SAFETY DATA SHEET
According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".

Mometasone Lotion Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Mometasone Lotion Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : Organon & Co.
   30 Hudson Street, 33nd floor
   07302 Jersey City, New Jersey, U.S.A
   Telephone : 551-430-6000
   E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

1.4 Emergency telephone number
   215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification T.R. SEA No 28848
   Flammable liquids, Category 2
   Eye irritation, Category 2
   Specific target organ toxicity - single exposure, Category 3
   Long-term (chronic) aquatic hazard, Category 2

   H225: Highly flammable liquid and vapour.
   H319: Causes serious eye irritation.
   H336: May cause drowsiness or dizziness.
   H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling T.R. SEA No 28848
   Hazard pictograms : ![Flammable](image)
   ![Danger](image)
   Signal word : Danger
   Hazard statements : H225 Highly flammable liquid and vapour.
   H319 Causes serious eye irritation.
   H336 May cause drowsiness or dizziness.
   H411 Toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
P233 Keep container tightly closed.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
P304 + P340 + P312 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Propan-2-ol

### 2.3 Other hazards

Vapours may form explosive mixture with air.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>200-661-7</td>
<td>Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>603-117-00-0</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mometasone</td>
<td>83919-23-7</td>
<td></td>
<td>Repr. 1B; H360Df STOT RE 2; H373 (Immune system, Liver, Kidney, Skin) Aquatic Chronic 1; H410</td>
<td>&gt;= 0,1 - &lt; 0,25</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity): 100</td>
<td></td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
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SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes serious eye irritation. May cause drowsiness or dizziness.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: High volume water jet
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5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products: Carbon oxides

5.3 Advice for firefighters

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

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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: 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).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Non-sparking tools should be used. Soak up with inert absorbent material. Suppress (knock down) gases/vapours/mists with a water spray jet. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.
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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSOANAL 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 vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled 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.

Advice on common storage: Do not store with the following product types:

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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.
SAFETY DATA SHEET
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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Date of first issue: 25.09.2017

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<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>Further information: Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm² Internal</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL):

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>500 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>888 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>89 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>319 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>26 mg/kg bw/day</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC):
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<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>Fresh water</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2251 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>28 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>160 mg/kg food</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57.2 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 mg/kg</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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

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.

Hand protection

Material
- Chemical-resistant gloves

Remarks
- Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

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.

Respiratory protection
- If adequate local exhaust ventilation is not available or expo-
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Sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to TS EN 14387

Filter type: Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Lotion</td>
</tr>
<tr>
<td>Colour</td>
<td>Colourless, clear, to, translucent</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour 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>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>18.4 °C</td>
</tr>
<tr>
<td>Method</td>
<td>Closed cup</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
- Flammability (liquids) : Ignitable (see flash point)
- Molecular weight : Not applicable
- Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions : Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- 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
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<tbody>
<tr>
<td>2.1</td>
<td>09.04.2021</td>
<td>1998188-00004</td>
<td>05.10.2020</td>
<td>25.09.2017</td>
</tr>
</tbody>
</table>

**Acute inhalation toxicity**
- LC50 (Rat): > 25 mg/l
- Exposure time: 6 h
- Test atmosphere: vapour

**Acute dermal toxicity**
- LD50 (Rabbit): > 5.000 mg/kg

**Mometasone**

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

**Acute inhalation toxicity**
- LC50 (Rat): > 3.3 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Remarks: No mortality observed at this dose.
- LC50 (Mouse): > 3.2 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist

**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

**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

**Mometasone:**
- Species: Rabbit
- Result: No eye irritation
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Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Propan-2-ol:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Mometasone:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Assessment: Does not cause skin sensitisation.
Result: negative
Remarks: The results of a test on guinea pigs showed this substance to be a weak skin 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

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

Test Type: Chromosomal aberration
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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 (vapour)  
Exposure time: 104 weeks  
Method: OECD Test Guideline 451  
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
Reproductive toxicity
Not classified based on available information.

Components:

Propan-2-ol:
Effects on fertility:
  Test Type: Two-generation reproduction toxicity study
  Species: Rat
  Application Route: Ingestion
  Result: negative

Effects on foetal development:
  Test Type: Embryo-foetal development
  Species: Rat
  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 foetal weight
  Result: No effects on fertility, Effect on reproduction capacity

Effects on foetal development:
  Test Type: Embryo-foetal development
  Species: Mouse
  Application Route: Subcutaneous
  Embryo-foetal toxicity: LOAEL: 0.06 mg/kg body weight
  Result: Embryotoxic effects, Teratogenicity and developmental toxicity

  Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Dermal
  Embryo-foetal toxicity: LOAEL: 0.3 mg/kg body weight
  Result: Embryo-foetal toxicity

  Test Type: Embryo-foetal development
  Species: Rabbit
  Application Route: Dermal
  Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
  Result: Embryo-foetal toxicity, Malformations were observed.

  Test Type: Embryo-foetal development
  Species: Rat
  Application Route: Subcutaneous
  Embryo-foetal toxicity: LOAEL: 0.15 mg/kg body weight
  Result: Effects on newborn
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Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Oral  
Embryo-foetal toxicity: LOAEL: 0,7 mg/kg body weight  
Result: Embryo-foetal toxicity, Malformations were observed.

Reproductive toxicity - Assessment  
Clear evidence of adverse effects on development, based on animal experiments., Some evidence of adverse effects on sexual function and fertility, based on animal experiments.

STOT - single exposure  
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:  
Exposure routes : inhalation (dust/mist/fume)  
Target Organs : Immune system, Liver, Kidney, Skin  
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Propan-2-ol:  
Species : Rat  
NOAEL : 12,5 mg/l  
Application Route : inhalation (vapour)  
Exposure time : 104 Weeks

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

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

12.1 Toxicity

**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

**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 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
**SAFETY DATA SHEET**

According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.

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<td>05.10.2020</td>
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</tr>
</tbody>
</table>

Remarks: No toxicity at the limit of solubility

**Toxicity to fish (Chronic toxicity)**

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

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

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

**M-Factor (Chronic aquatic toxicity)**

- 100

12.2 **Persistence and degradability**

**Components:**

**Propan-2-ol:**

- Biodegradability: Result: rapidly degradable
- BOD/COD:
  - BOD: 1.19 (BOD5)
  - COD: 2.23
  - BOD/COD: 53 %

**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

12.3 **Bioaccumulative potential**

**Components:**

**Propan-2-ol:**

- Partition coefficient: n-octanol/water: log Pow: 0.05

**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
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</table>

12.4 Mobility in soil

**Components:**

Mometasone:  
Distribution among environmental compartments: \( \log K_{oc} = 4.02 \)

12.5 Results of PBT and vPvB assessment

Not relevant

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number

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<td>IMDG</td>
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<tr>
<td>IATA</td>
<td>UN 1219</td>
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14.2 UN proper shipping name

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<tbody>
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<td>ISOPROPAÑOL, SOLUTION</td>
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<tr>
<td>ADR</td>
<td>ISOPROPAÑOL, SOLUTION</td>
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<tr>
<td>RID</td>
<td>ISOPROPAÑOL, SOLUTION</td>
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<tr>
<td>IMDG</td>
<td>ISOPROPAÑOL, SOLUTION (Mometasone)</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

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IATA : Isopropanol, solution

14.3 Transport hazard class(es)

ADN : 3
ADR : 3
RID : 3
IMDG : 3
IATA : 3

14.4 Packing group

ADN
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3

ADR
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3
Tunnel restriction code : (D/E)

RID
Packing group : II
Classification Code : F1
Hazard Identification Number : 33
Labels : 3

IMDG
Packing group : II
Labels : 3
EmS Code : F-E, S-D

IATA (Cargo)
Packing instruction (cargo aircraft) : 364
Packing instruction (LQ) : Y341
Packing group : II
Labels : Flammable Liquids

IATA (Passenger)
Packing instruction (passenger aircraft) : 353
Packing instruction (LQ) : Y341
Packing group : II
Labels : Flammable Liquids

14.5 Environmental hazards

ADN
Environmentally hazardous : yes
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ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Conditions of restriction for the following entries should be considered: Number on list 3
Regulation on Persistent Organic Pollutants (Number 30595) : Not applicable
Regulation on prevention of major industrial accidents. Reg number 30702 Quantity 1 Quantity 2
P5c FLAMMABLE LIQUIDS 5.000 t 50.000 t
E2 ENVIRONMENTAL HAZARDS 200 t 500 t

Other regulations:
According to 13 December 2014, No:29204, “Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I”.
Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.

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

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

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical
SAFETY DATA SHEET
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The SDS has been prepared by: Name: Gökhan Ardıç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September 2025

Full text of H-statements

- **H225**: Highly flammable liquid and vapour.
- **H319**: Causes serious eye irritation.
- **H336**: May cause drowsiness or dizziness.
- **H360DF**: May damage the unborn child. Suspected of damaging fertility.
- **H373**: May cause damage to organs through prolonged or repeated exposure if inhaled.
- **H410**: Very toxic to aquatic life with long lasting effects.

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

Full text of other abbreviations

- **Aquatic Chronic**: Long-term (chronic) aquatic hazard
- **Eye Irrit.**: Eye irritation
- **Flam. Liq.**: Flammable liquids
- **Repr.**: Reproductive toxicity
- **STOT RE**: Specific target organ toxicity - repeated exposure
- **STOT SE**: Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Dose 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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)
SAFETY DATA SHEET
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Further information

Classification of the mixture:

<table>
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<tr>
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<tbody>
<tr>
<td>Flam. Liq. 2</td>
<td>H225</td>
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<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>H336</td>
</tr>
<tr>
<td>Aquatic Chronic 2</td>
<td>H411</td>
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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.

TR / EN