SAFETY DATA SHEET

Mometasone Suspension Formulation

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: MSD
117 16th Road
07033 Halfway house, Midrand, South Africa

Telephone: +27 11 655 3000

Telefax: 908-735-1496

E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

1-908-423-6000

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

None known.
3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>Rep.1B; H360Df STOT RE2; H373 Aquatic Chronic1; H410</td>
<td>&gt;= 0,025 - &lt; 0,1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>100</td>
<td></td>
</tr>
<tr>
<td>Benzalkonium chloride</td>
<td>8001-54-5</td>
<td>Acute Tox.4; H302 Acute Tox.2; H330 Skin Corr.1B; H314 Eye Dam.1; H318 Aquatic Acute1; H400 Aquatic Chronic1; H410</td>
<td>&gt;= 0,0025 - &lt; 0,025</td>
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<td>M-Factor (Acute aquatic toxicity):</td>
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<td>M-Factor (Chronic aquatic toxicity):</td>
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</tr>
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<td></td>
<td></td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
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 and personal protective equipment recommendations.

6.2 Environmental precautions

Environmental precautions:
Discharge into the environment must be avoided.
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. 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.

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)

Specific use(s): No data available.
SECTION 8: Exposure controls/personal protection

8.1 Control parameters

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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<tbody>
<tr>
<td>Glycerine</td>
<td>56-81-5</td>
<td>TWA OEL-RL (Mist)</td>
<td>10 mg/m³</td>
<td>ZA OEL</td>
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<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA OEL-RL (Respirable dust)</td>
<td>5 mg/m³</td>
<td>ZA OEL</td>
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<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
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</table>

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
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<tbody>
<tr>
<td>Glycerine</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>56 mg/m³</td>
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<tr>
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<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>229 mg/kg bw/day</td>
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<tr>
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<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>33 mg/m³</td>
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### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

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<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
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<tr>
<td>Glycerine</td>
<td>Fresh water</td>
<td>0.885 mg/l</td>
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<td>Marine water</td>
<td>0.0885 mg/l</td>
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<td></td>
<td>Intermittent use/release</td>
<td>8.85 mg/l</td>
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<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
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<tr>
<td>Fresh water sediment</td>
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<td>3.3 mg/kg dry weight (d.w.)</td>
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<tr>
<td>Marine sediment</td>
<td>0.33 mg/kg dry weight (d.w.)</td>
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<tr>
<td>Soil</td>
<td>0.141 mg/kg dry weight (d.w.)</td>
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8.2 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.

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

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)
  Water solubility: soluble
Partition coefficient: n-octanol/water: Not applicable
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.

9.2 Other information
  Flammability (liquids): No data available
  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

**Inhalation**
- **Species:** Rabbit
- **Result:** No skin irritation

**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): 344 mg/kg
  - Remarks: Based on data from similar materials
- **Acute inhalation toxicity**
  - LC50 (Rat): 0.25 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 (Rabbit): 3.412 mg/kg
  - 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: Rabbit
Result: Corrosive after 3 minutes to 1 hour of exposure
Remarks: Based on data from similar materials

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
Remarks: Based on data from similar materials

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: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

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)  
  **Method:** OECD Test Guideline 471  
  **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:

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

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 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
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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 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: Immune system, Liver, Kidney, Skin
Assessment: May cause damage to organs through prolonged or repeated exposure.
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, Kidney, thymus gland, Liver

Benzalkonium chloride:

Species: Dog
NOAEL: 50 mg/kg
Application Route: Ingestion
Exposure time: 13 Weeks
Method: OECD Test Guideline 409
Remarks: Based on data from similar materials

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 re-
piratory 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

EC50 (Americamysis): > 5 mg/l
Exposure time: 96 h
Method: US-EPA OPPTS 850.1035
Remarks: No toxicity at the limit of solubility

**Toxicity to algae/aquatic plants**: EC50 (Pseudokirchneriella subcapitata (green algae)): > 3,2 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

**Toxicity to microorganisms**: EC50 : > 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

NOEC : 1.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility

**Toxicity to fish (Chronic tox-**: NOEC: 0.00014 mg/l
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<table>
<thead>
<tr>
<th>M-Factor (Chronic aquatic toxicity)</th>
<th>100</th>
</tr>
</thead>
</table>

### Benzalkonium chloride:

**Toxicity to fish**
- **LC50** (Oncorhynchus mykiss (rainbow trout)): 0.85 mg/l
  - Exposure time: 96 h
  - Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates**
- **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

**Toxicity to algae/aquatic plants**
- **EC50** (Pseudokirchneriella subcapitata (green algae)): 0.049 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials

- **EC10** (Pseudokirchneriella subcapitata (green algae)): 0.009 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials

**M-Factor (Acute aquatic toxicity)**
- 10

**Toxicity to microorganisms**
- **EC50**: 7.75 mg/l
  - Exposure time: 3 h
  - Method: OECD Test Guideline 209
  - Remarks: Based on data from similar materials

**Toxicity to fish (Chronic toxicity)**
- **NOEC**: > 32.2 mg/l
  - Exposure time: 34 d
  - Species: Pimephales promelas (fathead minnow)
  - Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- **NOEC**: 0.0125 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
  - Method: OECD Test Guideline 211
  - Remarks: Based on data from similar materials

**M-Factor (Chronic aquatic toxicity)**
- 1
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. Biodegradation: 95,5 %
  Exposure time: 28 d
  Method: OECD Test Guideline 301
  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:**
- Partition coefficient: n-octanol/water: log Pow: 0,004
  Remarks: Based on data from similar materials

12.4 Mobility in soil

**Components:**

**Mometasone:**
- Distribution among environmental compartments: log Koc: 4,02

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

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

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<th>ADR</th>
<th>RID</th>
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14.2 UN proper shipping name

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<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Benzalkonium chloride)</td>
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<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Mometasone, Benzalkonium chloride)</td>
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14.3 Transport hazard class(es)

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<td>9</td>
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</tbody>
</table>

14.4 Packing group

<table>
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<th>ADN</th>
</tr>
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<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Classification Code</td>
<td>M6</td>
</tr>
<tr>
<td>Hazard Identification Number</td>
<td>90</td>
</tr>
<tr>
<td>Labels</td>
<td>9</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Mometasone Suspension Formulation


ADR
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

IMDG
Packing group : III
Labels : 9
EmS Code : F-A, S-F

IATA (Cargo)
Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
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

The components of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H302: Harmful if swallowed.
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.

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
ZA OEL: South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL: Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL: Short term occupational exposure limits - recommended limit

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; AICS - Australian Inventory of Chemical Substances; 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 substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

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.

ZA / EN