SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone Ointment Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 855 Leandro N. Alem St., 8 Floor
Buenos Aires, Argentina C1001AFB
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
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
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.
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/ at-
SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 70 - &lt; 90</td>
</tr>
<tr>
<td></td>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td></td>
<td>Mometasone</td>
<td>83919-23-7</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.

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

None known.

Vapors may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Carbon oxides

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.

In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

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 spillages cannot be contained.

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.

See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

If sufficient ventilation is unavailable, use with local exhaust ventilation.

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
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>Petrolatum</td>
<td>8009-03-8</td>
<td>CMP (Mist)</td>
<td>5 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Sampled by a method which does not include vapour, lung.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT (Mist)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: lung</td>
<td></td>
</tr>
<tr>
<td>2-Methyl-2,4-pentanediol</td>
<td>107-41-5</td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Irritation</td>
<td></td>
</tr>
<tr>
<td></td>
<td></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 fraction, Aerosol only)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Engineering measures:  
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Essentially no open handling permitted.  
Use closed processing systems or containment technologies.

Personal protective equipment

Respiratory protection:  
If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the
recommended guidelines, use respiratory protection.

Filter type
Hand protection
Material : Combined particulates and organic vapor type
: Chemical-resistant gloves

Remarks

Eye protection
: Wear safety glasses with side shields or goggles.
: If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
: Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection
: Work uniform or laboratory coat.
: Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
: Use appropriate degowning techniques to remove potentially contaminated clothing.

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : ointment
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 : No data available
Flammability (solid, gas) : Not classified as a flammability hazard
Flammability (liquids) : Not applicable
SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
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:
Petrolatum:
Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

2-Methyl-2,4-pentanediol:
Acute oral toxicity: LD50 (Rat): > 2.000 mg/kg

Acute dermal toxicity: LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Mometasone:
Acute oral toxicity: LD50 (Rat): > 2.000 mg/kg
LD50 (Mouse): > 2.000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 3.3 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: No mortality observed at this dose.

LC50 (Mouse): > 3.2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute toxicity (other routes of administration): LD50 (Rat): 300 mg/kg
Application Route: Subcutaneous
Symptoms: Breathing difficulties

Skin corrosion/irritation
Not classified based on available information.

Components:
Petrolatum:
Species: Rabbit
## Mometasone Ointment Formulation

<table>
<thead>
<tr>
<th>Method</th>
<th>OECD Test Guideline 404</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

### Mometasone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

### Serious eye damage/eye irritation

Causes serious eye irritation.

#### Components:

### Petrolatum:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Irritation to eyes, reversing within 21 days</td>
</tr>
</tbody>
</table>

### Mometasone:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### Components:

### Petrolatum:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routes of exposure</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximization Test</th>
</tr>
</thead>
</table>
null
SAFETY DATA SHEET

Mometasone Ointment Formulation

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 fetal development: Test Type: Embryo-fetal 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 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:  
Petrolatum:  
Species: Rat  
NOAEL: 5,000 mg/kg  
Application Route: Ingestion  
Exposure time: 2 y

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

**Mometasone Ointment Formulation**

**Version**: 1.5  
**Revision Date**: 09/13/2019  
**SDS Number**: 1758815-00006  
**Date of last issue**: 24.04.2019  
**Date of first issue**: 14.06.2017

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mometasone</strong>:</td>
<td>Rat</td>
<td>0.005 mg/kg</td>
<td>0.3 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>0.5 mg/kg</td>
<td></td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>0.00013 mg/l</td>
<td></td>
<td>inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>0.0005 mg/l</td>
<td></td>
<td>inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver</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:**
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Petrolatum:

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

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

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

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

2-Methyl-2,4-pentanediol:

Toxicity to fish: LC50 (Gambusia affinis (Mosquito fish)): 8.510 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 2.800 mg/l
Exposure time: 48 h

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

Toxicity to microorganisms: NOEC: 200 mg/l
Exposure time: 10 d

Mometasone: Dermal absorption possible
Toxicity to fish

LC50 (Menidia beryllina (Silverside)): 0,11 mg/l
Exposure time: 96 h
Remarks: No toxicity at the limit of solubility.

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

Toxicity to daphnia and other aquatic invertebrates

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

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

Toxicity to algae/aquatic plants

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

Toxicity to 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:

Petrolatum:

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

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

Mometasone:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Stability in water: Hydrolysis: 50 %(12 d)
Method: OECD Test Guideline 111

Bioaccumulative potential

Components:

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

Mometasone:
Bioaccumulation: species: Lepomis macrochirus (Bluegill sunfish)
Bioconcentration factor (BCF): 107,1
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water: log Pow: 4,68

Mobility in soil

Components:

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

Other adverse effects
No data available

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

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

IMDG-Code
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Mometasone)
Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry : Not applicable

Control of precursors and essential chemicals for the : Not applicable
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**Mometasone Ointment Formulation**

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preparation of drugs.

**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**

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


**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **AR OEL**: Argentina. Occupational Exposure Limits
- **ACGIH / TWA**: 8-hour, time-weighted average
- **ACGIH / STEL**: Short-term exposure limit
- **AR OEL / CMP**: TLV (Threshold Limit Value)
- **AR OEL / CMP - CPT**: STEL (Short Term Limit Value)
- **AR OEL / CMP-C**: Ceiling value

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
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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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