SAFETY DATA SHEET

Mometasone Ointment Formulation

Version 2.1  Revision Date: 10.10.2020  SDS Number: 1751222-00008  Date of last issue: 23.03.2020  Date of first issue: 14.06.2017

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone Ointment Formulation

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

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

2. HAZARDS IDENTIFICATION

GHS Classification
Serious eye damage/eye irritation: Category 2
Long-term (chronic) aquatic hazard: Category 2

GHS label elements
Hazard pictograms:

Signal word: Warning
Hazard statements: H319 Causes serious eye irritation.
                  H411 Toxic to aquatic life with long lasting effects.
Precautionary statements:
Prevention:
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear eye protection/face protection.
Response:
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337 + P313 IF eye irritation persists: Get medical advice/attention.
P391 Collect spillage.
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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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

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

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed
Causes serious eye irritation.

Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
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Unsuitable extinguishing media: Dry chemical
None known.

Specific hazards during firefighting: Vapours may form explosive mixtures with air.
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: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions: Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the

3 / 19
Conditions for safe storage: Keep in properly labelled containers. Keep tightly closed. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>PEL (long term) (Mist)</td>
<td>5 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term) (Mist)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td>PEL (short term)</td>
<td>25 ppm</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Vapour)</td>
<td>121 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Vapour)</td>
<td>50 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Inhalable fraction, Aerosol only)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>PEL (long term)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 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>
<tr>
<td>Further information: Skin</td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures: Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). 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.
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.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: ointment

Colour: white to off-white

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: > 93.3 °C

Evaporation rate: No data available
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Vapours may form explosive mixture with air. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>None known.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

### 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Route</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
<td>Information on likely routes of skin contact.</td>
</tr>
</tbody>
</table>
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exposure
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

Petrolatum:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:
Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Propylene glycol monostearate:
Acute oral toxicity : LD50 (Mouse): > 5,000 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

Skin corrosion/irritation
Not classified based on available information.
**Components:**

**Petrolatum:**
Species: Rabbit  
Method: OECD Test Guideline 404  
Result: No skin irritation  
Remarks: Based on data from similar materials

**2-Methyl-2,4-pentanediol:**
Species: Rabbit  
Method: OECD Test Guideline 404  
Result: No skin irritation

**Propylene glycol monostearate:**
Result: No skin irritation

**Mometasone:**
Species: Rabbit  
Result: No skin irritation

**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

**Petrolatum:**
Species: Rabbit  
Result: No eye irritation  
Method: OECD Test Guideline 405  
Remarks: Based on data from similar materials

**2-Methyl-2,4-pentanediol:**
Species: Rabbit  
Result: Irritation to eyes, reversing within 21 days

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

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**Petrolatum:**
Test Type: Buehler Test
Exposure routes: Skin contact  
Species: Guinea pig  
Result: negative  
Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:
- Test Type: Maximisation Test  
- Exposure routes: Skin contact  
- Species: Guinea pig  
- Method: OECD Test Guideline 406  
- Result: negative

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 sensitizer.

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:
- Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro  
  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: Intraperitoneal injection  
  Method: OECD Test Guideline 474  
  Result: negative  
  Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:
- 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

  Test Type: Chromosome aberration test in vitro  
  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.

Carcinogenicity
Not classified based on available information.

Components:

Petrolatum:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
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
### Reproductive toxicity
Not classified based on available information.

### Components:

**Petrolatum:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Reproduction/Developmental toxicity screening test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Skin contact</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

**2-Methyl-2,4-pentanediol:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Reproduction/Developmental toxicity screening test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 421</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Ingestion</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 414</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

**Mometasone:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>Test Type: Fertility</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Species: Rat</td>
</tr>
<tr>
<td></td>
<td>Application Route: Subcutaneous</td>
</tr>
<tr>
<td></td>
<td>Fertility: NOAEL: 0.015 mg/kg body weight</td>
</tr>
<tr>
<td></td>
<td>Symptoms: Reduced embryonic survival, Reduced foetal weight</td>
</tr>
<tr>
<td></td>
<td>Result: No effects on fertility, Effect on reproduction capacity</td>
</tr>
</tbody>
</table>

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

**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:**

**Petrolatum:**
Species: Rat
NOAEL: 5,000 mg/kg
Application Route: Ingestion
Exposure time: 2 yr
### 2-Methyl-2,4-pentanediol:

**Species**: Rat  
**NOAEL**: $\geq 450$ mg/kg  
**Application Route**: Ingestion  
**Exposure time**: 90 Days  
**Method**: OECD Test Guideline 408

**Mometasone**:

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

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

**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

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

### Components:

**Mometasone**:  
Not applicable

### Experience with human exposure

**Components**:

**2-Methyl-2,4-pentanediol**:

**Eye contact**:  
**Target Organs**: Eyes  
**Symptoms**: Irritation

**Mometasone**:  
**Inhalation**:  
**Symptoms**: allergic rhinitis, Headache, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, Back pain,
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Date of first issue: 14.06.2017

### Skin contact

**Symptoms:** Dermatitis, Itching

### Further information

#### Components:

**Mometasone:**
Remarks: Dermal absorption possible

### 12. ECOLOGICAL INFORMATION

#### Ecotoxicity

**Components:**

**Petrolatum:**

**Toxicity to fish**
- LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
- Exposure time: 96 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 203
- Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
- Exposure time: 48 h
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials

**Toxicity to algae/aquatic plants**
- NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
- Exposure time: 72 h
- Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
- NOEC (Daphnia magna (Water flea)): 10 mg/l
- Exposure time: 21 d
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials

**2-Methyl-2,4-pentanediol:**

**Toxicity to fish**
- LC50 (Gambusia affinis (Mosquito fish)): 8,510 mg/l
- Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Ceriodaphnia dubia (water flea)): 2,800 mg/l
- Exposure time: 48 h

**Toxicity to algae/aquatic plants**
- ErC50 (Pseudokirchneriella subcapitata (green algae)): > 429 mg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201
- EC10 (Pseudokirchneriella subcapitata (green algae)): > 429 mg/l

musculoskeletal pain, immune system effects, indigestion
**Mometasone Ointment Formulation**

<table>
<thead>
<tr>
<th>Exposure time:</th>
<th>72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>NOEC:</th>
<th>200 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>10 d</td>
</tr>
</tbody>
</table>

**Mometasone:**

<table>
<thead>
<tr>
<th>Toxicity to fish</th>
<th>LC50 (Menidia beryllina (Silverside)): 0.11 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>96 h</td>
</tr>
<tr>
<td>Remarks:</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LC50 (Cyprinodon variegatus (sheepshead minnow)): &gt; 5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
</tr>
<tr>
<td>Remarks:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time:</td>
<td>48 h</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 202</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EC50 (Americamysis): &gt; 5 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>Method: US-EPA OPPTS 850.1035</td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 3.2 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 72 h</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 32 d</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 210</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): 0.34 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 21 d</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 211</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>M-Factor (Chronic aquatic toxicity)</th>
<th>100</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC50: &gt; 1,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 3 h</td>
<td></td>
</tr>
<tr>
<td>Test Type: Respiration inhibition</td>
<td></td>
</tr>
<tr>
<td>Method: OECD Test Guideline 209</td>
<td></td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NOEC: 1,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 209</td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>
Persistence and degradability

Components:

Petrolatum:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 81 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

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

Bioaccumulative potential

Components:

2-Methyl-2,4-pentanediol:
Partition coefficient: n-octanol/water: log Pow: 0
Remarks: Calculation

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

Mobility in soil

Components:

Mometasone:
Distribution among environmental compartments: log Koc: 4.02

Other adverse effects
No data available
13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
- Class: 9
- Packing group: III
- Labels: 9

IATA-DGR
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Mometasone)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes

IMDG-Code
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
- 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.
15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations : Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations : Not applicable

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 : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
SG OEL : Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
SG OEL / PEL (long term) : Permissible Exposure Level (PEL) Long Term
SG OEL / PEL (short term) : Permissible Exposure Level (PEL) Short Term

AICL - 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
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.

SG / EN