SAFETY DATA SHEET

Betamethasone / Salicylic Acid Lotion Formulation

Version 5.1  Revision Date: 23.03.2020  SDS Number: 1833495-00010  Date of last issue: 20.12.2019
Date of first issue: 13.07.2017

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone / Salicylic Acid Lotion Formulation

Manufacturer or supplier’s details
Company: MSD
Address: Briahnager - Off Pune Nagar Road Wagholi - Pune - India 412 207
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Very highly flammable liquids

GHS Classification
Flammable liquids: Category 2
Skin corrosion/irritation: 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)
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.
- 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.
- 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:
- 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&gt;= 0.5 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.025 - &lt; 0.1</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 and personal protective equipment recommendations.

Environmental precautions:
Discharge into the environment must be avoided.
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 dyed 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.

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.
If advised by assessment of the local exposure potential, use only in an area equipped with explosion-proof exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe vapours or spray mist.
Do not swallow.
Do not get in eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Non-sparking tools should be used.
Keep container tightly closed.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage : Keep in properly 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

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>TWA</td>
<td>200 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>400 ppm</td>
<td>ACGIH</td>
</tr>
<tr>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>TWA</td>
<td>100 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
Further information: DSEN

<table>
<thead>
<tr>
<th>Component</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>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>CEIL</td>
<td>2 mg/m3</td>
<td>IN OEL</td>
<td></td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information: Skin

| Wipe limit | 10 µg/100 cm² | Internal |

**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.

**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**

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.

Hygiene measures

If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working
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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>lotion</td>
</tr>
<tr>
<td>Colour</td>
<td>colourless, 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>4.6 - 5.3</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>21.4 - 22.2 °C</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>Flammability (liquids)</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>No data available</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>
</tbody>
</table>
10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reactivity</td>
<td>Not classified as a reactivity hazard.</td>
</tr>
<tr>
<td>Chemical stability</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Possibility of hazardous reactions</td>
<td>Highly flammable liquid and vapour. Vapours may form explosive mixture with air. Can react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Conditions to avoid</td>
<td>Heat, flames and sparks.</td>
</tr>
<tr>
<td>Incompatible materials</td>
<td>Oxidizing agents</td>
</tr>
<tr>
<td>Hazardous decomposition products</td>
<td>No hazardous decomposition products are known.</td>
</tr>
</tbody>
</table>

11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Route of exposure</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td></td>
</tr>
<tr>
<td>Skin contact</td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
</tr>
</tbody>
</table>

**Acute toxicity**
Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>Acute toxicity estimate: &gt; 5,000 mg/kg Method: Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td>Acute toxicity estimate: &gt; 10 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>Acute toxicity estimate: &gt; 5,000 mg/kg Method: Calculation method</td>
</tr>
</tbody>
</table>
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

Salicylic acid:
Acute oral toxicity: LD50 (Mouse): 480 mg/kg
LD50 (Rat): 891 mg/kg
LD50 (Rabbit): 1,300 mg/kg
Acute inhalation toxicity: LC50 (Rat): 0.9 mg/l
Exposure time: 1 h
Acute dermal toxicity: LD50 (Rabbit): 2,000 mg/kg
LD50 (Rabbit): 10,000 mg/kg

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

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
Causes skin irritation.

Components:

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

Salicylic acid:
Result: Skin irritation

Sodium hydroxide:
<table>
<thead>
<tr>
<th>Component</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>betamethasone</td>
<td>Corrosive after 3 minutes or less of exposure</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rabbit</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>Mild skin irritation</td>
<td></td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Causes serious eye irritation.</td>
<td></td>
</tr>
<tr>
<td>Propan-2-ol</td>
<td>Irritation to eyes, reversing within 21 days</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rabbit</td>
<td></td>
</tr>
<tr>
<td>salicylic acid</td>
<td></td>
<td>Severe eye irritation</td>
</tr>
<tr>
<td>Species</td>
<td>Rabbit</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>Irreversible effects on the eye</td>
<td>Based on skin corrosivity.</td>
</tr>
<tr>
<td>Result</td>
<td></td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>No eye irritation</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rabbit</td>
<td></td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Type</th>
<th>Exposure routes</th>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>Buehler Test</td>
<td>Skin contact</td>
<td>Guinea pig</td>
<td>OECD Test Guideline 406</td>
<td>negative</td>
</tr>
<tr>
<td>salicylic acid</td>
<td>Local lymph node assay (LLNA)</td>
<td></td>
<td>Mouse</td>
<td></td>
<td>negative</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Betamethasone / Salicylic Acid Lotion Formulation**

**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
  - 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

**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 spermato- gonia
    - 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  
: Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative

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

Test Type: Embryo-foetal development
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: 10 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

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

NOEC: 0.07 µg/l
Exposure time: 219 d
Species: Oryzias latipes (Japanese medaka)
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC: 8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
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: 2.23BOD/COD: 53 %

Bioaccumulative potential

Components:

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

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

Betamethasone:
Partition coefficient: n-octanol/water: log Pow: 2.11
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 IMO instruments
Not applicable for product as supplied.
Special precautions for user

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

15. REGULATORY INFORMATION

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

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

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


Date format:

- dd.mm.yyyy

Full text of other abbreviations:

- ACGIH: USA, ACGIH Threshold Limit Values (TLV)
- ACGIH BEI: ACGIH - Biological Exposure Indices (BEI)
- IN OEL: India. Permissible levels of certain chemical substances in work environment.

- ACGIH / TWA: 8-hour, time-weighted average
- ACGIH / STEL: Short-term exposure limit
- ACGIH / C: Ceiling limit
- IN OEL / CEIL: ceiling limit

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Or-
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.