SAFETY DATA SHEET

Betamethasone Cream Formulation

Version 5.0  Revision Date: 24.04.2020  SDS Number: 1841218-00008  Date of last issue: 23.03.2020  Date of first issue: 19.07.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone Cream 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
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard : Category 3
Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard
Hazard pictograms : 

Signal Word : Danger
Hazard Statements : 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.
H402 Harmful to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary Statements:

**Prevention:**
P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection.

**Response:**
P308 + P313 IF exposed or concerned: Get medical advice/attention.
P391 Collect spillage.

Other hazards which do not result in classification
None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture: Mixture

<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>Aspiration hazard, Category 1</td>
<td>&gt;= 10 &lt; 20</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>Acute toxicity (Oral), Category 5</td>
<td>&gt;= 5 &lt; 10</td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td>Acute toxicity (Oral), Category 5. Eye irritation,</td>
<td>&gt;= 1 &lt; 2,5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Category 2A Short-term (acute) aquatic hazard,</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Category 2</td>
<td></td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>Acute toxicity (Oral), Category 4. Skin corrosion,</td>
<td>&gt;= 0,1 &lt; 0,25</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Category 1C Serious eye damage, Category 1 Skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>sensitization, Sub-category 1B Specific target organ</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>toxicity - single exposure, Category 3 Short-term</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(acute) aquatic hazard, Category 1 Long-term (chronic)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>aquatic hazard, Category 3</td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>Acute toxicity (Inhalation), Category 2 Reproductive</td>
<td>&gt;= 0,025 &lt; 0,1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>toxicity, Category 2</td>
<td></td>
</tr>
</tbody>
</table>
## 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 soap and 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**: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

**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**: 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 firefighting**: Vapors may form explosive mixtures with air. 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 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. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 breathe vapors or spray mist. Do not swallow. Avoid contact with 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>Betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4) Internal</td>
<td></td>
</tr>
</tbody>
</table>

Further information: Skin Wipe limit 10 µg/100 cm² Internal

Engineering measures: All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic 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: cream

Color: No data available

Odor: No data available

Odor Threshold: No data available

pH: 5

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: > 93.3 °C

Evaporation rate: No data available

Flammability (solid, gas): Not applicable

Flammability (liquids): Not applicable

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) : Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity : Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions : Vapors may form explosive mixture with air. 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 : Inhalation
 : Skin contact
 : Ingestion
 : Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral 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

Hexadecan-1-ol. Ethoxylated:
Acute oral toxicity: LD50 (Rat): 2,500 mg/kg

4-Chloro-3-methylphenol:
Acute oral toxicity: LD50 (Mouse): 600 mg/kg
Acute inhalation toxicity: LC50 (Rat): > 2,871 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Rat): > 5,000 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
Not classified based on available information.

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

4-Chloro-3-methylphenol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Corrosive after 1 to 4 hours of exposure

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

**Serious eye damage/eye irritation**
Not classified based on available information.

**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

**Hexadecan-1-ol. Ethoxylated:**
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on data from similar materials

**4-Chloro-3-methylphenol:**
Species: Rabbit
Result: Irreversible effects on the eye
Method: OECD Test Guideline 405

**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

4-Chloro-3-methylphenol:
- Test Type : Maximization Test
- Routes of exposure : Skin contact
- Species : Guinea pig
- Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

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

4-Chloro-3-methylphenol:
- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
  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

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

4-Chloro-3-methylphenol:
- Effects on fertility: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative
- Effects on fetal development: Test Type: Reproduction/Developmental toxicity screening test Species: Rat Application Route: Ingestion Result: negative

Betamethasone:
- Effects on fetal 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.

Components:

**4-Chloro-3-methylphenol:**
Assessment  
May cause respiratory irritation.

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

**4-Chloro-3-methylphenol:**
Species  
Rat  
NOAEL  
200 mg/kg  
LOAEL  
400 mg/kg  
Application Route  
Ingestion
Exposure time: 28 Days

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:
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

Hexadecan-1-ol. Ethoxylated:
Toxicity to fish
LC50: > 1 - 10 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates
EC50: > 1 - 10 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants
EC50: > 10 - 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials
### 4-Chloro-3-methylphenol:

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l Exposure time: 96 h</td>
</tr>
<tr>
<td>Toxicity to daphnia and other</td>
<td>EC50 (Daphnia magna (Water flea)): 1,5 mg/l Exposure time: 48 h</td>
</tr>
<tr>
<td>aquatic invertebrates</td>
<td>Method: OECD Test Guideline 202</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Chlorella pyrenoidosa): 15 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>EC10 (Chlorella pyrenoidosa): 2,3 mg/l Exposure time: 72 h Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td>M-Factor (Acute aquatic toxicity)</td>
<td>1</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Oncorhynchus mykiss (rainbow trout)): 0,15 mg/l Exposure time: 28 d Method: OECD Test Guideline 204</td>
</tr>
<tr>
<td>Toxicity to daphnia and other</td>
<td>NOEC (Daphnia magna (Water flea)): 0,32 mg/l Exposure time: 21 d Method: OECD Test Guideline 211</td>
</tr>
<tr>
<td>aquatic invertebrates (Chronic toxicity)</td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50: 22,86 mg/l Exposure time: 60 h</td>
</tr>
</tbody>
</table>

### Betamethasone:

<table>
<thead>
<tr>
<th>Toxicity</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other</td>
<td>EC50 (Americamysis): &gt; 50 mg/l Exposure time: 96 h</td>
</tr>
<tr>
<td>aquatic invertebrates</td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0,052 mg/l Exposure time: 32 d Method: OECD Test Guideline 210</td>
</tr>
<tr>
<td></td>
<td>NOEC (Oryzias latipes (Japanese medaka)): 0,07 µg/l Exposure time: 219 d Method: OECD Test Guideline 229</td>
</tr>
</tbody>
</table>
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

Hexadecan-1-ol. Ethoxylated:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 99 %
Exposure time: 19 d

4-Chloro-3-methylphenol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 78 %
Exposure time: 15 d
Method: OECD Test Guideline 301

Bioaccumulative potential

Components:

4-Chloro-3-methylphenol:
Bioaccumulation: Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 5,5 - 13
Partition coefficient: n-octanol/water: log Pow: 0,477

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

Mobility in soil
No data available
SAFETY DATA SHEET

Betamethasone Cream Formulation

Version 5.0 Revision Date: 24.04.2020 SDS Number: 1841218-00008 Date of last issue: 23.03.2020
Date of first issue: 19.07.2017

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 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Betamethasone)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, 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 Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

Domestic regulation

ANTT
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
SAFETY DATA SHEET

Betamethasone Cream Formulation

Version 5.0  Revision Date: 24.04.2020  SDS Number: 1841218-00008  Date of last issue: 23.03.2020

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 : Phosphoric acid

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

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 other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

AICS - Australian Inventory of Chemical Substances; 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
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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