SAFETY DATA SHEET

Betamethasone / Salicylic Acid Ointment Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone / Salicylic Acid Ointment Formulation

Manufacturer or supplier’s details

Company : MSD
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil 13106-054
 Telephone : 908-740-4000
Emergency telephone : 55 19 3758 2000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Acute toxicity (Inhalation) : Category 5
Skin irritation : Category 3
Serious eye damage : 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 in accordance with ABNT NBR 14725 Standard

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:
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.

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td></td>
<td>86.93</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>Aspiration hazard, Category 1</td>
<td>10</td>
</tr>
<tr>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>Acute toxicity (Oral), Category 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute toxicity (Inhalation), Category 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Acute toxicity (Dermal), Category 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin irritation, Category 4</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Serious eye damage, Category 2</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reproductive toxicity, Category 1</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reproductive toxicity, Category 1B</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Specific target organ</td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>Acute toxicity (Inhalation), Category 2</td>
<td>0.064</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Reproductive toxicity, Category 1B</td>
<td></td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Betamethasone / Salicylic Acid Ointment Formulation

SECTION 4. 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.

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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting: Exposure to combustion products may be a hazard to health.
SAFETY DATA SHEET

Betamethasone / Salicylic Acid Ointment Formulation

Version 4.1  Revision Date: 23.03.2020  SDS Number: 1841156-00010  Date of last issue: 17.12.2019  Date of first issue: 21.08.2017

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- 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.

Methods and materials for containment and 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.

SECTION 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 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.
- Keep container tightly closed.
- 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.

Conditions for safe storage:
- Keep in properly labeled 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
  - Organic peroxides
  - Explosives
  - Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients 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 (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>salicylic acid</td>
<td>69-72-7</td>
<td>TWA</td>
<td>100 µg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: DSEN</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 100 µg/100 cm²</td>
<td>Internal</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></td>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 10 µg/100 cm²</td>
<td>Internal</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
Filter type
Hand protection
: recommended guidelines, use respiratory protection.
: Combined particulates and organic vapor 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, 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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
: ointment

Color
: white, translucent

Odor
: No data available

Odor 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
: No data available

Evaporation rate
: No data available

Flammability (solid, gas)
: Not classified as a flammability hazard

Flammability (liquids)
: No data available

Upper explosion limit / Upper flammability limit
: No data available

Lower explosion limit / Lower flammability limit
: No data available

Vapor pressure
: No data available

Relative vapor density
: No data available
Relative density : No data available
Density : No data available
Solubility(ies) : No data available
Water solubility : No data available
Partition coefficient: n-octanol/water : No data available
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity : No data available
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

SECTION 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.

SECTION 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
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Paraffin oil:
Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity: LD50 (Rabbit): > 2.000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

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

Betamethasone:
Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
LD50 (Mouse): > 4.500 mg/kg

Acute inhalation toxicity: LC50 (Rat): 0.4 mg/l
Exposure time: 4 h

Skin corrosion/irritation
Causes mild skin irritation.
Components:

Petrolatum:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

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:

Petrolatum:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
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 sensitization
Skin sensitization
Not classified based on available information.
Respiratory sensitization
Not classified based on available information.

Components:

Petrolatum:
Test Type: Buehler Test
Routes of exposure: 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:
Routes of exposure: Dermal
Species: Guinea pig
Result: Weak sensitizer

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

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-
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:

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 fetal development:
- Test Type: Embryofetal development
- Species: Rat
- Application Route: Skin contact
- Result: negative
- Remarks: Based on data from similar materials

Salicylic acid:
- Test Type: Embryofetal development
- Species: Rat
- Application Route: Subcutaneous
- Developmental Toxicity: LOAEL: 380 mg/kg body weight
- Result: Maternal toxicity observed, Embryo-fetal toxicity.

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

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

Betamethasone:
- 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 y

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 y

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

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 (Daphnia magna (Water flea)): 10 mg/l  
Exposure time: 21 d  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

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

Betamethasone:  
Toxicity to daphnia and other aquatic invertebrates:  
EC50 (Americamysis): > 50 mg/l  
Exposure time: 96 h

Toxicity to algae/aquatic:  
EC50 (Pseudokirchneriella subcapitata (green algae)): > 34
plants

<table>
<thead>
<tr>
<th>Exposure time: 72 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks: No toxicity at the limit of solubility.</td>
</tr>
</tbody>
</table>

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 (Pimephales promelas (fathead minnow)): 0,052 mg/l |
| Exposure time: 32 d |
| Method: OECD Test Guideline 210 |

NOEC (Oryzias latipes (Japanese medaka)): 0,07 µg/l
Exposure time: 219 d
Method: OECD Test Guideline 229

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

| NOEC (Daphnia magna (Water flea)): 8 mg/l |
| Exposure time: 21 d |
| 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

Paraffin oil:

Biodegradability: Result: Readily biodegradable.
Biodegradation: 82 %
Exposure time: 24 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

salicylic acid:
Partition coefficient: n-octanol/water: log Pow: 2,25

Betamethasone:
Partition coefficient: n-octanol/water: log Pow: 2,11
ocan/water

**Mobility in soil**
No data available

**Other adverse effects**
No data available

### SECTION 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. If not otherwise specified: Dispose of as unused product.

### SECTION 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
- **Packing instruction (passenger aircraft)**: 956
- **Environmentally hazardous**: yes

**IMDG-Code**
- **UN number**: UN 3077
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Betamethasone)
- **Class**: 9
- **Subsidiary risk**: ENVIRONM.
- **Packing group**: III
- **Labels**: 9 (ENVIRONM.)
- **EmS Code**: F-A, S-F
- **Marine pollutant**: yes
**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation**

**ANTT**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
- Class: 9
- Packing group: III
- Labels: 9
- Hazard Identification Number: 90

**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.

**SECTION 15. REGULATORY INFORMATION**

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

- National List of Carcinogenic Agents for Humans - (LINACH): Not applicable
- Brazil. List of chemicals controlled by the Federal Police: Not applicable

**International Regulations**

**The ingredients of this product are reported in the following inventories:**
- AICS: not determined
- DSL: not determined
- IECSC: not determined

**SECTION 16. OTHER INFORMATION**

**Further information**


**Full text of other abbreviations**

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
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.