas
Colour: white to off-white
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**Mometasone Metered Dose Inhaler Formula-**

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<tr>
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</tbody>
</table>

- **Odour**: odourless
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: -16 °C
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
- **Relative density**: No data available
- **Density**: 1 g/cm3
- **Solubility(ies)**
  - **Water solubility**: insoluble
  - **Partition coefficient: n-octanol/water**: No data available
  - **Auto-ignition temperature**: No data available
  - **Decomposition temperature**: No data available
- **Viscosity**
  - **Viscosity, kinematic**: No data available
- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.

### 9.2 Other information

- **Flammability (liquids)**: No data available
- **Molecular weight**: No data available
- **Particle size**: No data available
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SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
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.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
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

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

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Ethanol:
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 21 days

Mometasone:
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.

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
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</tbody>
</table>

- **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.

#### 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

#### 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 foetal weight  
  - **Result**: No effects on fertility, Effect on reproduction capacity

- **Effects on foetal develop-**: Test Type: Embryo-foetal development
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tion

Species: Mouse
Application Route: Subcutaneous
Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight
Result: Embryotoxic effects, Teratogenicity and development-
tal 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.

STOT - single exposure
Not classified based on available information.

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

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.
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, 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

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

Further information

Components:

Mometasone:
Remarks: Dermal absorption possible

SECTION 12: Ecological information

12.1 Toxicity

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 microorganisms:
EC50 (Pseudomonas putida): 6,500 mg/l
Exposure time: 16 h
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 9.6 mg/l
Exposure time: 9 d
Species: Daphnia magna (Water flea)

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
- 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 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

### Toxicity to fish (Chronic toxicity)
- NOEC: 0.00014 mg/l
- Exposure time: 32 d
- Species: Pimephales promelas (fathead minnow)
- Method: OECD Test Guideline 210

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

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

#### 12.2 Persistence and degradability

**Components:**

**Ethanol:**
- Biodegradability: Result: Readily biodegradable.
  - Biodegradation: 84 %
  - Exposure time: 20 d

Stability in water: Hydrolysis: 50% (12 d) Method: OECD Test Guideline 111

12.3 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

12.4 Mobility in soil

Components:

Mometasone:
Distribution among environmental compartments: log Koc: 4.02

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects

Global warming potential
Regulation (EU) No 517/2014 on fluorinated greenhouse gases
Product: 100-year global warming potential: 3,159

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
Mometasone Metered Dose Inhaler Formulation

SECTION 14: Transport information

14.1 UN number

<table>
<thead>
<tr>
<th>UN number</th>
<th>Details</th>
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<tbody>
<tr>
<td>ADN</td>
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<tr>
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<td>IATA</td>
<td>UN 1950</td>
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14.2 UN proper shipping name

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14.3 Transport hazard class(es)

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</tr>
<tr>
<td>ADR</td>
<td>2</td>
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<td>RID</td>
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<td>IMDG</td>
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<tr>
<td>IATA</td>
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14.4 Packing group

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<td>Labels</td>
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<tr>
<td>ADR</td>
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<tr>
<td>Classification Code</td>
<td>5A</td>
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<td>Labels</td>
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<tr>
<td>Tunnel restriction code</td>
<td>(E)</td>
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<tr>
<td>RID</td>
<td>Not assigned by regulation</td>
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<tr>
<td>Classification Code</td>
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</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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tion

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Date of first issue: 28.10.2014

IMDG
Packing group : Not assigned by regulation
Labels : 2.2
EmS Code : F-D, S-U

IATA (Cargo)
Packing instruction (cargo aircraft) : 203
Packing instruction (LQ) : Y203
Packing group : Not assigned by regulation
Labels : Non-flammable, non-toxic Gas

IATA (Passenger)
Packing instruction (passen-
erg aircraft) : 203
Packing instruction (LQ) : Y203
Packing group : Not assigned by regulation
Labels : Non-flammable, non-toxic Gas

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
: Not applicable
REACH - List of substances subject to authorisation (Annex XIV)
: Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
: Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants
: Not applicable
Regulation (EC) No 649/2012 of the European Parlia-
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The components of this product are reported in the following inventories:
- AICS: not determined
- DSL: not determined
- IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
- H225: Highly flammable liquid and vapour.
- H319: Causes serious eye irritation.
- H360Df: May damage the unborn child. Suspected of damaging fertility.
- H373: May cause damage to organs through prolonged or repeated exposure if inhaled.
- H410: Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
- Aquatic Chronic: Long-term (chronic) aquatic hazard
- Eye Irrit.: Eye irritation
- Flam. Liq.: Flammable liquids
- Repr.: Reproductive toxicity
- STOT RE: Specific target organ toxicity - repeated exposure
- IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
- IE OEL / OELV - 15 min (STEL): Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regula-
# Mometasone Metered Dose Inhaler Formulation

**Version** 1.13  **Revision Date:** 09/13/2019  **SDS Number:** 25990-00014  **Date of last issue:** 31.05.2019  **Date of first issue:** 28.10.2014

Futher information


**Classification of the mixture:**

<table>
<thead>
<tr>
<th>Class</th>
<th>Code</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aerosol 3</td>
<td>H229</td>
<td>Based on product data or assessment</td>
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<tr>
<td>Aquatic Chronic 2</td>
<td>H411</td>
<td>Calculation method</td>
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</table>

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.