1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name: Mometasone Ointment 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

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

GHS label elements

Hazard pictograms: ![Exclamation Mark] ![Fish]

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.
SAFETY DATA SHEET

Mometasone Ointment Formulation

Version 3.0
Revision Date: 2021/04/09
SDS Number: 1751217-00009
Date of last issue: 2020/10/10
Date of first issue: 2017/06/14

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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 70 - &lt; 80</td>
<td></td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td>&gt;= 10 - &lt; 20</td>
<td>2-240</td>
</tr>
<tr>
<td>Propylene glycol monostearate</td>
<td>1323-39-3</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-772, 2-2523</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td></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
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

Handling
- 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 as-
Avoidance of contact: Oxidizing agents
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.

Storage
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>Petrolatum</td>
<td>8009-03-8</td>
<td>OEL-M (Mist)</td>
<td>3 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td>TWA (Vapour)</td>
<td>25 ppm</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>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>
</tbody>
</table>
Mometasone Ointment Formulation

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:
Filter type: Combined particulates and organic vapour type
Hand protection:
Material: Chemical-resistant gloves
Remarks: Consider double gloving.
Eye protection:
Material: 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:
Material: 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: ointment
Colour: white to off-white
Odour: No data available
Odour Threshold: No data available
Melting point/freezing point: No data available
Boiling point, initial boiling point and boiling range: No data available
Flammability (solid, gas): Not classified as a flammability hazard
## Flammability (liquids)
- Not applicable

## Lower explosion limit and upper explosion limit / flammability limit
- Upper explosion limit / Upper flammability limit: No data available
- Lower explosion limit / Lower flammability limit: No data available

## Flash point
- > 93.3 °C

## Decomposition temperature
- No data available

## pH
- No data available

## Evaporation rate
- No data available

## Auto-ignition temperature
- No data available

## Viscosity
- Viscosity, kinematic: No data available

## Solubility(ies)
- Water solubility: No data available

## Partition coefficient: n-octanol/water
- No data available

## Vapour pressure
- No data available

## Density and / or relative density
- Relative density: No data available
- Density: No data available

## Relative vapour density
- No data available

## Explosive properties
- Not explosive

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

## Molecular weight
- No data available

## Particle characteristics
- Particle size: No data available

### 10. STABILITY AND REACTIVITY

- **Reactivity**: Not classified as a reactivity hazard.
- **Chemical stability**: Stable under normal conditions.
- **Possibility of hazardous reactions**:
  - Vapours may form explosive mixture with air.
  - 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:
Skin contact
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

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
SAFETY DATA SHEET
Mometasone Ointment Formulation

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:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Remarks: Based on data from similar materials

### 2-Methyl-2,4-pentanediol:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Mometasone:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Dermal</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Assessment</td>
<td>Does not cause skin sensitisation.</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Remarks: The results of a test on guinea pigs showed this substance to be a weak skin sensitiser.

### 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
**SAFETY DATA SHEET**

**Mometasone Ointment Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
<td>2021/04/09</td>
<td>1751217-00009</td>
<td>2020/10/10</td>
<td>2017/06/14</td>
</tr>
</tbody>
</table>

**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:

Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:

Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 421
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
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.

### 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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>5,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 yr</td>
</tr>
</tbody>
</table>

2-Methyl-2,4-pentanediol:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>&gt;= 450 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>

Mometasone:

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

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, musculoskeletal pain, immune system effects, indigestion

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)): \[\geq 100 \text{ mg/l} \]
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:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Endpoint</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50</td>
<td>(Gambusia affinis (Mosquito fish)): 8,510 mg/l</td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50</td>
<td>(Ceriodaphnia dubia (water flea)): 2,800 mg/l</td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50</td>
<td>(Pseudokirchneriella subcapitata (green algae)): &gt; 429 mg/l</td>
<td>Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC10</td>
<td>(Pseudokirchneriella subcapitata (green algae)): &gt; 429 mg/l</td>
<td>Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>NOEC</td>
<td>200 mg/l</td>
<td>Exposure time: 10 d</td>
</tr>
</tbody>
</table>

## Mometasone:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Endpoint</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50</td>
<td>(Menidia beryllina (Silverside)): 0.11 mg/l</td>
<td>Exposure time: 96 h Remarks: No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC</td>
<td>(Pimephales promelas (fathead minnow)): 0.00014 mg/l</td>
<td>Exposure time: 32 d Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
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</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC</td>
<td>(Daphnia magna (Water flea)): 0.34 mg/l</td>
<td>Exposure time: 21 d Method: OECD Test Guideline 211 Remarks: No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>
M-Factor (Chronic aquatic toxicity):
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

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
SAFETY DATA SHEET

Mometasone Ointment Formulation

Version 3.0 Revision Date: 2021/04/09 SDS Number: 1751217-00009 Date of last issue: 2020/10/10 Date of first issue: 2017/06/14

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

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 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.

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
Designated Flammable Substances, Flammable solid, (3000 kilogram)

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
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
<td>&gt;=70 - &lt;80</td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>593</td>
<td>&gt;=10 - &lt;20</td>
</tr>
</tbody>
</table>
Substances Subject to be Indicated Names

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>593</td>
</tr>
</tbody>
</table>

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 Y)
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**

Sources of key data used to compile the Safety Data Sheet:

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

**Date format**: yyyy/mm/dd

**Full text of other abbreviations**

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
- JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - 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 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; 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 Tem-
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.