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

Mometasone Metered Dose Inhaler Formula-
tion

Version 1.16  Revision Date: 09.04.2021  SDS Number: 25990-00017  Date of last issue: 16.10.2020  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: Organon & Co.
   30 Hudson Street, 33nd floor
   07302 Jersey City, New Jersey, U.S.A
   Telephone: 551-430-6000
   E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number
   215-631-6999

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:
   Hazard statements:
   H229: Pressurised container: May burst if heated.
   H411: Toxic to aquatic life with long lasting effects.
   Prevention:
   P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
   P251 Do not pierce or burn, even after use.
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
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

May displace oxygen and cause rapid suffocation.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</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 specific concentration limit Eye Irrit. 2; H319 &gt;= 50 %</td>
<td>&gt;= 1.8 - &lt;= 2.5</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410</td>
<td>&gt;= 0.08 - &lt;= 0.18</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
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<th>Date of first issue:</th>
</tr>
</thead>
</table>

M-Factor (Chronic aquatic toxicity): 100

For explanation of abbreviations see section 16.
# Voluntarily-disclosed non-hazardous substance

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.
If not breathing, give artificial respiration.
If breathing is difficult, give oxygen.
Get medical attention immediately.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Gas reduces oxygen available for breathing.

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
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 (see section 7) and personal protective equipment recommendations (see section 8).

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

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.
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Clean up remaining materials from spill with suitable absorb-
ent. Local or national regulations may apply to releases and dis-
posal of this material, as well as those materials and items
employed in the cleanup of releases. You will need to deter-
mine 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-
essment
Keep container tightly closed.
Keep away from heat, hot surfaces, sparks, open flames and
other ignition sources. No smoking.
Take care to prevent spills, waste and minimize release to the
environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye
flushing systems and safety showers close to the working
place. When using do not eat, drink or smoke. Wash contami-
nated 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
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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>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></td>
<td></td>
<td>Further information: Skin</td>
<td>Wipe limit</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 µg/100 cm²</td>
<td></td>
</tr>
</tbody>
</table>

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>Long-term systemic effects</td>
<td>950 mg/m3</td>
</tr>
<tr>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>343 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>114 mg/m3</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>206 mg/kg bw/day</td>
<td></td>
</tr>
<tr>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>87 mg/kg bw/day</td>
<td></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>Long-term systemic effects</td>
<td>6533 mg/m3</td>
<td></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>Freshwater - intermittent</td>
<td>2.75 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.79 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 dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>2.9 mg/kg dry</td>
</tr>
</tbody>
</table>

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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 expo-
sure assessment demonstrates exposures outside the rec-
ommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 137
Filter type : Self-contained breathing apparatus

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : Aerosol containing a dissolved gas
Colour : white to off-white
Odour : odourless
Odour Threshold : No data available
Melting point/freezing point : No data available
Initial boiling point and boiling range : -16 °C
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Flash point : No data available
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Decomposition temperature : No data available
pH : No data available
Viscosity
Viscosity, kinematic : No data available

weight (d.w.)

Soil 0.63 mg/kg dry weight (d.w.)
Oral (Secondary Poisoning) 380 mg/kg food
1,1,1,2,3,3,3-Heptafluoropropane Fresh water 0.1 mg/l
Intermittent use/release 1 mg/l
Sewage treatment plant 1.73 mg/l
Fresh water sediment 1.3 mg/kg
Solubility(ies)
Water solubility : insoluble
Partition coefficient: n-octanol/water : No data available
Vapour pressure : No data available
Relative density : No data available
Density : 1 g/cm³
Relative vapour density : No data available

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available
Molecular weight : No data available

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.
11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

**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
  - 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

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

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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>Based on available data, the classification criteria are not met.</td>
</tr>
</tbody>
</table>

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

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>Inhalation (dust/mist/fume), Immune system, Liver, Kidney, Skin</td>
</tr>
<tr>
<td>Ethanol</td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

### Repeated dose toxicity

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>Rat, 0.005 mg/kg, 0.3 mg/kg, Oral, 30 d, Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Ethanol</td>
<td>1,280 mg/kg, 3,156 mg/kg, Ingestion, 90 Days</td>
</tr>
<tr>
<td>Mometasone</td>
<td>Dog, 0.5 mg/kg, Oral</td>
</tr>
</tbody>
</table>
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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

Aspiration toxicity
Not classified based on available information.

Components:
Mometasone: Not applicable

11.2 Information on other hazards
Endocrine disrupting properties

Product:
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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
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 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: -0.35
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tion

12.4 Mobility in soil

Components:

Mometasone:
Distribution among environmental compartments: log Koc: 4.02

12.5 Results of PBT and vPvB assessment

Product:
Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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.
SECTION 14: Transport information

14.1 UN number or ID 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>
</tr>
<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>
</tr>
<tr>
<td>RID</td>
<td>AEROSOLS</td>
</tr>
<tr>
<td>IMDG</td>
<td>AEROSOLS (Mometasone)</td>
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<tr>
<td>IATA</td>
<td>Aerosols, non-flammable</td>
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</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
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<tbody>
<tr>
<td>ADR</td>
<td>2</td>
</tr>
<tr>
<td>RID</td>
<td>2</td>
</tr>
<tr>
<td>IMDG</td>
<td>2.2</td>
</tr>
<tr>
<td>IATA</td>
<td>2.2</td>
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</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
</tr>
<tr>
<td>Classification Code</td>
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<tr>
<td>Labels</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>ADR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
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<tr>
<td>Classification Code</td>
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<tr>
<td>Labels</td>
</tr>
<tr>
<td>Tunnel restriction code</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>RID</th>
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</thead>
<tbody>
<tr>
<td>Packing group</td>
</tr>
<tr>
<td>Classification Code</td>
</tr>
<tr>
<td>Hazard Identification Number</td>
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<tr>
<td>Labels</td>
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</tbody>
</table>
## IMDG

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Labels</td>
<td>2.2</td>
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<tr>
<td>EmS Code</td>
<td>F-D, S-U</td>
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</tbody>
</table>

### IATA (Cargo)

<table>
<thead>
<tr>
<th>Packing instruction (cargo aircraft)</th>
<th>203</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing instruction (LQ)</td>
<td>Y203</td>
</tr>
<tr>
<td>Packing group</td>
<td>Not assigned by regulation</td>
</tr>
<tr>
<td>Labels</td>
<td>Non-flammable, non-toxic Gas</td>
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</tbody>
</table>

### IATA (Passenger)

<table>
<thead>
<tr>
<th>Packing instruction (passenger aircraft)</th>
<th>203</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing instruction (LQ)</td>
<td>Y203</td>
</tr>
<tr>
<td>Packing group</td>
<td>Not assigned by regulation</td>
</tr>
<tr>
<td>Labels</td>
<td>Non-flammable, non-toxic Gas</td>
</tr>
</tbody>
</table>

### 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 Maritime transport in bulk according to IMO instruments

**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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)**: Not applicable
- **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
SAFETY DATA SHEET  
according to Regulation (EC) No. 1907/2006

Mometasone Metered Dose Inhaler Formula- 
tion

<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>
</table>

Regulation (EU) 2019/1021 on persistent organic pollu-
tants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parlia-
ment and the Council concerning the export and import
of dangerous chemicals : Not applicable

major-accident hazards involving dangerous substances.

<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quantity 1</td>
</tr>
<tr>
<td></td>
<td>200 t</td>
</tr>
</tbody>
</table>

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; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation;
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Mometasone Metered Dose Inhaler Formula-
tion

<table>
<thead>
<tr>
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<th>Revision Date:</th>
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<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
</table>

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; KECI - 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

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

IE / EN