SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Mometasone Suspension Formulation

Version: 3.1
Revision Date: 2020/10/16
SDS Number: 23592-00017
Date of last issue: 2020/03/23
Date of first issue: 2014/10/21

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone Suspension Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: 30 Hudson Street, 33nd floor
Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
Emergency telephone number: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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

2. HAZARDS IDENTIFICATION

Emergency Overview

<table>
<thead>
<tr>
<th>Appearance</th>
<th>liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>white to off-white, opaque</td>
</tr>
<tr>
<td>Odour</td>
<td>odourless</td>
</tr>
<tr>
<td>Harmful to aquatic life. Toxic to aquatic life with long lasting effects.</td>
<td></td>
</tr>
</tbody>
</table>

GHS Classification

Short-term (acute) aquatic hazard: Category 3
Long-term (chronic) aquatic hazard: Category 2

GHS label elements
Hazard pictograms: ![Hazard Pictogram]

Signal word: None
Hazard statements: H402 Harmful to aquatic life.
H411 Toxic to aquatic life with long lasting effects.

Precautionary statements
Prevention: P273 Avoid release to the environment.
Response: P391 Collect spillage.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.

Health hazards
Not classified based on available information.

Environmental hazards
Harmful to aquatic life. Toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Cellulose</td>
</tr>
<tr>
<td></td>
<td>Mometasone</td>
</tr>
<tr>
<td></td>
<td>Benzalkonium chloride</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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.

Most important symptoms and effects, both acute and delayed : None known.
Protection of first-aiders : No special precautions are necessary for first aid responders.
Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.
Specific hazards during firefighting : Exposure to combustion products may be a hazard to health.
Hazardous combustion products: Carbon oxides

Specific extinguishing methods:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Use water spray to cool unopened containers.
- Remove undamaged containers from fire area if it is safe to do so.
- Evacuate area.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

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

7. HANDLING AND STORAGE

Handling
- Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation: Use 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.
- Avoidance of contact: Oxidizing agents
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Version 3.1 Revision Date: 2020/10/16 SDS Number: 23592-00017 Date of last issue: 2020/03/23 Date of first issue: 2014/10/21

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>PC-TWA</td>
<td>10 mg/m³</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin Wipe limit 10 µg/100 cm² Internal

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

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapour type

Eye/face 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.

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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.
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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>white to off-white, opaque</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>4.3 - 4.9</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</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>Flammability (liquids)</td>
<td>No data available</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>soluble</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
</tbody>
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**Mometasone Suspension Formulation**

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</table>

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
   Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

Molecular weight : Not applicable

Particle size : Not applicable

**10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

**11. TOXICOLOGICAL INFORMATION**

Exposure routes : Inhalation  
   Skin contact  
   Ingestion  
   Eye contact

**Acute toxicity**
Not classified based on available information.

**Components:**

**Cellulose:**
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
   Exposure time: 4 h  
   Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

**Mometasone:**
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg  
   LD50 (Mouse): > 2,000 mg/kg
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</tbody>
</table>

#### Acute inhalation toxicity
- **Rat:** LC50: > 3.3 mg/l  
  Exposure time: 4 h  
  Test atmosphere: dust/mist  
  Remarks: No mortality observed at this dose.

- **Mouse:** LC50: > 3.2 mg/l  
  Exposure time: 4 h  
  Test atmosphere: dust/mist

#### 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

#### 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:

Cellulose:
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Ingestion
Result: negative

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
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Cell type</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse Lymphoma</td>
<td></td>
<td></td>
<td>positive</td>
</tr>
<tr>
<td>Micronucleus test</td>
<td>Mouse</td>
<td>Oral</td>
<td>negative</td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>Rat</td>
<td>Bone marrow</td>
<td>negative</td>
</tr>
<tr>
<td>unscheduled DNA synthesis assay</td>
<td>Rat</td>
<td>Liver cells</td>
<td>negative</td>
</tr>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td></td>
<td></td>
<td>negative</td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td></td>
<td></td>
<td>negative</td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td></td>
<td></td>
<td>negative</td>
</tr>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Mouse</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo:**
- Weight of evidence does not support classification as a germ cell mutagen.

**Benzalkonium chloride:**
- 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
- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
- Species: Mouse
- Application Route: Ingestion
- Method: OECD Test Guideline 474
- Result: negative
- Remarks: Based on data from similar materials

**Carcinogenicity**
Not classified based on available information.

**Components:**

**Cellulose:**
- Species: Rat
- Application Route: Ingestion
Mometasone Suspension Formulation

Exposure time: 72 weeks
Result: negative

**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:**

**Cellulose:**
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development: Test Type: Fertility/early embryonic development
Species: Rat
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:** Embryo-foetal toxicity, Malformations were observed.

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

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

## Reproductive toxicity - Assessment

- **Test Type:** Two-generation reproduction toxicity study  
- **Species:** Rat  
- **Application Route:** Ingestion  
- **Method:** OECD Test Guideline 416  
- **Result:** negative  
- **Remarks:** Based on data from similar materials

## Benzalkonium chloride:

- **Effects on fertility**
- **Test Type:** Embryo-foetal development  
- **Species:** Rabbit

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Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative
Remarks: Based on data from similar materials

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:
Cellulose:
Species: Rat
NOAEL: >= 9,000 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Mometasone:
Species: Rat
NOAEL: 0.005 mg/kg
LOAEL: 0.3 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species: Dog
LOAEL: 0.5 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland
## 12. ECOLOGICAL INFORMATION

### Ecotoxicity

**Components:**

**Cellulose:**

---

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

**Benzalkonium chloride:**

**Species:** Rat  
**NOAEL:** >= 100 mg/kg  
**Application Route:** Ingestion  
**Exposure time:** 12 Weeks  
**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
<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Oryzias latipes (Japanese medaka)): &gt; 100 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Mometasone:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Menidia beryllina (Silverside)): 0.11 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td>LC50 (Cyprinodon variegatus (sheepshead minnow)): &gt; 5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 7 d</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td>EC50 (Americamysis): &gt; 5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 3.2 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 32 d</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Daphnia magna (Water flea)): 0.34 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td><strong>M-Factor (Chronic aquatic toxicity)</strong></td>
<td>100</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC50: &gt; 1,000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td>NOEC: 1,000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>
## 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)
- 100

### Toxicity to fish (Chronic toxicity)
- NOEC (Pimephales promelas (fathead minnow)): 0.032 mg/l
- Exposure time: 34 d

## Persistence and degradability

### Components:

#### Cellulose:
- Biodegradability: Result: Readily biodegradable.

#### 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

## Bioaccumulative potential

### Components:

#### Mometasone:
- Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
- Bioconcentration factor (BCF): 107.1
- Method: OECD Test Guideline 305

#### Benzalkonium chloride:
- Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
- Bioconcentration factor (BCF): < 500
- Remarks: Based on data from similar materials
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Mometasone Suspension Formulation

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

Mobility in soil

Components:

Mometasone:
Distribution among environmental compartments: log Koc: 4.02

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Benzalkonium chloride)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Mometasone, Benzalkonium chloride)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Benzalkonium chloride)
Mometasone Suspension Formulation

Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

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

National Regulations

GB 6944/12268
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(Mometasone, Benzalkonium chloride)

Class: 9
Packing group: III
Labels: 9

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information
Date format: yyyy/mm/dd

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
CN OEL: Occupational exposure limits for hazardous agents in the workplace - Chemical hazardous agents.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Mometasone Suspension Formulation

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Date of first issue: 2014/10/21

ACGIH / TWA: 8-hour, time-weighted average
CN OEL / PC-TWA: Permissible concentration - time weighted average

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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.

CN / EN