SAFETY DATA SHEET

Betamethasone Cream Formulation

Version 3.1  Revision Date: 10.10.2020  SDS Number: 1841203-00009  Date of last issue: 24.04.2020
Date of first issue: 19.07.2017

1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone Cream Formulation

Manufacturer or supplier’s details
Company : MSD
Address : 50 Tuas West Drive
Singapore - Singapore 638408
Telephone : 908-740-4000
Emergency telephone number : 65 6697 2111 (24/7/365)
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

2. HAZARDS IDENTIFICATION

GHS Classification
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 : 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.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
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:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
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>&gt;= 10 - &lt; 20</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
</tr>
</tbody>
</table>

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 : May damage the unborn child.
and effects, both acute and delayed
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

<table>
<thead>
<tr>
<th>Suitable extinguishing media</th>
<th>Water spray</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Alcohol-resistant foam</td>
</tr>
<tr>
<td></td>
<td>Carbon dioxide (CO2)</td>
</tr>
<tr>
<td></td>
<td>Dry chemical</td>
</tr>
<tr>
<td>Unsuitable extinguishing media</td>
<td>None known.</td>
</tr>
<tr>
<td>Specific hazards during fire-fighting</td>
<td>Vapours may form explosive mixtures with air.</td>
</tr>
<tr>
<td></td>
<td>Exposure to combustion products may be a hazard to health.</td>
</tr>
<tr>
<td>Hazardous combustion products</td>
<td>Carbon oxides</td>
</tr>
<tr>
<td>Specific extinguishing methods</td>
<td>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</td>
</tr>
<tr>
<td></td>
<td>Use water spray to cool unopened containers.</td>
</tr>
<tr>
<td></td>
<td>Remove undamaged containers from fire area if it is safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Evacuate area.</td>
</tr>
<tr>
<td>Special protective equipment for firefighters</td>
<td>In the event of fire, wear self-contained breathing apparatus.</td>
</tr>
<tr>
<td></td>
<td>Use personal protective equipment.</td>
</tr>
</tbody>
</table>

6. ACCIDENTAL RELEASE MEASURES

<table>
<thead>
<tr>
<th>Personal precautions, protective equipment and emergency procedures</th>
<th>Use personal protective equipment.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</td>
</tr>
<tr>
<td>Environmental precautions</td>
<td>Avoid release to the environment.</td>
</tr>
<tr>
<td></td>
<td>Prevent further leakage or spillage if safe to do so.</td>
</tr>
<tr>
<td></td>
<td>Prevent spreading over a wide area (e.g. by containment or oil barriers).</td>
</tr>
<tr>
<td></td>
<td>Retain and dispose of contaminated wash water.</td>
</tr>
<tr>
<td></td>
<td>Local authorities should be advised if significant spills cannot be contained.</td>
</tr>
<tr>
<td>Methods and materials for containment and cleaning up</td>
<td>Soak up with inert absorbent material.</td>
</tr>
<tr>
<td></td>
<td>For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.</td>
</tr>
<tr>
<td></td>
<td>Clean up remaining materials from spill with suitable absorbent.</td>
</tr>
<tr>
<td></td>
<td>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.</td>
</tr>
<tr>
<td></td>
<td>Sections 13 and 15 of this SDS provide information regarding</td>
</tr>
</tbody>
</table>
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 mist or vapours.
- Do not swallow.
- Avoid contact with 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>PEL (long term) (Mist)</td>
<td>5 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term) (Mist)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></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>PEL (long term) (Mist)</td>
<td>5 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term) (Mist)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></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)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information:</td>
<td></td>
<td></td>
<td>Skin Wipe limit 10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
**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 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, mists or aerosols, wear the appropriate goggles. Wear a face shield 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.

**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>cream</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</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>5</td>
</tr>
</tbody>
</table>
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
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : Not applicable

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
  Vapours may form explosive mixture with air.
  Can react with strong oxidizing agents.
11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

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
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
**SAFETY DATA SHEET**

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**Version** 3.1  **Revision Date:** 10.10.2020  **SDS Number:** 1841203-00009  **Date of last issue:** 24.04.2020  **Date of first issue:** 19.07.2017

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**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

**4-Chloro-3-methylphenol:**

- **Test Type:** Maximisation Test
- **Exposure routes:** Skin contact
- **Species:** Guinea pig

  **Assessment:** Probability or evidence of low to moderate skin sensitisation rate in humans

**betamethasone:**

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

4-Chloro-3-methylphenol:
## Effects on fertility

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

## Effects on foetal development

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproduction/Developmental toxicity screening test</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
<tr>
<td>Reproduction/Developmental toxicity screening test</td>
<td>Rabbit</td>
<td>Intramuscular</td>
<td>CL 0.05 mg/kg body weight, Malformations were observed</td>
</tr>
<tr>
<td>Reproduction/Developmental toxicity screening test</td>
<td>Rat</td>
<td>Subcutaneous</td>
<td>CL 0.42 mg/kg body weight, Malformations were observed</td>
</tr>
<tr>
<td>Reproduction/Developmental toxicity screening test</td>
<td>Mouse</td>
<td>Intramuscular</td>
<td>CL 0.1 mg/kg body weight, Malformations were observed</td>
</tr>
</tbody>
</table>

## 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:

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland</td>
<td>Causes damage to organs through prolonged or repeated exposure</td>
</tr>
</tbody>
</table>
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

**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

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

- **Hexadecan-1-ol. Ethoxylated:**
  - **Toxicity to fish:** LC$_{50}$: > 1 - 10 mg/l
    - Exposure time: 96 h
    - Remarks: Based on data from similar materials
  - **Toxicity to daphnia and other aquatic invertebrates:** EC$_{50}$: > 1 - 10 mg/l
    - Exposure time: 48 h
    - Remarks: Based on data from similar materials
  - **Toxicity to algae/aquatic plants:** EC$_{50}$: > 10 - 100 mg/l
    - Exposure time: 72 h
    - Remarks: Based on data from similar materials

- **4-Chloro-3-methylphenol:**
  - **Toxicity to fish:** LC$_{50}$ (Oncorhynchus mykiss (rainbow trout)): 917 µg/l
    - Exposure time: 96 h
  - **Toxicity to daphnia and other aquatic invertebrates:** EC$_{50}$ (Daphnia magna (Water flea)): 1.5 mg/l
    - Exposure time: 48 h
    - Method: OECD Test Guideline 202
  - **Toxicity to algae/aquatic plants:** ErC$_{50}$ (Chlorella pyrenoidosa (algae)): 15 mg/l
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201
    - EC$_{10}$ (Chlorella pyrenoidosa (algae)): 2.3 mg/l
    - Exposure time: 72 h
    - Method: OECD Test Guideline 201

- **M-Factor (Acute aquatic toxicity):** 1

- **Toxicity to fish (Chronic toxicity):** NOEC (Oncorhynchus mykiss (rainbow trout)): 0.15 mg/l
  - Exposure time: 28 d
  - Method: OECD Test Guideline 204

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):** NOEC (Daphnia magna (Water flea)): 0.32 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

- **Toxicity to microorganisms:** EC$_{50}$: 22.86 mg/l
  - Exposure time: 60 h
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 (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

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

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
SAFETY DATA SHEET

Betamethasone Cream Formulation

Version 3.1
Revision Date: 10.10.2020
SDS Number: 1841203-00009
Date of last issue: 24.04.2020
Date of first issue: 19.07.2017

| 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.

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

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable

Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

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

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

16. OTHER INFORMATION

Further information
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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