1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Mometasone Suspension Formulation

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

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Short-term (acute) aquatic hazard: Category 3
Long-term (chronic) aquatic hazard: Category 2

GHS label elements
Hazard pictograms: 
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.

Other hazards which do not result in classification
None known.
3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (%)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>&gt;= 0.0025 - &lt; 0.025</td>
<td></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).
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
Hygiene measures : Oxidizing agents
: 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.

Storage
Conditions for safe storage : Keep in properly labelled containers.
: Store in accordance with the particular national regulations.
Materials to avoid : Do not store with the following product types:
: Strong oxidizing agents
Packaging material : Unsuitable material: None known.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>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

- **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.

9. PHYSICAL AND CHEMICAL PROPERTIES

- **Physical state**: liquid
- **Colour**: white to off-white, opaque
- **Odour**: odourless
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point, initial boiling point and boiling range</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>Lower explosion limit and upper explosion limit / flammability limit</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>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>4.3 - 4.9</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>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>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Density and/or relative density</td>
<td></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>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Particle characteristics</td>
<td></td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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

Information on likely routes of exposure:
- 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

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

Benzalkonium chloride:
- Acute oral toxicity: LD50 (Rat): 300 mg/kg
  Application Route: Subcutaneous
  Symptoms: Breathing difficulties
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 sensitisier.

**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

**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

Genotoxicity in vivo : 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  
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: 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 foetal development: Test Type: Embryo-foetal 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:
Exposure routes: inhalation (dust/mist/fume)
### Target Organs

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Assay</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzalkonium chloride</td>
<td>Rat</td>
<td>&gt;= 9,000 mg/kg</td>
<td></td>
<td>Ingestion</td>
<td>90 Days</td>
<td>Immune system, Liver, Kidney, Skin (Assessment: May cause damage to organs through prolonged or repeated exposure.)</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>0.5 mg/kg</td>
<td></td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland (Species: Dog)</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>0.00013 mg/l</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 (Species: Rat)</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>0.0005 mg/l</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 (Species: Dog)</td>
</tr>
<tr>
<td>Mometasone:</td>
<td>Rat</td>
<td>0.005 mg/kg</td>
<td>0.3 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland (Species: Rat)</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>0.5 mg/kg</td>
<td></td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland (Species: Dog)</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>0.00013 mg/l</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 (Species: Rat)</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>0.0005 mg/l</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 (Species: Dog)</td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>Rat</td>
<td>&gt;= 100 mg/kg</td>
<td></td>
<td>Ingestion</td>
<td>12 Weeks</td>
<td>(Species: Rat)</td>
</tr>
</tbody>
</table>

**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

- **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

### 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**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
### SAFETY DATA SHEET

**Mometasone Suspension Formulation**

<table>
<thead>
<tr>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>US-EPA OPPTS 850.1035</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

**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 (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

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

Mobility in soil
Components:
Mometasone:
Distribution among environmental compartments: log Koc: 4.02

Hazardous to the ozone layer
Not applicable

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)
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
Refer to section 15 for specific national regulation.

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

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Not applicable

Substances Subject to be Indicated Names
Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable
High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance(Category Z)
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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)
ACGIH / TWA : 8-hour, 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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organization 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; 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

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.

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