1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Betamethasone / Salicylic Acid Lotion Formulation

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

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Flammable liquids : Category 2
Skin corrosion/irritation : Category 2
Serious eye damage/eye irritation : Category 2
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)
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms
Signal word : Danger
Hazard statements : H225 Highly flammable liquid and vapour. H315 Causes skin irritation.
### SAFFETY DATA SHEET

**Betamethasone / Salicylic Acid 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>
</tr>
</thead>
<tbody>
<tr>
<td>5.2</td>
<td>2021/04/09</td>
<td>1832962-00012</td>
<td>2020/10/10</td>
<td>2017/07/13</td>
</tr>
</tbody>
</table>

**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.
**H410** Very toxic to aquatic life with long lasting effects.

**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.
  - P233 Keep container tightly closed.
  - P241 Use explosion-proof electrical/ventilating/lighting equipment.
  - P242 Use non-sparking tools.
  - P243 Take action to prevent static discharges.
  - 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.
  - P273 Avoid release to the environment.
  - P280 Wear protective gloves/protective clothing/eye protection/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 POISON CENTER/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 advice/attention.
  - P332 + P313 If skin irritation occurs: Get medical advice/attention.
  - P337 + P313 If eye irritation persists: Get medical advice/attention.
  - P362 + P364 Take off contaminated clothing and wash it before reuse.
  - P391 Collect spillage.

- **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

Important symptoms and outlines of the emergency assumed: Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Propan-2-ol</td>
</tr>
<tr>
<td></td>
<td>salicylic acid</td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxide</td>
</tr>
<tr>
<td></td>
<td>betamethasone</td>
</tr>
</tbody>
</table>

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 for at least 15 minutes while removing 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 skin irritation. 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.
5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : High volume water jet

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

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

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 dyeing 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 deter-
mine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling
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.

Avoidance of contact
Hygiene measures : Oxidizing agents
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.

Storage
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:
Oxidizing solids
Oxidizing liquids
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Form of exposure</th>
<th>Value type</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>ACL</td>
<td>200 ppm</td>
<td>Perhaps to concentration</td>
<td>JP OEL ISHL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-C</td>
<td>400 ppm</td>
<td>980 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>200 ppm</td>
<td></td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm</td>
<td></td>
<td>ACGIH</td>
</tr>
<tr>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>TWA</td>
<td>100 µg/m³ OEB 2</td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>OEL-C</td>
<td>2 mg/m³</td>
<td></td>
<td>JP OEL JSOH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>C</td>
<td>2 mg/m³</td>
<td></td>
<td>ACGIH</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ OEB 4</td>
<td></td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</td>
<td></td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: DSEN

Basis of sampling:
- End of shift at end of work-week

Biological occupational exposure limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Target substance</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.
SAFETY DATA SHEET
Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 2021/04/09 SDS Number: 1832962-00012 Date of last issue: 2020/10/10 Date of first issue: 2017/07/13

Filter type
Hand protection
: Combined particulates and organic vapour type

Material
: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state
: lotion

Colour
: colourless, translucent

Odour
: No data available

Odour Threshold
: No data available

Melting point/freezing point
: No data available

Boiling point, initial boiling point and boiling range
: No data available

Flammability (solid, gas)
: Not applicable

Flammability (liquids)
: Not applicable

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Upper flammability limit
: No data available

Lower explosion limit / Lower flammability limit
: No data available

Flash point
: 21.4 - 22.2 °C

Decomposition temperature
: No data available

pH
: 4.6 - 5.3

Evaporation rate
: No data available
SAFETY DATA SHEET
Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2  Revision Date: 2021/04/09  SDS Number: 1832962-00012  Date of last issue: 2020/10/10
Date of first issue: 2017/07/13

Auto-ignition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Vapour pressure : No data available
Density and / or relative density
Relative density : No data available
Density : No data available
Relative vapour density : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle characteristics
Particle size : No data available

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.

11. TOXICOLOGICAL INFORMATION
Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact
Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: \( > 2,000 \text{ mg/kg} \)
Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: \( > 5 \text{ mg/l} \)
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: \( > 2,000 \text{ mg/kg} \)
Method: Calculation method

Components:
Propan-2-ol:
Acute oral toxicity : LD50 (Rat): \( > 5,000 \text{ mg/kg} \)

Acute inhalation toxicity : LC50 (Rat): \( > 25 \text{ mg/l} \)
Exposure time: 6 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): \( > 5,000 \text{ mg/kg} \)

salicylic acid:
Acute oral toxicity : LD50 (Mouse): \( 480 \text{ mg/kg} \)
LD50 (Rat): \( 891 \text{ mg/kg} \)
LD50 (Rabbit): \( 1,300 \text{ mg/kg} \)

Acute inhalation toxicity : LC50 (Rat): \( 0.9 \text{ mg/l} \)
Exposure time: 1 h

Acute dermal toxicity : LD50 (Rat): \( 2,000 \text{ mg/kg} \)
LD50 (Rabbit): \( 10,000 \text{ mg/kg} \)

Sodium hydroxide:
Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

betamethasone:
Acute oral toxicity : LD50 (Rat): \( > 5,000 \text{ mg/kg} \)
LD50 (Mouse): \( > 4,500 \text{ mg/kg} \)

Acute inhalation toxicity : LC50 (Rat): \( 0.4 \text{ mg/l} \)
Exposure time: 4 h
Skin corrosion/irritation
Causes skin irritation.

Components:

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

Salicylic acid:
Result: Skin irritation

Sodium hydroxide:
Result: Corrosive after 3 minutes or less of exposure

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

Salicylic acid:
Species: Rabbit
Remarks: Severe eye irritation

Sodium hydroxide:
Result: Irreversible effects on the eye
Remarks: Based on skin corrosivity.

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

salicylic acid:
Test Type: Local lymph node assay (LLNA)
Species: Mouse
Result: negative

Sodium hydroxide:
Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: Skin contact
Result: negative

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

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

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

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

Genotoxicity in vivo: Test Type: Mammalian bone marrow sister chromatid exchange
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Test Type: Sister chromatid exchange analysis in spermatogonia
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

**salicylic acid:**
Species :
Mouse
Application Route :
Skin contact
Exposure time :
1 Years
NOAEL :
2 mg/cm2
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:
Species: Rat
Application Route: Ingestion
Result: negative

**salicylic acid:**
Effects on foetal development:
Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 380 mg/kg body weight
Result: Maternal toxicity observed., Embryo-foetal toxicity

Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 80 mg/kg body weight
Result: No effects on foetal development

Reproductive toxicity - Assessment: Suspected of damaging the unborn child.

**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

**salicylic acid:**
- Species: Rat
- NOAEL: 50 mg/kg
- Application Route: Ingestion
- Exposure time: 2 yr
- Species: Rat
- LOAEL: 500 mg/kg
- Application Route: Oral
- Exposure time: 3 d
- Target Organs: Liver

**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:

Salicylic acid:
Skin contact: Symptoms: Skin irritation
Eye contact: Symptoms: Severe irritation
Ingestion: Symptoms: Gastrointestinal discomfort, hearing loss, Dizziness, electrolyte imbalance

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

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

Salicylic acid:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 1,380 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 870 mg/l
Exposure time: 48 h
Toxicity to algae/aquatic plants:
- EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 10 mg/l
  Exposure time: 21 d

**Betamethasone:**

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

**M-Factor (Chronic aquatic toxicity):**
- 1,000

**Persistence and degradability**

**Components:**

**Propan-2-ol:**

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

**Bioaccumulative potential**

**Components:**

**Propan-2-ol:**

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

**salicylic acid:**
Partition coefficient: n-octanol/water
: log Pow: 2.25

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

**Mobility in soil**
No data available

**Hazardous to the ozone layer**
Not applicable

**Other adverse effects**
No data available

### 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.

### 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: ISOPROPANOL 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
Refer to section 15 for specific national regulation.

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.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Group 4, Alcohols, (400 litre), Hazardous rank II

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Isopropyl alcohol</td>
<td>102</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propyl alcohol</td>
<td>494</td>
<td>&gt;=30 - &lt;40</td>
</tr>
</tbody>
</table>
Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propyl alcohol</td>
<td>494</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Organic Solvents Class 2

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Inflammable Substance

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Flammable liquids (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Flammable liquid (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance(Category Z)
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Specially Controlled Industrial Waste
The components of this product are reported in the following inventories:

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

16. OTHER INFORMATION

**Further information**


Date format: yyyy/mm/dd

**Full text of other abbreviations**

- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
- JP OEL ISHL: Japan. Administrative Control Levels
- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
- ACGIH / C: Ceiling limit
- JP OEL ISHL / ACL: Administrative Control level
- JP OEL JSOH / OEL-C: Occupational Exposure Limit-Ceiling

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 Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No
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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