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
117 16th Road
07033 Halfway house, Midrand, South Africa
Telephone: +27 11 655 3000
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)

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, hot surfaces, sparks, open flames and other ignition sources. No smoking.
**SAFETY DATA SHEET**

**Mometasone Metered Dose Inhaler Formulation**

**Version** 1.13  
**Revision Date:** 09/13/2019  
**SDS Number:** 26006-00014  
**Date of last issue:** 31.05.2019  
**Date of first issue:** 28.10.2014

---

**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**  
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. EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethanol</td>
<td>64-17-5 200-578-6 603-002-00-5</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>Repr.1B; H360Df STOT RE2; H373 Aquatic Chronic1; H410 M-Factor (Chronic aquatic toxicity): 100</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/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 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 as-
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 pierce 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

### Occupational Exposure Limits

<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>TWA OEL-RL</td>
<td>1.000 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.900 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

Further information

Recommended Limit

Mometasone      | 83919-23-7 | TWA                      | 1 µg/m³ (OEB 4)    | Internal|

Further information

Skin           | Wipe limit | 10 µg/100 cm²             | Internal            |         |

**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>
</table>
Ethanol

<table>
<thead>
<tr>
<th>Workers</th>
<th>Inhalation</th>
<th>Acute local effects</th>
<th>1900 mg/m3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>343 mg/kg bw/day</td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>950 mg/m3</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>950 mg/m3</td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>206 mg/kg bw/day</td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>114 mg/m3</td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>87 mg/kg bw/day</td>
</tr>
</tbody>
</table>

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

| Workers | Inhalation | Long-term systemic effects | 61279 mg/m3 |
| Consumers | Inhalation | Long-term systemic effects | 6533 mg/m3 |

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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Aerosol containing a dissolved gas</td>
</tr>
<tr>
<td>Colour</td>
<td>white to off-white</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
</tbody>
</table>
### SECTION 1: Identification

**Chemical formula:**

**Synonyms:**

**Other names:**

**UN number:**

**CAS number:**

### SECTION 2: Physical data

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial boiling point and boiling range</td>
<td>-16 °C</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>Insoluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

### SECTION 3: Hazard Identification

- **Acute toxicity:**
- **Skin irritation:**
- **Eye irritation:**
- **Respiratory irritation:**
- **Systemic effects:**
- **Reproductive toxicity:**
- **Skin sensitization:**
- **Respiratory sensitization:**
- **Skin corrosion/irritation:**
- **Eye damage/irritation:**
- **Harmful if swallowed:**
- **Harmful if inhaled:**
- **Harmful in contact with skin:**
- **Precautionary statements:**
- **Emergency procedures:**

### SECTION 4: First aid measures

- **Inhalation:**
- **Skin contact:**
- **Eye contact:**
- **If swallowed:**

### SECTION 5: Firefighting measures

- **Extinguishing media:**
- **Special hazards during fire fighting:**
- **Special hazards during handling/hazardous reactions:**

### SECTION 6: Accidental release measures

- **Spill response:**
- **Disposal:**
- **Personal protective equipment:**

### SECTION 7: Handling and storage

- **Handling:**
- **Precautions for user:**
- **Storage:**
- **Incompatibilities:**
- **Stability:**
- **Reactivity:**

### SECTION 8: Exposure controls and personal protection

- **Exposure limits:**
- **Control parameters:**
- **Hygiene and safety measures:**
- **Respiratory protection:**
- **Eye protection:**
- **Skin protection:**
- **Other personal protection:**

### SECTION 9: Physical and chemical properties

- **Initial boiling point and boiling range:**
- **Flash point:**
- **Evaporation rate:**
- **Flammability (solid, gas):**
- **Upper explosion limit / Upper flammability limit:**
- **Lower explosion limit / Lower flammability limit:**
- **Vapour pressure:**
- **Relative vapour density:**
- **Relative density:**
- **Density:**
- **Solubility(ies):**
- **Partition coefficient: n-octanol/water:**
- **Auto-ignition temperature:**
- **Decomposition temperature:**
- **Viscosity:**
- **Explosive properties:**
- **Oxidizing properties:**

### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.
SAFETY DATA SHEET

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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
- **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

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

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

**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
- **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
  - 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

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

12.3 Bioaccumulative potential

Components:

Ethanol:  
Partition coefficient: n-octanol/water: log Pow: -035

Mometasone:  
Bioaccumulation: Species: Lepomis macrochirus (Blugill 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

No data available

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. If not otherwise specified: Dispose of as unused product. Please ensure aerosol cans are sprayed completely empty (including propellant)

SECTION 14: Transport information

14.1 UN number

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 1950</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>UN 1950</td>
</tr>
<tr>
<td>RID</td>
<td>UN 1950</td>
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<tr>
<td>IMDG</td>
<td>UN 1950</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 1950</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>AEROSOLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>AEROSOLS</td>
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<tr>
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<td>AEROSOLS</td>
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<td>AEROSOLS</td>
</tr>
</tbody>
</table>

(Mometasone)
SAFETY DATA SHEET

Mometasone Metered Dose Inhaler Formulation

Version                          Revision Date:    SDS Number:    Date of last issue: 31.05.2019
1.13                             09/13/2019        26006-00014        Date of first issue: 28.10.2014

IATA     :  Aerosols, non-flammable

14.3 Transport hazard class(es)

    ADN     : 2
    ADR     : 2
    RID     : 2
    IMDG    : 2.2
    IATA    : 2.2

14.4 Packing group

    ADN
    Packing group : Not assigned by regulation
    Classification Code : 5A
    Labels : 2.2

    ADR
    Packing group : Not assigned by regulation
    Classification Code : 5A
    Labels : 2.2
    Tunnel restriction code : (E)

    RID
    Packing group : Not assigned by regulation
    Classification Code : 5A
    Hazard Identification Number : 20
    Labels : 2.2

    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 (passenger 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
SAFETY DATA SHEET

Mometasone Metered Dose Inhaler Formula-
tion

Version 1.13 | Revision Date: 09/13/2019 | SDS Number: 26006-00014 | Date of last issue: 31.05.2019
Date of first issue: 28.10.2014

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 var-
iations 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 mix-
ture
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

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 fertili-
ty.
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
ZA OEL: South Africa. Hazardous Chemical Substances Regulations,
SAFETY DATA SHEET

Mometasone Metered Dose Inhaler Formula-
tion

Version 1.13  Revision Date: 09/13/2019  SDS Number: 26006-00014  Date of last issue: 31.05.2019

Date of first issue: 28.10.2014

Occupational Exposure Limits

ZA OEL / TWA OEL-RL: Long term occupational exposure limits - recommended limit

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 Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information


Classification of the mixture:

Aerosol 3  H229
Aquatic Chronic 2  H411

Classification procedure:

Based on product data or assessment  
Calculation method

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.

ZA / EN