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

Betamethasone / Salicylic Acid Ointment Formulation

Version: 3.6
Revision Date: 10.10.2020
SDS Number: 1884771-00011
Date of last issue: 23.03.2020
Date of first issue: 21.08.2017

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

1.1 Product identifier
   Trade name: Betamethasone / Salicylic Acid Ointment 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)
- Serious eye damage, Category 1
- Reproductive toxicity, Category 1B
- Specific target organ toxicity - repeated exposure, Category 1
- Long-term (chronic) aquatic hazard, Category 1

   H318: Causes serious eye damage.
   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.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms: 
   Signal word: Danger
   Hazard statements: H318 Causes serious eye damage.
   H360D May damage the unborn child.
   H372 Causes damage to organs through prolonged or re-
peated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Hazardous components which must be listed on the label:
salicylic acid
betamethasone

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>232-384-2</td>
<td></td>
<td>Asp. Tox. 1; H304</td>
<td>10</td>
</tr>
</tbody>
</table>
| salicylic acid        | 69-72-7                  | 200-712-3 | 607-732-00-5 | Acute Tox. 4; H302
Acute Tox. 2; H330
Acute Tox. 4; H312
Skin Irrit. 2; H315
Eye Dam. 1; H318
Repr. 2; H361d      | 3                      |
| betamethasone         | 378-44-9                 | 206-825-4 |             | Acute Tox. 2; H330
Repr. 1B; H360D
STOT RE 1; H372
(Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) Aquatic Chronic 1; H410 | 0.064                 |
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Betamethasone / Salicylic Acid Ointment Formulation

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<thead>
<tr>
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</tr>
</tbody>
</table>

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

For explanation of abbreviations see section 16.

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. Remove 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 immediately.

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 serious eye damage. 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:
- None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:
- 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:
- 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.
- 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:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- 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.
Advice on safe handling : Do not get on skin or clothing.
Do not breathe dust, fume, gas, mist, vapours or spray.
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
Keep container tightly closed.
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. Store in accordance with the particular national regulations.
Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)
Specific use(s) : No data available
**SEASON 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>salicylic acid</td>
<td>69-72-7</td>
<td>TWA</td>
<td>100 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: DSEN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>100 µg/100 cm²</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: Skin</td>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
</tr>
</tbody>
</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>Paraffin oil</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>5 mg/m³</td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Short-term exposure</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>5 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>5 mg/m³</td>
<td></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>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
</tr>
</tbody>
</table>

### 8.2 Exposure controls

**Engineering measures**

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).

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.

**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.

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 BS 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Ointment</td>
</tr>
<tr>
<td>Colour</td>
<td>White, translucent</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>4.6 - 5.3</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not classified as a flammability hazard</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

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:
- Skin contact
- Ingestion
- Eye contact
Acute toxicity
Not classified based on available information.

**Product:**

<table>
<thead>
<tr>
<th>Acute toxicity</th>
<th>Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>&gt; 2,000 mg/kg</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>&gt; 2,000 mg/kg</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>&gt; 5 mg/l</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

**Exposure time:** 4 h
**Test atmosphere:** dust/mist

**Components:**

**Paraffin oil:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>

**Assessment:** The substance or mixture has no acute dermal toxicity

**Salicylic acid:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Mouse): 480 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Rat): 891 mg/kg</td>
<td></td>
</tr>
<tr>
<td>LD50 (Rabbit): 1,300 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 0.9 mg/l</td>
</tr>
<tr>
<td>Exposure time: 1 h</td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rat): 2,000 mg/kg</td>
</tr>
<tr>
<td>LD50 (Rabbit): 10,000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

**Betamethasone:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Mouse): &gt; 4,500 mg/kg</td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): 0.4 mg/l</td>
</tr>
<tr>
<td>Exposure time: 4 h</td>
<td></td>
</tr>
</tbody>
</table>

**Skin corrosion/irritation**
Not classified based on available information.
### Components:

**Paraffin oil:**
- Species: Rabbit
- Result: No skin irritation

**salicylic acid:**
- Result: Skin irritation

**betamethasone:**
- Species: Rabbit
- Result: Mild skin irritation

#### Serious eye damage/eye irritation
Causes serious eye damage.

### Components:

**Paraffin oil:**
- Species: Rabbit
- Result: No eye irritation

**salicylic acid:**
- Species: Rabbit
- Remarks: Severe eye irritation

**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:

**salicylic acid:**
- Test Type: Local lymph node assay (LLNA)
- Species: Mouse
- Result: negative

**betamethasone:**
- Exposure routes: Dermal
- Species: Guinea pig
- Result: Weak sensitizer
Germ cell mutagenicity
Not classified based on available information.

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

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

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

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

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

Test Type: Chromosome aberration test in vitro
Result: positive

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

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

Carcinogenicity
Not classified based on available information.

Components:
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:

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

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

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

betamethasone:
Effects on foetal development : Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0.42 mg/kg body weight
Result: Malformations were observed.

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

Reproductive toxicity - Assessment : Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

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
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Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Paraffin oil:
Species: Rat, female
LOAEL: 161 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

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.

Components:

Paraffin oil:
The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

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:

Paraffin oil:
Toxicity to fish: LL50 (Scophthalmus maximus (turbot)): > 1,028 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EL50 (Acartia tonsa): > 3,193 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EL50 (Skeletonema costatum (marine diatom)): > 3,200 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): 993 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Salicylic acid:
Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 1,380 mg/l
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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:
Paraffin oil:
Biodegradability: Result: Readily biodegradable.  
Biodegradation: 82%  
Exposure time: 24 d  
Method: OECD Test Guideline 301F  
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

- **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.  
  If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

- **ADN**: UN 3077  
- **ADR**: UN 3077  
- **RID**: UN 3077  
- **IMDG**: UN 3077  
- **IATA**: UN 3077

14.2 UN proper shipping name
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>9</td>
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14.4 Packing group

<table>
<thead>
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<th>ADN</th>
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<th>IMDG</th>
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<tr>
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<td>Tunnel restriction code: (-)</td>
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</table>

<table>
<thead>
<tr>
<th>IATA (Cargo)</th>
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</thead>
<tbody>
<tr>
<td>Packing instruction (cargo): 956</td>
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</tbody>
</table>
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Betamethasone / Salicylic Acid Ointment Formulation

Version 3.6 Revision Date: 10.10.2020 SDS Number: 1884771-00011 Date of last issue: 23.03.2020
Date of first issue: 21.08.2017

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : 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) : Not applicable
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>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS: not determined

DSL: not determined

IECSC: not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H302: Harmful if swallowed.
H304: May be fatal if swallowed and enters airways.
H312: Harmful in contact with skin.
H315: Causes skin irritation.
H318: Causes serious eye damage.
H330: Fatal if inhaled.
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

Acute Tox.: Acute toxicity
Aquatic Chronic: Long-term (chronic) aquatic hazard
Asp. Tox.: Aspiration hazard
Eye Dam.: Serious eye damage
Repr.: Reproductive toxicity
Skin Irrit.: Skin irritation
STOT RE: Specific target organ toxicity - repeated exposure
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Betamethasone / Salicylic Acid Ointment Formulation

Version 3.6 Revision Date: 10.10.2020 SDS Number: 1884771-00011 Date of last issue: 23.03.2020
Date of first issue: 21.08.2017

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Classification</th>
<th>Value</th>
<th>Calculation procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Dam. 1</td>
<td>H318</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text.
Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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