SECTION 1. IDENTIFICATION

Product name: Mometasone Lotion Formulation
Other means of identification: No data available

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

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
Flammable liquids: Category 2
Eye irritation: Category 2A
Reproductive toxicity: Category 1B
Specific target organ toxicity - single exposure: Category 3

GHS label elements
Hazard pictograms: 
Signal Word: Danger

Precautionary Statements: Prevention:
P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P261 Avoid breathing mist or vapors.
**SAFETY DATA SHEET**

**Mometasone Lotion Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>SDS Number:</th>
<th>Date of last issue: 10/05/2020</th>
<th>Date of first issue: 02/15/2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5</td>
<td>1288466-00012</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **P264** Wash skin thoroughly after handling.
- **P271** Use only outdoors or in a well-ventilated area.
- **P280** Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**
- **P303 + P361 + P353** IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
- **P304 + P340 + P312** IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a doctor if you feel unwell.
- **P305 + P351 + P338** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- **P308 + P313** IF exposed or concerned: Get medical attention.
- **P337 + P313** IF eye irritation persists: Get medical attention.

**Storage:**
- **P405** Store locked up.

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

**Other hazards**
- Vapors may form explosive mixture with air.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>Isopropyl alcohol</td>
<td>67-63-0</td>
<td>&gt;= 30 - &lt; 60 *</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>1,2-Propanediol</td>
<td>57-55-6</td>
<td>&gt;= 10 - &lt; 30 *</td>
</tr>
<tr>
<td>Mometasone</td>
<td>No data available</td>
<td>83919-23-7</td>
<td>&gt;= 0.1 - &lt; 1 *</td>
</tr>
</tbody>
</table>

* Actual concentration or concentration range is withheld as a trade secret

### 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 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 cause drowsiness or dizziness. 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: High volume water jet

Specific hazards during fire fighting: Do not use a solid water stream as it may scatter and spread fire. Flash back possible over considerable distance. Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for 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: Remove all sources of ignition. Ventilate the area. Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapors/mists with a water spray jet.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- 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.
- Use explosion-proof electrical, ventilating and lighting equipment.

Advice on safe handling

- Do not get on skin or clothing.
- Avoid breathing mist or vapors.
- 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
- Non-sparking tools should be used.
- Keep container tightly closed.
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage

Keep in properly labeled containers.
- Store locked up.
- Keep tightly closed.
- Keep in a cool, well-ventilated place.
- Store in accordance with the particular national regulations.
- Keep away from heat and sources of ignition.

Materials to avoid

- Do not store with the following product types:
  - Strong oxidizing agents
  - Organic peroxides
  - Flammable solids
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Substances and mixtures which in contact with water emit flammable gases
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>Propan-2-ol</td>
<td>67-63-0</td>
<td>TWA</td>
<td>200 ppm 492 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm 984 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV</td>
<td>400 ppm 983 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV</td>
<td>500 ppm 1,230 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>CA ON OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Vapour and aerosols)</td>
<td>50 ppm 155 mg/m³</td>
<td>CA ON OEL</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>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Control parameters</th>
<th>Biological specimen</th>
<th>Sampling time</th>
<th>Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>Acetone</td>
<td>Urine</td>
<td>End of shift at end of work-week</td>
<td>40 mg/l</td>
<td>ACGIH BEI</td>
</tr>
</tbody>
</table>

Engineering measures: 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.
If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the...
potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Use explosion-proof electrical, ventilating and lighting equipment.

**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

**Material**: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

**Remarks**: 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**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>lotion</td>
</tr>
<tr>
<td>Color</td>
<td>colorless, clear, to, translucent</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>4.5</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
</tbody>
</table>
Initial boiling point and boiling range: No data available

Flash point: 18.4 °C
   Method: closed cup

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): Ignitable (see flash point)

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor density: No data available

Relative density: No data available

Density: No data available

Solubility(ies)
   Water solubility: No data available

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

Autoignition temperature: No data available

Decomposition temperature: No data available

Viscosity
   Viscosity, kinematic: No data available

Explosive properties: Not explosive

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

Molecular weight: Not applicable

Particle size: Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.

Chemical stability: Stable under normal conditions.

Possibility of hazardous reactions
   Highly flammable liquid and vapor.
   Vapors may form explosive mixture with air.
Can react with strong oxidizing agents.

- Conditions to avoid: Heat, flames and sparks.
- Incompatible materials: Oxidizing agents
- Hazardous decomposition products: No hazardous decomposition products are known.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

- **Inhalation**
- **Skin contact**
- **Ingestion**
- **Eye contact**

**Acute toxicity**

Not classified based on available information.

#### Components:

**Propan-2-ol:**

- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rat): > 25 mg/l
  - Exposure time: 6 h
  - Test atmosphere: vapor
- Acute dermal toxicity: LD50 (Rabbit): > 5,000 mg/kg

**Propylene glycol:**

- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- Acute inhalation toxicity: LC50 (Rabbit): > 159 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
- Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  - 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:

Propan-2-ol:
  Species: Rabbit
  Result: No skin irritation

Propylene glycol:
  Species: Rabbit
  Method: OECD Test Guideline 404
  Result: No skin irritation

Mometasone:
  Species: Rabbit
  Result: No skin irritation

Serious eye damage/eye irritation
Causes serious eye irritation.

Components:

Propan-2-ol:
  Species: Rabbit
  Result: Irritation to eyes, reversing within 21 days

Propylene glycol:
  Species: Rabbit
  Result: No eye irritation
  Method: OECD Test Guideline 405

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:

Propan-2-ol:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Propylene glycol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
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:

Propan-2-ol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
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
Result: negative

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

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative
### Mometasone:

**Genotoxicity in vitro**
- Test Type: Bacterial reverse mutation assay (AMES)
  - Result: negative
- Test Type: Chromosomal aberration
  - Test system: Chinese hamster lung cells
  - Result: negative
- Test Type: Chromosomal aberration
  - Test system: Chinese hamster ovary cells
  - Result: positive
- Test Type: Mouse Lymphoma
  - Result: negative

**Genotoxicity in vivo**
- Test Type: Micronucleus test
  - Species: Mouse
  - Application Route: Oral
  - Result: negative
- Test Type: Chromosomal aberration
  - Species: Rat
  - Cell type: Bone marrow
  - Result: negative
- Test Type: unscheduled DNA synthesis assay
  - Species: Rat
  - Cell type: Liver cells
  - Result: negative

**Germ cell mutagenicity - Assessment**
- Weight of evidence does not support classification as a germ cell mutagen.

### Carcinogenicity
Not classified based on available information.

### Components:

#### Propan-2-ol:
- **Species**: Rat
- **Application Route**: Inhalation (vapor)
- **Exposure time**: 104 weeks
- **Method**: OECD Test Guideline 451
- **Result**: negative

#### Propylene glycol:
- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 2 Years
- **Result**: negative

#### Mometasone:
- **Species**: Rat
<table>
<thead>
<tr>
<th>Application Route</th>
<th>Inhalation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Dose</td>
<td>0.067 mg/kg body weight</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

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:**

**Propan-2-ol:**

Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

**Propylene glycol:**

Effects on fertility: Test Type: Three-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on fetal development: Test Type: Embryo-fetal development
Species: Mouse
Application Route: Ingestion
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
May cause drowsiness or dizziness.

Components:

Propan-2-ol:  
Assessment : May cause drowsiness or dizziness.

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:**

**Propan-2-ol:**
- Species: Rat
- NOAEL: 12.5 mg/l
- Application Route: Inhalation (vapor)
- Exposure time: 104 Weeks

**Propylene glycol:**
- Species: Rat, male
- NOAEL: 1,700 mg/kg
- Application Route: Ingestion
- 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
- LOAEL: 0.5 mg/kg
- Application Route: Oral
- Exposure time: 30 d
- Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

- Species: Rat
- NOAEL: 0.00013 mg/l
- Application Route: Inhalation (dust/mist/fume)
- Exposure time: 90 d
- Target Organs: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

- Species: Dog
- NOAEL: 0.0005 mg/l
- Application Route: Inhalation (dust/mist/fume)
- Exposure time: 90 d
- Target Organs: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver

**Aspiration toxicity**

Not classified based on available information.

**Components:**

**Mometasone:**
Not applicable
Experience with human exposure

Components:

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:

Propan-2-ol:
- Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l
  Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
  Exposure time: 24 h
- Toxicity to microorganisms: EC50 (Pseudomonas putida): > 1,050 mg/l
  Exposure time: 16 h

Propylene glycol:
- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
  Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
  Exposure time: 48 h
- Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
  Exposure time: 7 d
- Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l
  Exposure time: 18 h

Mometasone:
- 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.

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:

Propan-2-ol:
Biodegradability: Result: rapidly degradable

BOD/COD: BOD: 1.19 (BOD5)COD: 2.23 BOD/COD: 53 %
Biodegradability
- Result: Readily biodegradable.
  - Biodegradation: 98.3%
  - 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:

Propan-2-ol:
Partition coefficient: n-octanol/water
- log Pow: 0.05

Propylene glycol:
Partition coefficient: n-octanol/water
- log Pow: -1.07

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. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or
death.
If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

**UNRTDG**
- UN number: UN 1219
- Proper shipping name: ISOPROPNOL SOLUTION
- Class: 3
- Packing group: II
- Labels: 3

**IATA-DGR**
- UN/ID No.: UN 1219
- Proper shipping name: Isopropanol solution
- Class: 3
- Packing group: II
- Labels: Flammable Liquids
- Packing instruction (cargo aircraft): 364
- Packing instruction (passenger aircraft): 353

**IMDG-Code**
- UN number: UN 1219
- Proper shipping name: ISOPROPNOL SOLUTION (Mometasone)
- Class: 3
- Packing group: II
- Labels: 3
- EmS Code: F-E, S-D
- 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**

**TDG**
- UN number: UN 1219
- Proper shipping name: ISOPROPNOL SOLUTION
- Class: 3
- Packing group: II
- Labels: 3
- ERG Code: 129
- Marine pollutant: yes(Mometasone)

**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.
The ingredients of this product are reported in the following inventories:

- AICS: not determined
- DSL: not determined
- IECSC: not determined

Full text of other abbreviations:

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
- CA BC OEL: Canada. British Columbia OEL
- CA ON OEL: Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act.
- CA QC OEL: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants

ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
CA AB OEL / TWA: 8-hour Occupational exposure limit
CA AB OEL / STEL: 15-minute occupational exposure limit
CA BC OEL / TWA: 8-hour time weighted average
CA BC OEL / STEL: short-term exposure limit
CA ON OEL / TWA: Time-Weighted Average Limit (TWA)
CA QC OEL / TWAEV: Time-weighted average exposure value
CA QC OEL / STEV: Short-term exposure value

AIIIC - 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 Standardization; 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
SAFETY DATA SHEET

Mometasone Lotion Formulation

Version 3.5 Revision Date: 04/09/2021 SDS Number: 1288466-00012 Date of last issue: 10/05/2020 Date of first issue: 02/15/2017

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


Revision Date: 04/09/2021 Date format: mm/dd/yyyy

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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