SAFETY DATA SHEET

Betamethasone Lotion Formulation

Section 1: Identification

Product name : Betamethasone Lotion Formulation

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

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

Section 2: Hazard identification

GHS Classification
Flammable liquids : Category 2
Serious eye damage/eye irritation : Category 2A
Reproductive toxicity : Category 1B
Specific target organ toxicity - single exposure : Category 3
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

GHS label elements
Hazard pictograms :
Signal word : Danger
Hazard statements : H225 Highly flammable liquid and vapour.
H319 Causes serious eye irritation.
H336 May cause drowsiness or dizziness.
H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.
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/ sparks/ open flames/ hot surfaces. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical/ ventilating/ lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P271 Use only outdoors or in a well-ventilated area.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P281 Use personal protective equipment as required.

Response:
P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
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.
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 advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

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

Other hazards which do not result in classification
Vapours may form explosive mixture with air.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.01 - &lt; 0.3</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 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. Causes damage to organs through prolonged or repeated exposure.

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. Vapours 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.
SAFETY DATA SHEET
Betamethasone Lotion Formulation

Evacuate area.

Special protective equipment for firefighters
Hazchem Code

In the event of fire, wear self-contained breathing apparatus.
2YE

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/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.
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.
Do not breathe 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.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment.

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

Conditions for safe storage:
Keep in properly 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.

Materials to avoid:
Do not store with the following product types:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Flammable gases
Pyrophoric liquids
Pyrophoric solids
Self-heating substances and mixtures
Poisonous gases
Explosives

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>WES-TWA</td>
<td>400 ppm 983 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-STE</td>
<td>500 ppm 1,230 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 ppm ACGIH</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm ACGIH</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>WES-TWA (particulate)</td>
<td>10 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-TWA (Vapour and particulates)</td>
<td>150 ppm 474 mg/m3</td>
<td>NZ OEL</td>
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<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
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</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 vapour type

Hand protection: Chemical-resistant gloves

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

Eye protection: Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially contaminated clothing.

Section 9: Physical and chemical properties

Appearance: lotion

Colour: colourless
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Odour</td>
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<tr>
<td>Odour Threshold</td>
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<tr>
<td>pH</td>
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<td>Melting point/freezing point</td>
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<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
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<tr>
<td>Flash point</td>
<td>21.4 °C</td>
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<tr>
<td>Method</td>
<td>closed cup</td>
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<tr>
<td>Evaporation rate</td>
<td>No data available</td>
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<tr>
<td>Flammability (solid, gas)</td>
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<tr>
<td>Flammability (liquids)</td>
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<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
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</tr>
<tr>
<td>Relative vapour density</td>
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<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
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<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
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<td></td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
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<tr>
<td>Decomposition temperature</td>
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<tr>
<td>Viscosity</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>
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 vapour.
- Vapours 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

Exposure routes:
- 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: vapour
- 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

Betamethasone:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  LD50 (Mouse): > 4,500 mg/kg
- Acute inhalation toxicity: LC50 (Rat): 0.4 mg/l
  Exposure time: 4 h
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

Betamethasone:
Species: Rabbit
Result: Mild 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

Betamethasone:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

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

**betamethasone:**
Exposure routes: Dermal
Species: Guinea pig
Result: Weak sensitizer

**Chronic toxicity**

**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

Genotoxicity in vivo:
Test Type: In vitro mammalian cell gene mutation test
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

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

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: Chromosome aberration test in vitro
Result: positive
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Oral
Result: equivocal

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

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

Reproductive toxicity
May damage the unborn child.

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

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

Effects on foetal development: Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative
betamethasone:
Effects on foetal development:
Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0.42 mg/kg body weight
Result: Malformations were observed.

Species: Mouse
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Malformations were observed.

Reproductive toxicity - Assessment:
Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
May cause drowsiness or dizziness.

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

STOT - repeated exposure
Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Components:

betamethasone:
Target Organs: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment: Causes 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

Propylene glycol:
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

betamethasone:
Species: Rabbit
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 10 - 30 d
Target Organs: Pituitary gland, Immune system, muscle

Species: Rat
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland

Species: Mouse
LOAEL: 0.1 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland

Species: Dog
LOAEL: 0.05 mg/kg
Application Route: Oral
Exposure time: 28 d
Target Organs: Blood, thymus gland, Adrenal gland

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

betamethasone:
Inhalation: Target Organs: Adrenal gland
Skin contact: Symptoms: Redness, pruritis, Irritation

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

betamethasone:
Toxicity to daphnia and other aquatic invertebrates : EC50 (Americamysis): > 50 mg/l
                                                     Exposure time: 96 h
Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l
                                      Exposure time: 72 h
                                      Method: OECD Test Guideline 201
                                      Remarks: No toxicity at the limit of solubility
                                      NOEC (Pseudokirchneriella subcapitata (green algae)): 34 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)): 0.052 mg/l
                                     Exposure time: 32 d
                                     Method: OECD Test Guideline 210
                                     NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l
                                     Exposure time: 219 d
                                     Method: OECD Test Guideline 229
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 8 mg/l
                                                                      Exposure time: 21 d
                                                                      Method: OECD Test Guideline 211

Persistence and degradability

Components:

Propan-2-ol:
Biodegradability : Result: rapidly degradable
BOD/COD : BOD: 1.19 (BOD5) COD: 2.23 BOD/COD: 53 %

**Propylene glycol:**
Biodegradability : Result: Readily biodegradable.  
Biodegradation: 98.3 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301F

**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

**betamethasone:**
Partition coefficient: n-octanol/water : log Pow: 2.11

**Mobility in soil**
No data available

**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 : ISOPROPANOL 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 (betamethasone)
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.

National Regulations

NZS 5433
UN number        : UN 1219
Proper shipping name : ISOPROPNOL SOLUTION
Class            : 3
Packing group    : II
Labels          : 3
Hazchem Code     : 2YE

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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:
AICS         : not determined
# SAFETY DATA SHEET

**Betamethasone Lotion Formulation**

<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>
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<td>09.04.2021</td>
<td>1288509-00012</td>
<td>10.10.2020</td>
<td>16.02.2017</td>
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DSL : not determined  
IECSC : not determined

## Section 16: Other information

### Further information

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### Full text of other abbreviations

- **ACGIH**: USA, ACGIH Threshold Limit Values (TLV)  
- **ACGIH BEI**: ACGIH - Biological Exposure Indices (BEI)  
- **NZ OEL**: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

**ACGIH / TWA**: 8-hour, time-weighted average  
**ACGIH / STEL**: Short-term exposure limit  
**NZ OEL / WES-TWA**: Workplace Exposure Standard - Time Weighted average  
**NZ OEL / WES- STEL**: Workplace Exposure Standard - Short-Term Exposure Limit

**AIIC** - Australian Inventory of Industrial Chemicals; **ANTT** - National Agency for Transport by Land of Brazil; **ASTM** - American Society for the Testing of Materials; **bw** - Body weight; **CMR** - Carcinogen, Mutagen or Reproductive Toxicant; **DIN** - Standard of the German Institute for Standardisation; **DSL** - Domestic Substances List (Canada); **ECx** - Concentration associated with x% response; **ELx** - Loading rate associated with x% response; **EmS** - Emergency Schedule; **ENCS** - Existing and New Chemical Substances (Japan); **ErCx** - Concentration associated with x% growth rate response; **ERG** - Emergency Response Guide; **GHS** - Globally Harmonized System; **GLP** - Good Laboratory Practice; **IARC** - International Agency for Research on Cancer; **IATA** - International Air Transport Association; **IBC** - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; **IC50** - Half maximal inhibitory concentration; **ICAO** - International Civil Aviation Organization; **IECSC** - Inventory of Existing Chemicals in China; **IMDG** - International Maritime Dangerous Goods; **IMO** - International Maritime Organization; **ISHL** - Industrial Safety and Health Law (Japan); **IC50** - 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; **Chilean Norm**; **NO(A)EC**: No Observed (Adverse) Effect Concentration; **NO(A)EL**: No Observed (Adverse) Effect Level; **NOELR**: No Observable Effect Loading Rate; **NOM**: Official Mexican Norm; **NTP**: National Toxicology Program; **NZIoC**: New Zealand Inventory of Chemicals; **OECD**: Organization for Economic Co-operation and Development; **OPPTS**: Office of Chemical Safety and Pollution Prevention; **PBT**: Persistent, Bioaccumulative and Toxic substance; **PICCS**: Philippines Inventory of Chemicals and Chemical Substances; **(Q)SAR**: (Quantitative) Structure Activity Relationship; **REACH**: Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; **SADT**: Self-Accelerating Decomposition Temperature; **SDS**: Safety Data Sheet; **TCSI**: Taiwan Chemical Substance Inventory; **TDG**: Transportation of Dangerous Goods; **TSCA**: Toxic Substances Control Act (United States); **UN**: United Nations; **UNRTDG**: United Nations Recommendations on the Transport of Dangerous Goods; **vPvB**: Very Persistent and Very Bioaccumulative; **WHMIS**: Workplace Hazardous Materials Information System
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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