SAFETY DATA SHEET

Mometasone Cream Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Mometasone Cream Formulation

Manufacturer or supplier's details
Company : MSD
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
Telephone : 908-740-4000
Emergency telephone : 55 19 3758 2000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Eye irritation : Category 2A
Reproductive toxicity : Category 1B
Long-term (chronic) aquatic hazard : Category 2

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms :
Signal Word : Danger
Hazard Statements : H319 Causes serious eye irritation.
H360Df May damage the unborn child. Suspected of damaging fertility.
H411 Toxic to aquatic life with long lasting effects.

Precautionary Statements : Prevention:
P201 Observe special instructions before use.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
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Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.
P391 Collect spillage.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>Flammable liquids, Category 4 Acute toxicity (Oral), Category 5 Eye irritation, Category 2A</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td></td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Titanium dioxide</td>
<td>13463-67-7</td>
<td>Carcinogenicity (Inhalation), Category 2</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Inhalation) (Immune system, Liver, Kidney, Skin), Category 2 Long-term (chronic) aquatic hazard, Category 1</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
</tr>
</tbody>
</table>

SECTION 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. May damage the unborn child. Suspected of damaging fertility.

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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Metal 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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spills 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.

SECTION 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. 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.

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.

Conditions for safe storage : Keep in properly labeled 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 Organic peroxides Explosives Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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 fraction)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td>TWA (Vapor)</td>
<td>25 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Vapor)</td>
<td>50 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Inhalable)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Titanium dioxide

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Limit</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA 1 µg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(OEB 4)</td>
<td></td>
</tr>
<tr>
<td>Further info.</td>
<td></td>
<td>Wipe limit 10 µg/100 cm²</td>
<td>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 vapor type

Hand protection:
- 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:
- Cream

Color:
- White to off-white

Odor:
- No data available
### Odor 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

### Vapor pressure
Not applicable

### Relative vapor 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

### Autoignition temperature
No data available

### Decomposition temperature
No data available

### Viscosity

- **Viscosity, kinematic**
  Not applicable

### Explosive properties
Not explosive

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

### Particle size
No data available

### SECTION 10. STABILITY AND REACTIVITY

- **Reactivity**: Not classified as a reactivity hazard.
- **Chemical stability**: Stable under normal conditions.
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Version 4.2  Revision Date: 09/13/2019  SDS Number: 1688390-00008  Date of last issue: 24.04.2019
Date of first issue: 21.05.2017

Possibility of hazardous reactions:
- Vapors 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- 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

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 sensitization
Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:
White mineral oil (petroleum):
Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

2-Methyl-2,4-pentanediol:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative

Titanium dioxide:
Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Result : negative

Mometasone:
Test Type : Maximization Test
Routes of exposure : Dermal
Species : Guinea pig
Assessment : Does not cause skin sensitization.
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:**

**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
- 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

**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
  - 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
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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
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
May damage the unborn child. Suspected of damaging fertility.
## 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 fetal development**
- Test Type: Embryo-fetal 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 fetal development**
- Test Type: Embryo-fetal 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 fetal weight.
  - Result: No effects on fertility., Effect on reproduction capacity.

**Effects on fetal development**
- Test Type: Embryo-fetal development
- Species: Mouse
- Application Route: Subcutaneous
- Embryo-fetal toxicity.: LOAEL: 0,06 mg/kg body weight
  - Result: Embryotoxic effects., Teratogenicity and developmental toxicity

- Test Type: Embryo-fetal development
  - Species: Rat
  - Application Route: Dermal
  - Embryo-fetal toxicity.: LOAEL: 0,3 mg/kg body weight
  - Result: Embryo-fetal toxicity.

- Test Type: Embryo-fetal development
  - Species: Rabbit
  - Application Route: Dermal
  - Embryo-fetal toxicity.: LOAEL: 0,15 mg/kg body weight
  - Result: Embryo-fetal toxicity., Malformations were observed.
Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Subcutaneous  
Embryo-fetal toxicity: LOAEL: 0,15 mg/kg body weight  
Result: Effects on newborn.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-fetal toxicity: LOAEL: 0,7 mg/kg body weight  
Result: Embryo-fetal 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:
Routes of exposure: 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 y

Mometasone:
Species: Rat
NOAEL: 0,005 mg/kg
LOAEL: 0,3 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species: Dog
NOAEL: 0,5 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species: Rat
NOAEL: 0,00013 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 90 d
Target Organs: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

Species: Dog
NOAEL: 0,0005 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 90 d
Target Organs: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver

**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

SECTION 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

- Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

- Toxicity to fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): 1.000 mg/l
  Exposure time: 28 d

- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 1.000 mg/l
  Exposure time: 21 d

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 429 mg/l</th>
<th>Exposure time: 72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC10 (Pseudokirchneriella subcapitata (green algae)): &gt; 429 mg/l</th>
<th>Exposure time: 72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

| Substance                          | NOEC: 200 mg/l | Exposure time: 10 d |

### Titanium dioxide:

#### Toxicity to fish

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 100 mg/l</th>
<th>Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 203</td>
<td></td>
</tr>
</tbody>
</table>

#### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</th>
<th>Exposure time: 48 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Skeletonema costatum (marine diatom)): &gt; 10.000 mg/l</th>
<th>Exposure time: 72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
<td></td>
</tr>
</tbody>
</table>

### Mometasone:

#### Toxicity to fish

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Menidia beryllina (Silverside)): 0,11 mg/l</th>
<th>Exposure time: 96 h</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Cyprinodon variegatus (sheepshead minnow)): &gt; 5 mg/l</th>
<th>Exposure time: 7 d</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td></td>
</tr>
</tbody>
</table>

#### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 5 mg/l</th>
<th>Exposure time: 48 h</th>
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<td></td>
<td>Method: OECD Test Guideline 202</td>
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<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Americamysis): &gt; 5 mg/l</th>
<th>Exposure time: 96 h</th>
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<td>Method: US-EPA OPPTS 850.1035</td>
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<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 3,2 mg/l</th>
<th>Exposure time: 72 h</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
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</tbody>
</table>

| Substance                          | NOEC (Pimephales promelas (fathead minnow)): 0,00014             |                     |

### Remarks:

- No toxicity at the limit of solubility.


- Method: OECD Test Guideline 202

- Method: OECD Test Guideline 201

- Method: OECD Test Guideline 209
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):

- Value: 100

Toxicity to microorganisms:

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

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

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: log Pow: 0
octanol/water          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

### SECTION 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.

### SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**

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<th>UN 3077</th>
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<td>Proper shipping name</td>
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<td>Labels</td>
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**IATA-DGR**

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<td>Environmentally hazardous substance, solid, n.o.s. (Mometasone)</td>
</tr>
<tr>
<td>Class</td>
<td>9</td>
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<td>Packing group</td>
<td>III</td>
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<td>Labels</td>
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<td>Packing instruction (passenger aircraft)</td>
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<tr>
<td>Environmentally hazardous</td>
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SAFETY DATA SHEET

Mometasone Cream Formulation

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.

Domestic regulation

ANTT
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
Class : 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH)
Group 2B: Possibly carcinogenic to humans
Titanium dioxide : 13463-67-7

Brazil. Ordinance No. 1274 on the control and monitoring of chemicals. : Not applicable

International Regulations

The ingredients of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined
SECTION 16. OTHER INFORMATION

Further information

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

AICS - Australian Inventory of Chemical Substances; 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 Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.
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