SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone Cream Formulation

Manufacturer or supplier’s details

Company : MSD
Address : 26 Talavera Road, Talavera Corp Centre, Macquarie Park New South Wales, 2113 Australia
Telephone : (61)-02-8988-8000
Emergency telephone number : (61)-02-8988-8000
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

Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

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.

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. P281 Use personal protective equipment as required.
SAFETY DATA SHEET
Betamethasone Cream Formulation

Response: 
P308 + P313 IF exposed or concerned: Get medical advice/attention.

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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Petrolatum</td>
</tr>
<tr>
<td></td>
<td>Paraffin oil</td>
</tr>
<tr>
<td></td>
<td>Hexadecan-1-ol. Ethoxylated</td>
</tr>
<tr>
<td></td>
<td>4-Chloro-3-methylphenol</td>
</tr>
<tr>
<td></td>
<td>Betamethasone</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. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Vapours 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 firefighters: In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Hazchem Code: •3Z

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 dyking or other appropriate containment to keep material from spreading. If dyked 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 vapours 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 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

SECTION 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>AU OEL</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Mist)</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)</td>
<td>Internal</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 vapour type
  - **Hand protection**: Chemical-resistant gloves
  - **Remarks**: Consider double gloving.

- **Eye protection**: Wear safety glasses with side shields or goggles.
  - 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
- **Colour**: No data available
- **Odour**: No data available
- **Odour 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

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

SECTION 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.

Conditions to avoid: None known.

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes:

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
  - 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 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

Chronic toxicity

**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
**SAFETY DATA SHEET**

**Betamethasone Cream 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>
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<tr>
<td>3.0</td>
<td>24.04.2020</td>
<td>1841220-00008</td>
<td>23.03.2020</td>
<td>19.07.2017</td>
</tr>
</tbody>
</table>

**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**  
  Test Type: One-generation reproduction toxicity study  
  Species: Rat  
  Application Route: Ingestion  
  Result: negative

- **Effects on foetal development**  
  Test Type: Reproduction/Developmental toxicity screening test  
  Species: Rat  
  Application Route: Ingestion  
  Result: negative
SAFETY DATA SHEET

Betamethasone Cream Formulation

Version 3.0  Revision Date: 24.04.2020  SDS Number: 1841220-00008  Date of last issue: 23.03.2020  Date of first issue: 19.07.2017

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.

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 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
### Ecological Information

**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:

| Toxicity to fish | LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l | Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): 1.5 mg/l | Exposure time: 48 h  
Method: OECD Test Guideline 202 |
| Toxicity to algae/aquatic plants | ErC50 (Chlorella pyrenoidosa (algae)): 15 mg/l | Exposure time: 72 h  
Method: OECD Test Guideline 201  
EC10 (Chlorella pyrenoidosa (algae)): 2.3 mg/l | Exposure time: 72 h  
Method: OECD Test Guideline 201 |
| 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 | EC50: 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

**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:**
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)

<table>
<thead>
<tr>
<th>Class</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>9</td>
</tr>
</tbody>
</table>

IATA-DGR
UN/ID No. : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (betamethasone)

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<td>Packing instruction (passenger aircraft)</td>
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<td>Environmentally hazardous</td>
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IMDG-Code
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)

<table>
<thead>
<tr>
<th>Class</th>
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<tbody>
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<td>Packing group</td>
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<td>Labels</td>
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<td>EmS Code</td>
<td>F-A, S-F</td>
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<tr>
<td>Marine pollutant</td>
<td>yes</td>
</tr>
</tbody>
</table>

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.
National Regulations

ADG
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : •3Z

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

Prohibition/Licensing Requirements : There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

SECTION 16. OTHER INFORMATION

Further information
Revision Date : 24.04.2020

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

Date format : dd.mm.yyyy

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Con-
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