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

Mometasone Suspension Formulation

Version 2.15  Revision Date: 09.04.2021  SDS Number: 23596-00018  Date of last issue: 16.10.2020
Date of first issue: 21.10.2014

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

1.1 Product identifier
   Trade name : Mometasone Suspension 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.
              Shotton Lane
              NE23 3JU  Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   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)
   Long-term (chronic) aquatic hazard, Category 2
   H411: Toxic to aquatic life with long lasting effects.

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

   Hazard statements : H411  Toxic to aquatic life with long lasting effects.

   Precautionary statements : Prevention:
                            P273  Avoid release to the environment.
                            Response:
                            P391  Collect spillage.
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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td></td>
<td></td>
<td></td>
<td>Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 100</td>
<td></td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td></td>
<td></td>
<td></td>
<td>Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Corr. 1; H314 Eye Dam. 1; H318 Aquatic Acute 1; H400 Aquatic Chronic 2; H411</td>
<td>&gt;= 0.0025 - &lt; 0.025</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Acute aquatic toxicity): 100</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

Protection of first-aiders : No special precautions are necessary for first aid responders.

If inhaled : If inhaled, remove to fresh air.
Get medical attention if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.
Get medical attention if symptoms occur.

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 if symptoms occur. 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.

Hazardous combustion products: Carbon oxides

5.3 Advice for firefighters
Special protective equipment for firefighters: Wear self-contained breathing apparatus for firefighting if necessary. 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: 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.
- 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:

- Use only with adequate ventilation.

Advice on safe handling:

- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Take care to prevent spills, waste and minimize release to the environment.
- 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.
- The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:

- Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage:

- Do not store with the following product types: Strong oxidizing agents

7.3 Specific end use(s)
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>Glycerine</td>
<td>56-81-5</td>
<td>TWA (Mist)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit should be used.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA (inhalable dust)</td>
<td>10 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: For the purposes of these limits, respirable dust and inhalable dust are those fractions of airborne dust which will be collected when sampling is undertaken in accordance with the methods described in MDHS14/4 General methods for sampling and gravimetric analysis or respirable, thoracic and inhalable aerosols. The COSHH definition of a substance hazardous to health includes dust of any kind when present at a concentration in air equal to or greater than 10 mg.m⁻³ 8-hour TWA of inhalable dust or 4 mg.m⁻³ 8-hour TWA of respirable dust. This means that any dust will be subject to COSHH if people are exposed to dust above these levels. Some dusts have been assigned specific WELs and exposure to these must comply with the appropriate limits. Most industrial dusts contain particles of a wide range of sizes. The behaviour, deposition and fate of any particular particle after entry into the human respiratory system, and the body response that it elicits, depend on the nature and size of the particle. HSE distinguishes two size fractions for limit-setting purposes termed ‘inhalable’ and ‘respirable’. Inhalable dust approximates to the fraction of airborne material that enters the nose and mouth during breathing and is therefore available for deposition in the respiratory tract. Respirable dust approximates to the fraction that penetrates to the gas exchange region of the lung. Fuller definitions and explanatory material are given in MDHS14/4. Where dusts contain components that have their own assigned WEL, all the relevant limits should be complied with.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable dust)</td>
<td>4 mg/m³</td>
<td>GB EH40</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tbody>
</table>
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<table>
<thead>
<tr>
<th>STEL (inhalable dust)</th>
<th>20 mg/m³</th>
<th>GB EH40</th>
</tr>
</thead>
</table>

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<table>
<thead>
<tr>
<th>Substance</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>56 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>229 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>33 mg/m³</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) 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>Glycerine</td>
<td>Fresh water</td>
<td>0.885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.0885 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>8.85 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>3.3 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>0.33 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>
Section 8: Exposure controls

Engineering measures
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material: Chemical-resistant gloves
Remarks: Consider double gloving.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387

Filter type: Combined particulates and organic vapour type (A-P)

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: liquid
Colour: white to off-white, opaque
Odour: odourless
Odour Threshold: No data available
pH: 4.3 - 4.9
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: No data available
Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1 g/cm³

Solubility(ies) : soluble

Partition coefficient: n-octanol/water : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Molecular weight : Not applicable

Particle size : Not applicable

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 : 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:

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

Benzalkonium chloride:
- Acute oral toxicity: LD50 (Rat): 240 mg/kg

Acute inhalation toxicity:
- LC50 (Rat, male): > 0.05 - 0.5 mg/l
- Exposure time: 4 h
- Test atmosphere: dust/mist
- Method: OECD Test Guideline 403
- Assessment: Corrosive to the respiratory tract.
- Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat, female): 704 mg/kg
Skin corrosion/irritation
Not classified based on available information.

Components:

Mometasone:
Species: Rabbit
Result: No skin irritation

Benzalkonium chloride:
Species: Human
Result: Corrosive after 4 hours or less of exposure

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

Components:

Mometasone:
Species: Rabbit
Result: No eye irritation

Benzalkonium chloride:
Species: Rabbit
Result: Irreversible effects on the eye

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

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.

Benzalkonium chloride:
Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: Skin contact
Species: Humans
Result: negative
Germ cell mutagenicity
Not classified based on available information.

Components:

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.

Benzalkonium chloride:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: In vitro mammalian cell gene mutation test
  Method: OECD Test Guideline 476
  Result: negative
  Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative
  Remarks: Based on data from similar materials

Genotoxicity in vivo:
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
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

Benzalkonium chloride:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: negative
Remarks: Based on data from similar materials

Species: Mouse
Application Route: Skin contact
Exposure time: 80 weeks
Result: negative

Species: Rabbit
Application Route: Skin contact
Exposure time: 90 weeks
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:

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

Species: Mouse
Application Route: Ingestion
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials
### Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Embryo-foetal toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Mouse</td>
<td>Subcutaneous</td>
<td>LOAEL: 0.06 mg/kg body weight</td>
<td>Embryotoxic effects, Teratogenicity and developmental toxicity</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Dermal</td>
<td>LOAEL: 0.3 mg/kg body weight</td>
<td>Embryo-foetal toxicity</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rabbit</td>
<td>Dermal</td>
<td>LOAEL: 0.15 mg/kg body weight</td>
<td>Embryo-foetal toxicity, Malformations were observed.</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>LOAEL: 0.15 mg/kg body weight</td>
<td>Effects on newborn</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>LOAEL: 0.7 mg/kg body weight</td>
<td>Embryo-foetal toxicity, Malformations were observed.</td>
</tr>
</tbody>
</table>

### 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.

### Benzalkonium chloride:

#### Effects on fertility

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>OECD Test Guideline 416</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rabbit</td>
<td>Ingestion</td>
<td>OECD Test Guideline 414</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
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Date of first issue: 21.10.2014

**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.

**Benzalkonium chloride:**
Assessment: No significant health effects observed in animals at concentrations of 100 mg/kg bw or less.

**Repeated dose toxicity**

**Components:**

**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
NOAEL: 0.5 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species: Rat
NOAEL: 0.00013 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 90 d
Target Organs: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

Species: Dog
NOAEL: 0.0005 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 90 d
Target Organs: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow,
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</tr>
</thead>
</table>

Kidney, thymus gland, Liver

**Benzalkonium chloride:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 100 mg/kg</td>
<td>Ingestion</td>
<td>12 Weeks</td>
</tr>
</tbody>
</table>

**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:**

**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
## Toxicity to algae/aquatic plants

- **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 microorganisms

- **EC50** (Pseudokirchneriella subcapitata (green algae)): > 3.2 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201  
  Remarks: No toxicity at the limit of solubility

## Toxicity to fish (Chronic toxicity)

- **NOEC**: 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)

- **M-Factor**: 100

## Benzalkonium chloride:

### Toxicity to fish

- **LC50** (Pimephales promelas (fathead minnow)): 0.28 mg/l  
  Exposure time: 96 h

### Toxicity to daphnia and other aquatic invertebrates

- **EC50** (Daphnia magna (Water flea)): 0.0056 mg/l  
  Exposure time: 48 h

### Toxicity to algae/aquatic plants

- **ErC50** (Chlorella pyrenoidosa (algae)): 0.09 mg/l  
  Exposure time: 72 h

## M-Factor (Acute aquatic toxicity)

- **M-Factor**: 100

### Toxicity to fish (Chronic toxicity)

- **NOEC**: 0.032 mg/l  
  Exposure time: 34 d  
  Species: Pimephales promelas (fathead minnow)
12.2 Persistence and degradability

Components:

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

Benzalkonium chloride:
Biodegradability: Result: Readily biodegradable.
Method: OECD Test Guideline 301D
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

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

Benzalkonium chloride:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): < 500
Remarks: Based on data from similar materials

Partition coefficient: n-octanol/water: log Pow: 1.692
Remarks: Calculation

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
12.6 Other adverse effects

**Product:**
Endocrine disrupting potential: 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.

### 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.

### SECTION 14: Transport information

14.1 UN number

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>ADN</td>
<td>UN 3082</td>
</tr>
<tr>
<td>ADR</td>
<td>UN 3082</td>
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<tr>
<td>RID</td>
<td>UN 3082</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 3082</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3082</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th></th>
<th>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Benzalkonium chloride)</th>
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</thead>
<tbody>
<tr>
<td>ADN</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Benzalkonium chloride)</td>
</tr>
<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Benzalkonium chloride)</td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Benzalkonium chloride)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Benzalkonium chloride)</td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (Mometasone, Benzalkonium chloride)</td>
</tr>
</tbody>
</table>
Mometasone Suspension Formulation

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>Transport Hazard Class(es)</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
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<td>9</td>
</tr>
<tr>
<td>ADR</td>
<td>9</td>
</tr>
<tr>
<td>RID</td>
<td>9</td>
</tr>
<tr>
<td>IMDG</td>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>Packing Group</th>
<th>Packing Group</th>
<th>Classification Code</th>
<th>Hazard Identification Number</th>
<th>Labels</th>
<th>Tunnel Restriction Code</th>
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<tbody>
<tr>
<td>ADN</td>
<td>III</td>
<td>M6</td>
<td>90</td>
<td>9</td>
<td>(-)</td>
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<tr>
<td>ADR</td>
<td>III</td>
<td>M6</td>
<td>90</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>RID</td>
<td>III</td>
<td>M6</td>
<td>90</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>IMDG</td>
<td>III</td>
<td></td>
<td></td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>IATA (Cargo)</td>
<td>III</td>
<td></td>
<td></td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>IATA (Passenger)</td>
<td>III</td>
<td></td>
<td></td>
<td>9</td>
<td></td>
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</tbody>
</table>

14.5 Environmental hazards

<table>
<thead>
<tr>
<th>Environmental Hazard</th>
<th>Value</th>
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<tr>
<td>ADN</td>
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</tr>
<tr>
<td>ADR</td>
<td>yes</td>
</tr>
<tr>
<td>RID</td>
<td>yes</td>
</tr>
</tbody>
</table>
Environmentally hazardous  : yes
IMDG
Marine pollutant  : yes
IATA (Passenger)
Environmentally hazardous  : yes
IATA (Cargo)
Environmentally hazardous  : 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 - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)  : Conditions of restriction for the following entries should be considered: Number on list 3
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 (EU) 2019/1021 on persistent organic pollutants (recast)  : Not applicable

<table>
<thead>
<tr>
<th>E2</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>200 t</td>
<td>500 t</td>
<td></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
Mometasone Suspension Formulation

Full text of H-statements

H301: Toxic if swallowed.
H311: Toxic in contact with skin.
H314: Causes severe skin burns and eye damage.
H318: Causes serious eye damage.
H330: Fatal if inhaled.
H360Df: May damage the unborn child. Suspected of damaging fertility.
H373: May cause damage to organs through prolonged or repeated exposure if inhaled.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H411: Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Aquatic Acute: Short-term (acute) aquatic hazard
Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Dam.: Serious eye damage
Repr.: Reproductive toxicity
Skin Corr.: Skin corrosion
STOT RE: Specific target organ toxicity - repeated exposure
GB EH40: UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA: Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL: Short-term exposure limit (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; 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 sub-
Mometasone Suspension Formulation

**Further information**

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

**Classification of the mixture:**

Aquatic Chronic 2 H411

**Classification procedure:**

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.

GB / EN