SAFETY DATA SHEET

Betamethasone / Salicylic Acid Lotion Formulation

Version 5.1  Revision Date: 01.08.2019  SDS Number: 1832979-00007  Date of last issue: 24.04.2019
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
117 16th Road
07033  Halfway house, Midrand, South Africa
Telephone : +27 11 655 3000
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 : 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:
Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No. EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Propan-2-ol</td>
<td>67-63-0</td>
<td>Flam. Liq.2; H225 Eye Irrit.2; H319 STOT SE3; H336</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>200-661-7</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>603-117-00-0</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Salicylic acid</td>
<td>69-72-7</td>
<td>Acute Tox.4; H302 Acute Tox.2; H330 Acute Tox.4; H312 Skin Irrit.2; H315 Eye Dam.1; H318 Aquatic Chronic2; H411</td>
<td>&gt;= 1 - &lt; 2,5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>200-712-3</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>607-732-00-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>Met. Corr.1; H290 Skin Corr.1A; H314 Eye Dam.1; H318</td>
<td>&gt;= 0,5 - &lt; 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>215-185-5</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>011-002-00-6</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>betamethasone</td>
<td>378-44-9</td>
<td>Acute Tox.2; H330</td>
<td>&gt;= 0,025 - &lt;</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 and personal protective equipment recommendations.

6.2 Environmental precautions

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).
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 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.

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.
- 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.

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>STEL OEL-RL</td>
<td>500 ppm</td>
<td>ZA OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.225 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>Absorption through the skin, Recommended Limit</td>
<td>TWA OEL-RL</td>
<td>400 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>960 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>Absorption through the skin, Recommended Limit</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
</tr>
<tr>
<td>Salicylic acid</td>
<td>69-72-7</td>
<td>TWA</td>
<td>100 µg/m³</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td></td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>STEL OEL-RL</td>
<td>2 mg/m³</td>
<td>ZA OEL</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td>Recommended Limit</td>
<td>Recommended Limit</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>
</tr>
<tr>
<td>Further information</td>
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<td>Skin</td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
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<td></td>
<td></td>
<td>Internal</td>
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</table>
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>
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<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>89 mg/m³</td>
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<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>
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<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
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
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.

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 flammability limit:

No data available

Lower explosion limit / Lower flammability limit:

No data available

Vapour pressure:

No data available

Relative vapour density:

No data available

Relative density:

No data available

Density:

No data available

Solubility(ies)

Water solubility:

No data available

Partition coefficient: n-octanol/water:

No data available

Auto-ignition temperature:

No data available
Decomposition temperature : No data available

Viscosity
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

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
Information on likely routes of exposure : Inhalation
                                            Skin contact
                                            Ingestion
                                            Eye contact

Acute toxicity
Not classified based on available information.
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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:
- Species: Rabbit
- Result: Severe 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:
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<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Salicylic acid:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Local lymph node assay (LLNA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Mouse</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

Sodium hydroxide:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Human repeat insult patch test (HRIPT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
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</tbody>
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betamethasone:

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>Weak sensitizer</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity
Not classified based on available information.

Components:

Propan-2-ol:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: In vitro mammalian cell gene mutation test Result: negative</td>
</tr>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Species: Mouse Application Route: Intraperitoneal injection Result: negative</td>
</tr>
</tbody>
</table>

Salicylic acid:

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Mammalian bone marrow sister chromatid exchange Species: Mouse Application Route: Intraperitoneal injection Result: negative</td>
</tr>
<tr>
<td></td>
<td>Test Type: Sister chromatid exchange analysis in spermato-</td>
</tr>
</tbody>
</table>
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
Results: negative

Effects on foetal development:
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative

Salicylic acid:
- Test Type: Embryo-foetal development
- Species: Rat
- Application Route: Subcutaneous
- Developmental Toxicity: LOAEL: 380 mg/kg body weight
- Result: No effects on foetal development

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

betamethasone:
- Test Type: Embryo-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.
SAFETY DATA SHEET

Betamethasone / Salicylic Acid Lotion Formulation

Components:

betamethasone:

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td></td>
</tr>
<tr>
<td>NOAEL</td>
<td>12.5 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (vapour)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>104 Weeks</td>
</tr>
</tbody>
</table>

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 |
| NOAEL | 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, pruritus, 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)): 1,37 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

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

14.2 UN proper shipping name

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

Betamethasone / Salicylic Acid Lotion Formulation

Version 5.1  Revision Date: 01.08.2019  SDS Number: 1832979-00007  Date of last issue: 24.04.2019
Date of first issue: 13.07.2017

14.3 Transport hazard class(es)

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

14.4 Packing group

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA (Cargo)</th>
<th>IATA (Passenger)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
<td>II</td>
<td>Packing group</td>
<td>II</td>
<td>Packing instruction (cargo aircraft)</td>
<td>364</td>
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<tr>
<td>Classification Code</td>
<td>F1</td>
<td>Hazard Identification Number</td>
<td>33</td>
<td>Packing instruction (cargo aircraft)</td>
<td>353</td>
</tr>
<tr>
<td>Hazard Identification Number</td>
<td>33</td>
<td>Labels</td>
<td>3</td>
<td>Packing instruction (LQ)</td>
<td>Y341</td>
</tr>
<tr>
<td>Labels</td>
<td>3</td>
<td>Tunnel restriction code</td>
<td>(D/E)</td>
<td>Packing group</td>
<td>II</td>
</tr>
<tr>
<td>EmS Code</td>
<td>F-E, S-D</td>
<td>Flammable Liquids</td>
<td>Flammable Liquids</td>
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<td></td>
</tr>
</tbody>
</table>

14.5 Environmental hazards

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmentally hazardous</td>
<td>yes</td>
<td>Environmentally hazardous</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET
Betamethasone / Salicylic Acid Lotion Formulation

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
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.
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.
H372 : Causes damage to organs through prolonged or repeated exposure.
H410 : Very toxic to aquatic life with long lasting effects.
H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations
SAFETY DATA SHEET

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Date of first issue: 13.07.2017

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
ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits
ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit
ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

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; AICS - Australian Inventory of Chemical Substances; 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; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information
SAFETY DATA SHEET

Betamethasone / Salicylic Acid Lotion Formulation

Classification of the mixture:
- Flam. Liq. 2: H225
- Skin Irrit. 2: H315
- Eye Irrit. 2: H319
- Repr. 1B: H360D
- STOT SE 3: H336
- STOT RE 1: H372
- Aquatic Chronic 1: H410

Classification procedure:
- Based on product data or assessment
- Calculation method

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.

ZA / EN