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

Betamethasone / Salicylic Acid Lotion Formulation

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

1.4 Emergency telephone number
215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Flammable liquids, Category 2             H225: Highly flammable liquid and vapour.
Skin irritation, Category 2             H315: Causes skin irritation.
Eye irritation, Category 2             H319: Causes serious eye irritation.
Reproductive toxicity, Category 1B             H360D: May damage the unborn child.
Specific target organ toxicity - single exposure, Category 3             H336: May cause drowsiness or dizziness.
Specific target organ toxicity - repeated exposure, Category 1             H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 1             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
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>Flam. Liq. 2; H225</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td>200-661-7</td>
<td>Eye Irrit. 2; H319</td>
<td></td>
</tr>
</tbody>
</table>
## Betamethasone / Salicylic Acid Lotion Formulation

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>Classification</th>
<th>Specific Concentration Limit</th>
</tr>
</thead>
<tbody>
<tr>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>Acute Tox. 4; H302</td>
<td>&gt;= 1 - &lt; 3</td>
</tr>
<tr>
<td></td>
<td>200-712-3</td>
<td>Acute Tox. 2; H330</td>
<td></td>
</tr>
<tr>
<td></td>
<td>607-732-00-5</td>
<td>Acute Tox. 4; H312</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin Irrit. 2; H315</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye Dam. 1; H318</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repr. 2; H361d</td>
<td></td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>Met. Corr. 1; H290</td>
<td>&gt;= 0.5 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td>215-185-5</td>
<td>Skin Corr. 1A; H314</td>
<td></td>
</tr>
<tr>
<td></td>
<td>011-002-00-6</td>
<td>Eye Dam. 1; H318</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>EUH014, EUH071</td>
<td></td>
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<td></td>
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<td></td>
<td></td>
<td>Specific Concentration Limit:</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Skin Corr. 1A; H314</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;= 5 %</td>
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<tr>
<td></td>
<td></td>
<td>Skin Corr. 1B; H314</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>2 - &lt; 5 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin Irrit. 2; H315</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.5 - &lt; 2 %</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.5 - &lt; 2 %</td>
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<tr>
<td></td>
<td></td>
<td>EUH071</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;= 2 %</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>Acute Tox. 2; H330</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
<tr>
<td></td>
<td>206-825-4</td>
<td>Repr. 1B; H360D</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT RE 1; H372</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic 1; H410</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>M-Factor (Chronic aquatic toxicity):</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.000</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specific Concentration Limit:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STOT RE 1; H372</td>
<td>&gt;= 0.01 %</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repr. 1B; H360D</td>
<td>&gt;= 0.01 %</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of first aid measures

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

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

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

In case of skin contact: In case of contact, immediately flush skin with plenty of water 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. 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 protective equipment recommendations (see section 8).

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

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

**Occupational Exposure Limits**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>TWA</td>
<td>100 ppm 245 mg/m³</td>
<td>FOR-2011-12-06-1358</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>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>T</td>
<td>2 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
</tbody>
</table>

Further information: DSEN

Further information: Ceiling value is an instantaneous value which indicates the maximum concentration of a chemical in the breathing zone that should not be exceeded.

Further information: Skin

<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>
</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
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops. Use explosion-proof electrical, ventilating and lighting equipment.

#### Personal protective equipment

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

- **Hand protection**
  - **Material**: Chemical-resistant gloves
  - **Remarks**: Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.
  - **Skin and body protection**: Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS 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

- Physical state: lotion
- Colour: colourless, translucent
- Odour: No data available
- Odour Threshold: No data available
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- Flammability (solid, gas): Not applicable
- Flammability (liquids): Not applicable
- 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
- Auto-ignition temperature: No data available
- Decomposition temperature: No data available
- Decomposition temperature: No data available
- pH: 4.6 - 5.3
- Viscosity: No data available
- 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
Relative density : No data available
Density : No data available
Relative vapour density : No data available
Particle characteristics
  Particle size : No data available

9.2 Other information
Explosives : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Evaporation rate : No data available
Molecular weight : 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 hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure : Inhalation
                                            Skin contact
                                            Ingestion
                                            Eye contact
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Acute toxicity
Not classified based on available information.

Product:

Acute oral toxicity
Method: Calculation method

Acute inhalation toxicity
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity
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
  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
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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 : 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

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

**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 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.

11.2 Information on other hazards
Endocrine disrupting properties

Product: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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 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
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>
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<td>09.04.2021</td>
<td>1833492-00012</td>
<td>10.10.2020</td>
<td>13.07.2017</td>
</tr>
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ic toxicity) 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**

**Product:**
- Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

**12.6 Other adverse effects**

**Product:**
- Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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 or ID number

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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14.2 UN proper shipping name

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<td>ISOPROPANOL, SOLUTION</td>
<td>ISOPROPANOL, SOLUTION</td>
<td>ISOPROPANOL, SOLUTION (betamethasone)</td>
<td>Isopropanol, solution</td>
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14.3 Transport hazard class(es)

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<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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14.4 Packing group

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</tr>
</thead>
<tbody>
<tr>
<td>Packing group: II</td>
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</tbody>
</table>
Betamethasone / Salicylic Acid Lotion Formulation

Classification Code : F1
Hazard Identification Number : 33
Labels : 3

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

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

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

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

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

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

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 Maritime transport in bulk according to IMO instruments

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
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
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

<table>
<thead>
<tr>
<th>P5c</th>
<th>FLAMMABLE LIQUIDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>5.000 t</td>
<td>50.000 t</td>
</tr>
</tbody>
</table>

| E1           | ENVIRONMENTAL HAZARDS | 100 t | 200 t |

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

<table>
<thead>
<tr>
<th>AICS</th>
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</thead>
<tbody>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

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.
Betamethasone / Salicylic Acid Lotion Formulation

Version: 5.3  Revision Date: 09.04.2021  SDS Number: 1833492-00012  Date of last issue: 10.10.2020  Date of first issue: 13.07.2017

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.
H318 : 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.
H372 : Causes damage to organs through prolonged or repeated exposure.
H410 : Very toxic to aquatic life with long lasting effects.
EUH014 : Reacts violently with water.
EUH071 : Corrosive to the respiratory tract.

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
FOR-2011-12-06-1358 : Norway. Occupational Exposure limits
FOR-2011-12-06-1358 / TWA : Long term exposure limit
FOR-2011-12-06-1358 / T : Ceiling

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; 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
Further information

Classification of the mixture:

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

NO / EN