SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 10.10.2020 SDS Number: 1833496-00011 Date of last issue: 23.03.2020

Date of first issue: 13.07.2017

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

1.1 Product identifier
Trade name: Betamethasone / Salicylic Acid Lotion Formulation

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

1.3 Details of the supplier of the safety data sheet
Company: MSD
Innishannon
County Cork - Ireland

Telephone: 353 214329300
Telefax: 908-735-1496
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Flammable liquids, Category 2
Skin irritation, Category 2
Eye irritation, Category 2
Reproductive toxicity, Category 1B
Specific target organ toxicity - single exposure, Category 3
Specific target organ toxicity - repeated exposure, Category 1
Long-term (chronic) aquatic hazard, Category 1

H225: Highly flammable liquid and vapour.
H315: Causes skin irritation.
H319: Causes serious eye irritation.
H360D: May damage the unborn child.
H336: May cause drowsiness or dizziness.
H372: Causes damage to organs through prolonged or repeated exposure.
H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
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 through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:

P201 Obtain special instructions before use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:

Propan-2-ol
betamethasone

2.3 Other hazards

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td></td>
<td>200-661-7 603-117-00-0</td>
<td>Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>200-712-3 607-732-00-5</td>
<td>Acute Tox. 4; H302 Acute Tox. 2; H330 Acute Tox. 4; H312 Skin Irrit. 2; H315 Eye Dam. 1; H318 Repr. 2; H361d</td>
<td>&gt;= 1 - &lt; 3</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2 215-185-5 011-002-00-6</td>
<td></td>
<td>Met. Corr. 1; H290 Skin Corr. 1A; H314 Eye Dam. 1; H318</td>
<td>&gt;= 0.5 - &lt; 1</td>
<td></td>
</tr>
</tbody>
</table>
SECTIONS 4: First aid measures

4.1 Description of first aid measures

General advice: In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with plenty of water 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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: Causes skin irritation.

For explanation of abbreviations see section 16.
Causes serious eye irritation.  
May cause drowsiness or dizziness.  
May damage the unborn child.  
Causes damage to organs through prolonged or repeated exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: High volume water jet

5.2 Special hazards arising from the substance or mixture

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

Hazardous combustion products: Carbon oxides

5.3 Advice for firefighters

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

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Remove all sources of ignition.  
Ventilate the area.  
Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal pro-
6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
- Non-sparking tools should be used.
- Soak up with inert absorbent material.
- Suppress (knock down) gases/vapours/mists with a water spray jet.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

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

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition.

Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Flammable solids
- Pyrophoric liquids
- Pyrophoric solids
- Self-heating substances and mixtures
- Substances and mixtures, which in contact with water, emit flammable gases
- Explosives
- Gases

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

No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>OELV - 8 hrs (TWA)</td>
<td>200 ppm</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body.
Further information: Substances which have the capacity to penetrate intact skin when they come in contact with it, and be absorbed into the body

Salicylic acid 69-72-7 TWA 100 µg/m³ (OEB 2) Internal
Further information: DSEN
Wipe limit 100 µg/100 cm² Internal

Sodium hydroxide 1310-73-2 OELV - 15 min (STEL) 2 mg/m³ IE OEL
betamethasone 378-44-9 TWA 1 µg/m³ (OEB 4) Internal
Further information: Skin
Wipe limit 10 µg/100 cm² Internal

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>500 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>888 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>89 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>319 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>26 mg/kg bw/day</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>1 mg/m³</td>
</tr>
</tbody>
</table>

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>Fresh water</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>140.9 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2251 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>552 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>28 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>160 mg/kg food</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
Use explosion-proof electrical, ventilating and lighting equipment.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Betamethasone / Salicylic Acid Lotion Formulation

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**

**Eye protection**
- Wear safety glasses with side shields or goggles.
- If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
- Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**

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

**Skin and body protection**
- Work uniform or laboratory coat.
- Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
- Use appropriate degowning techniques to remove potentially contaminated clothing.

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

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

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

- **Appearance**: lotion
- **Colour**: colourless, translucent
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: 4.6 - 5.3
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: 21.4 - 22.2 °C
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Upper explosion limit / Upper**: No data available
Betamethasone / Salicylic Acid Lotion Formulation

9.2 Other information
   Flammability (liquids) : Not applicable
   Molecular weight : No data available
   Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
   Not classified as a reactivity hazard.

10.2 Chemical stability
   Stable under normal conditions.

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

10.4 Conditions to avoid
   Conditions to avoid : Heat, flames and sparks.
### 10.5 Incompatible materials

Materials to avoid: Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

<table>
<thead>
<tr>
<th>Exposure Route</th>
<th>Acute toxicity estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>&gt; 2,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Skin contact</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Acute toxicity**

Not classified based on available information.

**Product:**

- **Acute oral toxicity**
  - Acute toxicity estimate: > 2,000 mg/kg
  - Method: Calculation method

- **Acute inhalation toxicity**
  - Acute toxicity estimate: > 5 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: Calculation method

- **Acute dermal toxicity**
  - Acute toxicity estimate: > 2,000 mg/kg
  - Method: Calculation method

**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 (Rat): 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:
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
<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>10.10.2020</td>
<td>1833496-00011</td>
<td>23.03.2020</td>
<td>13.07.2017</td>
</tr>
</tbody>
</table>

**Betamethasone / Salicylic Acid Lotion Formulation**

**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 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
Betamethasone / Salicylic Acid Lotion Formulation

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
Betamethasone / Salicylic Acid Lotion Formulation

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 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
Betamethasone / Salicylic Acid Lotion Formulation

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

**SECTION 12: Ecological information**

**12.1 Toxicity**

**Components:**

**Propan-2-ol:**

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 9,640 mg/l
**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>10.10.2020</td>
<td>1833496-00011</td>
<td>23.03.2020</td>
<td>13.07.2017</td>
</tr>
</tbody>
</table>

Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Species)</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>sa salicylic acid</td>
<td>EC50 (Daphnia magna (Water flea)): 870 mg/l</td>
<td>48 h</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC50 (Desmodesmus subspicatus (green algae)): &gt; 100 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>EC50 (Americamysis): &gt; 50 mg/l</td>
<td>96 h</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to microorganisms**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Species)</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50 (Pseudomonas putida): &gt; 1,050 mg/l</td>
<td>16 h</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50 (Species)</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50 (Pimephales promelas (fathead minnow)): 1,380 mg/l</td>
<td>96 h</td>
</tr>
<tr>
<td></td>
<td>NOEC: 10 mg/l</td>
<td>21 d</td>
</tr>
<tr>
<td></td>
<td>Species: Daphnia magna (Water flea)</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Substance</th>
<th>LC50 (Species)</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEC: 0.052 mg/l</td>
<td>32 d</td>
</tr>
<tr>
<td></td>
<td>Species: Pimephales promelas (fathead minnow)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC: 0.07 µg/l</td>
<td>219 d</td>
</tr>
<tr>
<td></td>
<td>Species: Oryzias latipes (Japanese medaka)</td>
<td></td>
</tr>
</tbody>
</table>

**Remarks:**

- NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l
- Method: OECD Test Guideline 201
- Remarks: No toxicity at the limit of solubility
- NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l
- Method: OECD Test Guideline 201
- Remarks: No toxicity at the limit of solubility
- NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l
- Method: OECD Test Guideline 201
- Remarks: No toxicity at the limit of solubility
- NOEC: 8 mg/l
- 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
aquatic invertebrates (Chronic toxicity) Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211  

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

## 12.2 Persistence and degradability

**Components:**

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

## 12.3 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

## 12.4 Mobility in soil

No data available

## 12.5 Results of PBT and vPvB assessment

Not relevant

## 12.6 Other adverse effects

No data available

### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

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

- **Contaminated packaging:** Empty containers should be taken to an approved waste handling site for recycling or disposal.
Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

<table>
<thead>
<tr>
<th>ADN</th>
<th>UN 1219</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>UN 1219</td>
</tr>
<tr>
<td>RID</td>
<td>UN 1219</td>
</tr>
<tr>
<td>IMDG</td>
<td>UN 1219</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 1219</td>
</tr>
</tbody>
</table>

14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ISOPROPANOL, SOLUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>ISOPROPANOL, SOLUTION</td>
</tr>
<tr>
<td>RID</td>
<td>ISOPROPANOL, SOLUTION</td>
</tr>
<tr>
<td>IMDG</td>
<td>ISOPROPANOL, SOLUTION (betamethasone)</td>
</tr>
<tr>
<td>IATA</td>
<td>Isopropanol, solution</td>
</tr>
</tbody>
</table>

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>3</td>
</tr>
<tr>
<td>RID</td>
<td>3</td>
</tr>
<tr>
<td>IMDG</td>
<td>3</td>
</tr>
<tr>
<td>IATA</td>
<td>3</td>
</tr>
</tbody>
</table>

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
<th>II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
<td>II</td>
</tr>
<tr>
<td>Classification Code</td>
<td>F1</td>
</tr>
<tr>
<td>Hazard Identification Number</td>
<td>33</td>
</tr>
<tr>
<td>Labels</td>
<td>3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ADR</th>
<th>II</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
<td>II</td>
</tr>
<tr>
<td>Classification Code</td>
<td>F1</td>
</tr>
<tr>
<td>Hazard Identification Number</td>
<td>33</td>
</tr>
<tr>
<td>Labels</td>
<td>3</td>
</tr>
<tr>
<td>Tunnel restriction code</td>
<td>(D/E)</td>
</tr>
</tbody>
</table>

| RID  |  |
Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2  Revision Date: 10.10.2020  SDS Number: 1833496-00011  Date of last issue: 23.03.2020  Date of first issue: 13.07.2017

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

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

IATA (Cargo)

IATA (Passenger)

14.5 Environmental hazards

ADN
Environmentally hazardous: yes

ADR
Environmentally hazardous: yes

RID
Environmentally hazardous: yes

IMDG
Marine pollutant: yes

14.6 Special precautions for user

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

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Conditions of restriction for the following entries should be considered: Number on list 3
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 10.10.2020 SDS Number: 1833496-00011 Date of last issue: 23.03.2020
Date of first issue: 13.07.2017

REACH - List of substances subject to authorisation (Annex XIV):
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable

Seveso II:
Quantity 1 Quantity 2
E1 ENVIRONMENTAL HAZARDS 100 t 200 t
P5c FLAMMABLE LIQUIDS 5,000 t 50,000 t

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements
H225: Highly flammable liquid and vapour.
H290: May be corrosive to metals.
H302: Harmful if swallowed.
H312: Harmful in contact with skin.
H314: Causes severe skin burns and eye damage.
H315: Causes skin irritation.
H317: Causes serious eye damage.
H319: Causes serious eye irritation.
H330: Fatal if inhaled.
H336: May cause drowsiness or dizziness.
H360D: May damage the unborn child.
H361d: Suspected of damaging the unborn child.
Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 10.10.2020
SDS Number: 1833496-00011 Date of last issue: 23.03.2020
Date of first issue: 13.07.2017

H372 : Causes damage to organs through prolonged or repeated exposure.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations
Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids
Met. Corr. : Corrosive to metals
Repr. : Reproductive toxicity
Skin Corr. : Skin corrosion
Skin Irrit. : Skin irritation
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL) : Occupational exposure limit value (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; IC95 - 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS -
Betamethasone / Salicylic Acid Lotion Formulation

Version 5.2 Revision Date: 10.10.2020 SDS Number: 1833496-00011 Date of last issue: 23.03.2020

Date of first issue: 13.07.2017

Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Flam. Liq. 2</th>
<th>H225</th>
<th>Based on product data or assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin Irrit. 2</td>
<td>H315</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>H336</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

IE / EN