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

Betamethasone / Salicylic Acid Lotion Formulation

Version 5.1  Revision Date: 23.03.2020  SDS Number: 1833492-00010  Date of last issue: 20.12.2019
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
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone: 44 1 670 59 30 00
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: 

1 / 23
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.</th>
<th>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>200-661-7</td>
<td>603-117-00-0</td>
<td></td>
<td>Flam. Liq.2; H225</td>
<td>&gt;= 30 - &lt; 50</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit.2; H319</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>STOT SE3; H336</td>
<td></td>
</tr>
<tr>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>200-712-3</td>
<td>607-732-00-5</td>
<td></td>
<td>Acute Tox.4; H302</td>
<td>&gt;= 1 - &lt; 3</td>
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<td></td>
<td></td>
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<td>Acute Tox.2; H330</td>
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<td>Acute Tox.4; H312</td>
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<td></td>
<td>Skin Irrit.2; H315</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Eye Dam.1; H318</td>
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<td></td>
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<td></td>
<td></td>
<td>Repr.2; H361d</td>
<td></td>
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<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td></td>
<td></td>
<td>Met. Corr.1; H290</td>
<td>&gt;= 0.5 - &lt; 1</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Skin Corr.1A; H314</td>
<td></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). 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 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 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>
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<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>
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<tr>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
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<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>
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</table>

Further information: DSEN

<table>
<thead>
<tr>
<th></th>
<th>Wipe limit</th>
<th>Control parameters</th>
<th>Basis</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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.
Betamethasone / Salicylic Acid Lotion Formulation

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>
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<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>
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<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>89 mg/m³</td>
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<tr>
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<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
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
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

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.

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
**Betamethasone / Salicylic Acid Lotion Formulation**

**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
Betamethasone / Salicylic Acid Lotion Formulation

Version 5.1  Revision Date: 23.03.2020  SDS Number: 1833492-00010  Date of last issue: 20.12.2019  Date of first issue: 13.07.2017

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

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

Test Type: Sister chromatid exchange analysis in spermato-gonia
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

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

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

Test Type: Chromosome aberration test in vitro
Result: positive

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Oral
Result: equivocal

Germ cell mutagenicity- Assessment: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity
Not classified based on available information.

Components:

Propan-2-ol:
Species: Rat
Application Route: inhalation (vapour)
Exposure time: 104 weeks
Method: OECD Test Guideline 451
Result: negative

salicylic acid:
Species: Mouse
Application Route: Skin contact
Exposure time: 1 Years
Reproductive toxicity
May damage the unborn child.

Components:

Propan-2-ol:
Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

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

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

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

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

betamethasone:
Effects on foetal development : Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 0,05 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0,42 mg/kg body weight
Result: Malformations were observed.

Species: Mouse
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Malformations were observed.

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on
Assessment 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
Betamethasone / Salicylic Acid Lotion Formulation

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 Exposure time: 96 h
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10.000 mg/l Exposure time: 24 h
- Toxicity to microorganisms: EC50 (Pseudomonas putida): > 1.050 mg/l Exposure time: 16 h

Salicylic acid:
Toxicity to fish

LC50 (Pimephales promelas (fathead minnow)): 1.380 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 870 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants

EC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC: 10 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

betamethasone:

Toxicity to daphnia and other aquatic invertebrates

EC50 (Americamysis): > 50 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity)

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

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC: 8 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity)

1.000
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>ADR</th>
<th>RID</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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14.4 Packing group

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## Betamethasone / Salicylic Acid Lotion Formulation

### Version 5.1

<table>
<thead>
<tr>
<th>SDS Number: 1833492-00010</th>
<th>Date of last issue: 20.12.2019</th>
</tr>
</thead>
</table>

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

Betamethasone / Salicylic Acid Lotion Formulation

Version 5.1  Revision Date: 23.03.2020  SDS Number: 1833492-00010  Date of last issue: 20.12.2019
Date of first issue: 13.07.2017

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals

P5c  FLAMMABLE LIQUIDS
Quantity 1  5.000 t  Quantity 2  50.000 t

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:
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.
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.

Full text of other abbreviations
# Betamethasone / Salicylic Acid Lotion Formulation

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<th>Version</th>
<th>Revision Date:</th>
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<th>Date of last issue: 20.12.2019</th>
<th>Date of first issue: 13.07.2017</th>
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| 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 | : Long term exposure limit |
| TWA | : 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; 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; DOM - 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**

Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
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.

NO / EN