SAFETY DATA SHEET
Betamethasone / Salicylic Acid Ointment Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone / Salicylic Acid Ointment Formulation

Manufacturer or supplier's details
Company : Organon & Co.
Address : 30 Hudson Street, 33nd floor
           Jersey City, New Jersey, U.S.A 07302
Telephone : 551-430-6000
Emergency telephone number : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989
Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Acute toxicity (Inhalation) : Category 5
Skin corrosion/irritation : Category 3
Serious eye damage/eye irritation : Category 1
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms : 
Signal word : Danger
Hazard statements: H316 Causes mild skin irritation. 
H318 Causes serious eye damage. 
H333 May be harmful if inhaled. 
H360D May damage the unborn child. 
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure. 
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

Prevention:
P203 Obtain, read and follow all safety instructions before use. 
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray. 
P264 Wash skin thoroughly after handling. 
P270 Do not eat, drink or smoke when using this product. 
P273 Avoid release to the environment. 
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response: 
P304 + P317 IF INHALED: Get medical help. 
P305 + P354 + P338 + P317 IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical help. 
P318 IF exposed or concerned, get medical advice. 
P332 + P317 If skin irritation occurs: Get medical help. 
P391 Collect spillage.

Storage: 
P405 Store locked up.

Disposal: 
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (%) w/w</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>86.93</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>10</td>
</tr>
<tr>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>3</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>0.064</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

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

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.

Most important symptoms and effects, both acute and delayed:
Causes mild skin irritation.
Causes serious eye damage.
May be harmful if inhaled.
May damage the unborn child.
Causes damage to organs through prolonged or repeated exposure.

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).

Notes to physician:
Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media:
None known.

Specific hazards during firefighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides

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.

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

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protection:
Use personal protective equipment.
7. HANDLING AND STORAGE

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.

Conditions for safe storage : Keep in properly labelled containers.
                                Store locked up.
                                Keep tightly closed.
                                Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:
                               Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Mist)</td>
<td>5 mg/m3</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m3</td>
<td>IN OEL</td>
</tr>
</tbody>
</table>
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

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 particulate and organic vapour type

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

Eye protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mist 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.

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.

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.

9. 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</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
<td></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>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></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></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
May be harmful if inhaled.

Product:
Acute oral toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute inhalation toxicity: Acute toxicity estimate: 7.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

Petrolatum:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
## Safety Data Sheet

**Betamethasone / Salicylic Acid Ointment Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>4.3</td>
<td>09.04.2021</td>
<td>1884769-00012</td>
<td>10.10.2020</td>
<td>21.08.2017</td>
</tr>
</tbody>
</table>

### Method
OECD Test Guideline 402

### Assessment
The substance or mixture has no acute dermal toxicity

### Remarks
Based on data from similar materials

## Paraffin oil:

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

### Acute dermal toxicity
Assessment: The substance or mixture has no acute dermal toxicity

### salicylic acid:

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

### betamethasone:

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

## Skin corrosion/irritation
Causes mild skin irritation.

## Components:

### Petrolatum:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Paraffin oil:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

### salicylic acid:
Result: Skin irritation

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

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

**Components:**

**Petrolatum:**
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation
Remarks: Based on data from similar materials

**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:**

**Petrolatum:**
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

**salicylic acid:**
Test Type: Local lymph node assay (LLNA)
Species: Mouse
Result: negative
**Betamethasone / Salicylic Acid Ointment Formulation**

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

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**betamethasone:**

**Exposure routes**: Dermal  
**Species**: Guinea pig  
**Result**: Weak sensitizer  

**Germ cell mutagenicity**  
Not classified based on available information.

**Components:**

**Petrolatum:**

**Genotoxicity in vitro**  
Result: negative  
Remarks: Based on data from similar materials

**Genotoxicity in vivo**  
Result: negative  
Remarks: Based on data from similar materials

**salicylic acid:**

**Genotoxicity in vitro**  
Result: negative  

**Genotoxicity in vivo**  
Result: negative  
Remarks: Based on data from similar materials

**betamethasone:**

**Genotoxicity in vitro**  
Result: negative  
Test Type: Bacterial reverse mutation assay (AMES)  
Test Type: In vitro mammalian cell gene mutation test  
Test Type: Chromosome aberration test in vitro  
Result: positive  

**Genotoxicity in vivo**  
Result: negative  
Test Type: Mammalian erythrocyte micronucleus test (in vivo...
Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

**Carcinogenicity**
Not classified based on available information.

**Components:**

### Petrolatum:
- **Species**: Rat
- **Application Route**: Ingestion
- **Exposure time**: 2 Years
- **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:**

### Petrolatum:
- **Effects on fertility**: Test Type: Reproduction/Developmental toxicity screening test
  - **Species**: Rat
  - **Application Route**: Ingestion
  - **Result**: negative
  - **Remarks**: Based on data from similar materials

### Effects on foetal development:
- **Test Type**: Embryo-foetal development
  - **Species**: Rat
  - **Application Route**: Skin contact
  - **Result**: negative
  - **Remarks**: Based on data from similar materials

### 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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) 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:**

**Petrolatum:**

Species: Rat
NOAEL: 5,000 mg/kg
Application Route: Ingestion
Exposure time: 2 yr
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

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Petrolatum:**
- **Toxicity to fish:** LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
  - Exposure time: 96 h
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 203
  - Remarks: Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
  - Exposure time: 48 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials

- **Toxicity to algae/aquatic plants:** NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC: 10 mg/l
  - Exposure time: 21 d
  - Species: Daphnia magna (Water flea)
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials

**Paraffin oil:**
- **Toxicity to fish:** LL50 (Scophthalmus maximus (turbot)): > 100 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 (Acarti tonsa): > 100 mg/l
  - Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>EL50 (Skeletonema costatum (marine diatom)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

**salicylic acid:**

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Test substance:</th>
<th>LC50 (Pimephales promelas (fathead minnow)): 1,380 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Test substance:</th>
<th>EC50 (Daphnia magna (Water flea)): 870 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Test substance:</th>
<th>EC50 (Desmodesmus subspicatus (green algae)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Test substance:</th>
<th>NOEC: 10 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Species</td>
<td>Daphnia magna (Water flea)</td>
</tr>
</tbody>
</table>

**betamethasone:**

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Test substance:</th>
<th>EC50 (Americamysis): &gt; 50 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
<tr>
<td>Remarks</td>
<td></td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Test substance:</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance:</th>
<th>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

**Toxicity to fish (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Test substance:</th>
<th>NOEC: 0.052 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>32 d</td>
</tr>
<tr>
<td>Species</td>
<td>Pimephales promelas (fathead minnow)</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance:</th>
<th>NOEC: 0.07 µg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>219 d</td>
</tr>
</tbody>
</table>
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

**Persistence and degradability**

**Components:**

**Petrolatum:**

Biodegradability:
- Result: Not readily biodegradable.
- Biodegradation: 31 %
- Exposure time: 28 d
- Method: OECD Test Guideline 301F
- Remarks: Based on data from similar materials

**Bioaccumulative potential**

**Components:**

**Paraffin oil:**

Partition coefficient: $n$-octanol/water:
- log Pow: > 4
- Remarks: Calculation

**Salicylic acid:**

Partition coefficient: $n$-octanol/water:
- log Pow: 2.25

**Betamethasone:**

Partition coefficient: $n$-octanol/water:
- log Pow: 2.11

**Mobility in soil**

No data available

**Other adverse effects**

No data available

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### 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

- **Waste from residues**: Dispose of in accordance with local regulations.
- **Contaminated packaging**: Empty containers should be taken to an approved waste handling site for recycling or disposal.
14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
- **UN number**: UN 3077
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9

**IATA-DGR**
- **UN/ID No.**: UN 3077
- **Proper shipping name**: Environmentally hazardous substance, solid, n.o.s. (betamethasone)
- **Class**: 9
- **Packing group**: III
- **Labels**: Miscellaneous
- **Packing instruction (cargo aircraft)**: 956
- **Environmentally hazardous**: yes

**IMDG-Code**
- **UN number**: UN 3077
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9
- **EmS Code**: F-A, S-F
- **Marine pollutant**: yes

**Transport in bulk according to IMO instruments**
Not applicable for product as supplied.

**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.

15. REGULATORY INFORMATION

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

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

Betamethasone / Salicylic Acid Ointment Formulation

Version 4.3
Revision Date: 09.04.2021
SDS Number: 1884769-00012
Date of last issue: 10.10.2020
Date of first issue: 21.08.2017

AICS: not determined
DSL: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information
Sources of key data used to compile the Safety Data Sheet:

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
IN OEL: India. Permissible levels of certain chemical substances in work environment.
ACGIH / TWA: 8-hour, time-weighted average
IN OEL / TWA: Time-Weighted Average Concentration (TWA) (8 hrs.)
IN OEL / STEL: Short-term exposure Limit STEL (15 min)

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response Guide; 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 Chemicals 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

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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