**SAFETY DATA SHEET**

**Mometasone Suspension Formulation**

<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>

**SECTION 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: 215-631-6999

E-mail address: EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

**SECTION 2. HAZARDS IDENTIFICATION**

**GHS Classification**

Short-term (acute) aquatic hazard: Category 3

Long-term (chronic) aquatic hazard: Category 2

**GHS label elements**

Hazard pictograms:

- **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.

**Other hazards which do not result in classification**

None known.
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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>&gt;= 0.0025 - &lt; 0.025</td>
</tr>
</tbody>
</table>

SECTION 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.

SECTION 5. FIRE-FIGHTING 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 fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment: Follow safe handling advice (see section 7) and personal protective equipment.
Section 6. Precautions to be Taken in Case of Spill or Leak

- 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 spills cannot be contained.

Section 7. Handling and Storage

- 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.
- Conditions for safe storage: Keep in properly labeled containers. Store in accordance with the particular national regulations.
- Materials to avoid: Do not store with the following product types: Strong oxidizing agents.

Section 8. Exposure Controls/Personal Protection

Ingredients 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>Glycerine</td>
<td>56-81-5</td>
<td>CMP (Mist)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Irritation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>CMP</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Irritation</td>
<td></td>
<td></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

<table>
<thead>
<tr>
<th>Wipe limit</th>
<th>Internal</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 µg/100 cm²</td>
<td></td>
</tr>
</tbody>
</table>

**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 vapor type

**Hand protection**

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

**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.

**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.

**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.

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**

liquid

**Color**

white to off-white, opaque

**Odor**

odorless

**Odor 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

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1 g/cm³

Solubility(ies)
   Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Autoignition 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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
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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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity:
Not classified based on available information.

Components:

**Glycerine:**
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity: LD50 (Guinea pig): > 5,000 mg/kg

**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

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:

Glycerine:
- Species: Rabbit
- Result: No skin irritation

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:

Glycerine:
- Species: Rabbit
- Result: No eye irritation

Mometasone:
- Species: Rabbit
- Result: No eye irritation

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

Respiratory or skin sensitization:

Skin sensitization:
Not classified based on available information.

Respiratory sensitization:
Not classified based on available information.
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Components:
Mometasone:
Test Type: Maximization Test
Routes of exposure: Dermal
Species: Guinea pig
Assessment: Does not cause skin sensitization.
Result: negative
Remarks: The results of a test on guinea pigs showed this substance to be a weak skin sensitizer.

Benzalkonium chloride:
Test Type: Human repeat insult patch test (HRIPT)
Routes of exposure: Skin contact
Species: Humans
Result: negative

Germ cell mutagenicity
Not classified based on available information.

Components:
Glycerine:
Genotoxicity in vitro:
Test Type: In vitro mammalian cell gene mutation test
Result: negative
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosome aberration test in vitro
Result: negative
Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

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
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test System</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chromosomal aberration</td>
<td>Chinese hamster lung cells</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>Chinese hamster ovary cells</td>
<td>positive</td>
<td></td>
</tr>
<tr>
<td>Mouse Lymphoma</td>
<td></td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Micronucleus test</td>
<td>Mouse</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>Rat</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>Rat</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Unscheduled DNA synthesis assay</td>
<td>Rat</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test System</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micronucleus test</td>
<td>Mouse</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>Rat</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Chromosomal aberration</td>
<td>Rat</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>Unscheduled DNA synthesis assay</td>
<td>Rat</td>
<td>negative</td>
<td></td>
</tr>
</tbody>
</table>

**Germ cell mutagenicity - Assessment**

Weight of evidence does not support classification as a germ cell mutagen.

**Benzalkonium chloride:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test System</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bacterial reverse mutation assay (AMES)</td>
<td></td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td>In vitro mammalian cell gene mutation test</td>
<td>OECD Test Guideline 476</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Chromosome aberration test in vitro</td>
<td>OECD Test Guideline 473</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Genotoxicity in vivo**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Test System</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Mouse</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Carcinogenicity**

Not classified based on available information.
Components:

Glycerine:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

Cellulose:
Species: Rat
Application Route: Ingestion
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:

Glycerine:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat  
Application Route: Ingestion  
Result: negative

**Effects on fetal development**:  
Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

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

Effects on fetal 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 fetal weight.  
Result: No effects on fertility., Effect on reproduction capacity.

Effects on fetal development:  
Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Subcutaneous  
Embryo-fetal toxicity.: LOAEL: 0,06 mg/kg body weight  
Result: Embryotoxic effects., Teratogenicity and developmental toxicity

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Dermal  
Embryo-fetal toxicity.: LOAEL: 0,3 mg/kg body weight  
Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Dermal  
Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight  
Result: Embryo-fetal toxicity., Malformations were observed.

Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Subcutaneous  
Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight  
Result: Effects on newborn.
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**
- 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

**Effects on fetal development**
- Test Type: Embryo-fetal development
- Species: Rabbit
- 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:**
- Routes of exposure: 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:**

**Glycerine:**
<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL (mg/kg)</th>
<th>LOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.167</td>
<td>0.622</td>
<td>Inhalation (dust/mist/fume)</td>
<td>13 Weeks</td>
<td>Adrenal gland, Lungs, Lymph nodes, Skin, thymus gland</td>
</tr>
<tr>
<td>Rabbit</td>
<td>8.000 - 10.000</td>
<td></td>
<td>Ingestion</td>
<td>2 y</td>
<td></td>
</tr>
<tr>
<td>Dog</td>
<td>0.005</td>
<td>0.3</td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td>0.00013</td>
<td></td>
<td>Inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
<tr>
<td>Rat</td>
<td>0.00013</td>
<td></td>
<td>Inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland</td>
</tr>
</tbody>
</table>

**Cellulose:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 9.000</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
</tbody>
</table>

**Mometasone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL (mg/kg)</th>
<th>LOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.005</td>
<td>0.3</td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td>0.5</td>
<td></td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Rat</td>
<td>0.00013</td>
<td></td>
<td>Inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td>0.0005</td>
<td></td>
<td>Inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver</td>
</tr>
</tbody>
</table>

**Benzalkonium chloride:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL (mg/kg)</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 100</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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

---

**SECTION 12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Glycerine:**
- Toxicity to fish:
  - LC50 (Oncorhynchus mykiss (rainbow trout)): 54.000 mg/l
  - Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates:**
- EC50 (Daphnia magna (Water flea)): 1.955 mg/l
  - Exposure time: 48 h

**Toxicity to microorganisms:**
- NOEC (Pseudomonas putida): > 10.000 mg/l
  - Exposure time: 16 h
  - Method: DIN 38 412 Part 8

**Cellulose:**
- Toxicity to fish:
  - LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials

**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 fish (Chronic toxicity):

NOEC (Pimephales promelas (fathead minnow)): 0,00014 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

NOEC (Daphnia magna (Water flea)): 0,34 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility.

M-Factor (Chronic aquatic toxicity):

100

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.

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):** 0,09 mg/l
- **Exposure time:** 72 h

## M-Factor (Acute aquatic toxicity)
- **M-Factor:** 100

## Toxicity to fish (Chronic toxicity)
- **NOEC (Pimephales promelas (fathead minnow)):** 0,032 mg/l
- **Exposure time:** 34 d

## Persistence and degradability

### Components:

#### Glycerine:
- **Biodegradability**
  - Result: Readily biodegradable.
  - Biodegradation: 92%
  - Exposure time: 30 d
  - Method: OECD Test Guideline 301D

#### 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:

#### Glycerine:
- **Partition coefficient: n-octanol/water**
  - log Pow: -1,75

#### 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

**Partition coefficient: n-octanol/water:**  
\[ \text{log Pow: 1.692} \]  
**Remarks:** Calculation

### Mobility in soil

#### Components:

**Mometasone:**  
Distribution among environmental compartments:  
\[ \text{log Koc: 4.02} \]

#### Other adverse effects

No data available

### SECTION 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.

### SECTION 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 Suspension Formulation

(Mometasone, Benzalkonium chloride)

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.

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Argentina. Carcinogenic Substances and Agents Registry: Not applicable
Control of precursors and essential chemicals for the preparation of drugs: Not applicable

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

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
AR OEL: Argentina. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
AR OEL / CMP: TLV (Threshold Limit Value)

AIIC - 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 -
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.