Mometasone Cream Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone Cream Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: 30 Hudson Street, 33rd 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

Emergency Overview

Appearance: cream
Colour: white to off-white
Odour: No data available

Causes serious eye irritation. Toxic to aquatic life with long lasting effects.

GHS Classification
Serious eye damage/eye irritation: Category 2A
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.
**SAFETY DATA SHEET**
according to GB/T 16483 and GB/T 17519

**Mometasone Cream Formulation**

**Version**: 3.8  
**Revision Date**: 2021/04/09  
**SDS Number**: 1688394-00011  
**Date of last issue**: 2020/10/10  
**Date of first issue**: 2017/05/21

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**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.

**Disposal**:  
P501 Dispose of contents/container to an approved waste disposal plant.

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**Physical and chemical hazards**  
Not classified based on available information.

**Health hazards**  
Causes serious eye irritation.

**Environmental hazards**  
Toxic to aquatic life with long lasting effects.

**Other hazards which do not result in classification**  
None known.

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**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>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</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>

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**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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Unsuitable extinguishing media</th>
<th>Specific hazards during firefighting</th>
<th>Hazardous combustion products</th>
<th>Specific extinguishing methods</th>
<th>Special protective equipment for firefighters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water spray</td>
<td>None known.</td>
<td>Vapours may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.</td>
<td>Carbon oxides</td>
<td>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.</td>
<td>In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.</td>
</tr>
<tr>
<td>Alcohol-resistant foam</td>
<td></td>
<td></td>
<td>Metal oxides</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbon dioxide (CO2)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dry chemical</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Environmental precautions</th>
<th>Methods and materials for containment and cleaning up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</td>
<td>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.</td>
<td>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</td>
</tr>
</tbody>
</table>
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 breathe vapours.
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 environment.

Avoidance of contact : Oxidizing agents

Storage
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

Packaging material : Unsuitable material; None known.

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>White mineral oil (petroleum)</td>
<td>8042-47-5</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>MAC</td>
<td>100 mg/m3</td>
<td>CN OEL</td>
</tr>
<tr>
<td></td>
<td></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>Titanium dioxide</td>
<td>13463-67-7</td>
<td>PC-TWA (Total dust)</td>
<td>8 mg/m3</td>
<td>CN OEL</td>
</tr>
</tbody>
</table>

Further information: G2B - Possibly carcinogenic to humans
50% TWA 10 mg/m³ (Titanium dioxide) 83919-23-7 TWA 1 µg/m³ (OEB 4) Internal
Further information: Skin

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>10 mg/m³ (Titanium dioxide)</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4) Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm² Internal</td>
</tr>
</tbody>
</table>

These substance(s) are inextricably bound in the product and therefore do not contribute to a dust inhalation hazard. Titanium dioxide

**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

Eye/face 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.

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : cream
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 : Not applicable
Flammability (solid, gas) : Not classified as a flammability hazard
Flammability (liquids) : Not applicable
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies) Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
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Oxidizing properties: The substance or mixture is not classified as oxidizing.

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

Exposure routes:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

White mineral oil (petroleum):
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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
Titanium dioxide:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity:
  LC50 (Rat): > 6.82 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity

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:

White mineral oil (petroleum):
Species: Rabbit
Result: No skin irritation

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

Titanium dioxide:
Species: Rabbit
Result: No skin irritation

Mometasone:
Species: Rabbit
Result: No skin irritation
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**SAFETY DATA SHEET**
according to GB/T 16483 and GB/T 17519

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

**Components:**

**White mineral oil (petroleum):**
Species: Rabbit  
Result: No eye irritation

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

**Titanium dioxide:**
Species: Rabbit  
Result: No eye irritation

**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:**

**White mineral oil (petroleum):**
Test Type: Buehler Test  
Exposure routes: Skin contact  
Species: Guinea pig  
Result: negative

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

**Titanium dioxide:**
Test Type: Local lymph node assay (LLNA)  
Exposure routes: Skin contact  
Species: Mouse  
Result: negative
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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.

Germ cell mutagenicity
Not classified based on available information.

Components:

White mineral oil (petroleum):
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: 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

Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative

Genotoxicity in vivo: Test Type: Chromosome aberration test in vitro
Result: negative

Titanium dioxide:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

Mometasone:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vitro: Test Type: Chromosomal aberration
Test system: Chinese hamster lung cells
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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:

White mineral oil (petroleum):
Species: Rat
Application Route: Ingestion
Exposure time: 24 Months
Result: negative

Titanium dioxide:
Species: Rat
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in inhalation studies with animals.

Mometasone:
Species: Rat
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**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:**

**White mineral oil (petroleum):**

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

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

**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
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Application Route: Subcutaneous
Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight
Result: Embryotoxic effects., Teratogenicity and developmen-
tal 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 - As-
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:

White mineral oil (petroleum):
Species : Rat
LOAEL : 160 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat
LOAEL : >= 1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Method : OECD Test Guideline 412

2-Methyl-2,4-pentanediol:
Species : Rat
NOAEL : >= 450 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Method : OECD Test Guideline 408

Titanium dioxide:
Species : Rat
NOAEL : 24,000 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

Species : Rat
NOAEL : 10 mg/m3
Application Route : inhalation (dust/mist/fume)
Exposure time : 2 yr

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
**SAFETY DATA SHEET**
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</table>

**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, musculoskeletal pain, immune system effects, indigestion
    - **Skin contact**
      - **Symptoms**: Dermatitis, Itching

**Further information**

**Components**:

- **Mometasone**:
  - **Remarks**: Dermal absorption possible

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components**:

- **White mineral oil (petroleum)**:
  - **Toxicity to fish**
    - **LC50** (*Oncorhynchus mykiss* (rainbow trout)): > 100 mg/l
    - **Exposure time**: 96 h
    - **Method**: OECD Test Guideline 203
  - **Toxicity to daphnia and other aquatic invertebrates**
    - **EC50** (*Daphnia magna* (Water flea)): > 100 mg/l
    - **Exposure time**: 48 h
    - **Method**: OECD Test Guideline 202
| Substance | Toxicity to algae/aquatic plants | Toxicity to fish (Chronic toxicity) | Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | 2-Methyl-2,4-pentanediol: | Toxicity to microorganisms | Titanium dioxide: | Toxicity to fish | Toxicity to daphnia and other aquatic invertebrates | Toxicity to algae/aquatic plants | Toxicity to microorganisms | Memetasone: | Toxicity to fish |
|-----------|---------------------------------|-----------------------------------|------------------------------------------------|----------------|----------------|----------------|----------------|---------------------------------|-------------------------------|----------------|----------------|----------------|----------------------------------|
|           | NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l | NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l | NOEC (Daphnia magna (Water flea)): 1,000 mg/l | LC50 (Gambusia affinis (Mosquito fish)): 8,510 mg/l | NOEC: 200 mg/l | LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l | EC50 (Daphnia magna (Water flea)): 2,800 mg/l | EC50 (Daphnia magna (Water flea)): > 100 mg/l | ErC50 (Pseudokirchneriella subcapitata (green algae)): > 429 mg/l | NOEC: > 1,000 mg/l | Memetasone (Menidia beryllina (Silverside)): 0.11 mg/l |
|           | Method: OECD Test Guideline 201 | | | | | | | | | | | |
## Toxicity to daphnia and other aquatic invertebrates

**LC50 (Cyprinodon variegatus (sheepshead minnow)):** > 5 mg/l  
**Exposure time:** 7 d  
**Remarks:** No toxicity at the limit of solubility

**EC50 (Daphnia magna (Water flea)):** > 5 mg/l  
**Exposure time:** 48 h  
**Method:** OECD Test Guideline 202  
**Remarks:** No toxicity at the limit of solubility

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

## Toxicity to algae/aquatic plants

**EC50 (Pseudokirchneriella subcapitata (green algae)):** > 3.2 mg/l  
**Exposure time:** 72 h  
**Method:** OECD Test Guideline 201  
**Remarks:** No toxicity at the limit of solubility

## Toxicity to fish (Chronic toxicity)

**NOEC (Pimephales promelas (fathead minnow)):** 0.00014 mg/l  
**Exposure time:** 32 d  
**Method:** OECD Test Guideline 210

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

**NOEC (Daphnia magna (Water flea)):** 0.34 mg/l  
**Exposure time:** 21 d  
**Method:** OECD Test Guideline 211  
**Remarks:** No toxicity at the limit of solubility

## M-Factor (Chronic aquatic toxicity)

**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:

**White mineral oil (petroleum):**

**Biodegradability**

**Result:** Not readily biodegradable.  
**Biodegradation:** 31 %  
**Exposure time:** 28 d
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.

**National Regulations**

**GB 6944/12268**

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

**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

National regulatory information
Law on the Prevention and Control of Occupational Diseases

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

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Determination</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data Sheet:
- Date format: yyyy/mm/dd

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>ACGIH / STEL</td>
<td>Short-term exposure limit</td>
</tr>
<tr>
<td>CN OEL / PC-TWA</td>
<td>Permissible concentration - time weighted average</td>
</tr>
<tr>
<td>CN OEL / MAC</td>
<td>Maximum allowable concentration</td>
</tr>
</tbody>
</table>

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; NZToC - New Zealand toxicity class.
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Mometasone Cream Formulation

Version 3.8 Revision Date: 2021/04/09 SDS Number: 1688394-00011 Date of last issue: 2020/10/10 Date of first issue: 2017/05/21

Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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.

CN / EN