1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone (0.05%) Cream Formulation

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

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

2. HAZARDS IDENTIFICATION

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 dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
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;= 20 - &lt;= 30</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>3</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>0.1</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>0.064</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical 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.

### 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>
</tbody>
</table>

| Unsuitable extinguishing media | None known. |

<table>
<thead>
<tr>
<th>Specific hazards during firefighting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapours may form explosive mixtures with air.</td>
</tr>
<tr>
<td>Exposure to combustion products may be a hazard to health.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hazardous combustion products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carbon oxides</td>
</tr>
<tr>
<td>Silicon oxides</td>
</tr>
<tr>
<td>Formaldehyde</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Specific extinguishing methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.</td>
</tr>
<tr>
<td>Use water spray to cool unopened containers.</td>
</tr>
<tr>
<td>Remove undamaged containers from fire area if it is safe to do so.</td>
</tr>
<tr>
<td>Evacuate area.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Special protective equipment for firefighters</th>
</tr>
</thead>
<tbody>
<tr>
<td>In the event of fire, wear self-contained breathing apparatus.</td>
</tr>
<tr>
<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>
</tr>
</thead>
<tbody>
<tr>
<td>Use personal protective equipment.</td>
</tr>
<tr>
<td>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Environmental precautions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Avoid release to the environment.</td>
</tr>
<tr>
<td>Prevent further leakage or spillage if safe to do so.</td>
</tr>
<tr>
<td>Retain and dispose of contaminated wash water.</td>
</tr>
<tr>
<td>Local authorities should be advised if significant spillages cannot be contained.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Methods and materials for containment and cleaning up</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweep up or vacuum up spillage and collect in suitable container for disposal.</td>
</tr>
<tr>
<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>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.</td>
</tr>
</tbody>
</table>

### 7. HANDLING AND STORAGE

<table>
<thead>
<tr>
<th>Technical measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Local/Total ventilation</th>
</tr>
</thead>
<tbody>
<tr>
<td>If sufficient ventilation is unavailable, use with local exhaust ventilation.</td>
</tr>
</tbody>
</table>
Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe dust, fume, gas, mist, vapours or spray.
- 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>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>PEL (long term)</td>
<td>10 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA ( Respirable particulate matter)</td>
<td>3 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: Skin</td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Occupational exposure limits of decomposition products

<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>Formaldehyde</td>
<td>50-00-0</td>
<td>PEL (short term)</td>
<td>0.3 ppm 0.37 mg/m3</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>0.1 ppm</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
5. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Appearance</th>
<th>: cream</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colour</td>
<td>: white</td>
</tr>
<tr>
<td>Odour</td>
<td>: No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>: No data available</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions:
- Vapours may form explosive mixture with air.
- Can react with strong oxidizing agents.
- Hazardous decomposition products will be formed at elevated temperatures.

Conditions to avoid:
- None known.

Incompatible materials:
- Oxidizing agents

Hazardous decomposition products:
- Formaldehyde

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- 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

Glyceryl monostearate:
- 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
Remarks: Based on data from similar materials

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

**Glyceryl monostearate:**
- **Species:** Rabbit
- **Result:** No skin irritation
- **Remarks:** Based on data from similar materials

**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

**Glyceryl monostearate:**
- **Species:** Rabbit
- **Result:** No eye irritation
- **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

Glyceryl monostearate:
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 sensitiser

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

**Glyceryl monostearate:**

Genotoxicity in vitro : Test Type: Chromosome aberration test in vitro  
Method: OECD Test Guideline 473  
Result: negative  
Remarks: Based on data from similar materials  

Test Type: Bacterial reverse mutation assay (AMES)  
Method: OECD Test Guideline 471  
Result: negative  
Remarks: Based on data from similar materials  

Test Type: In vitro mammalian cell gene mutation test  
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
Betamethasone (0.05%) Cream Formulation

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>2 Years</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**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

**Glyceryl monostearate:**
Effects on fertility:
Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
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

**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

Glyceryl monostearate:
Species: Rat
NOAEL: >= 12,500 mg/kg
Application Route: Ingestion
Exposure time: 84 Days
Remarks: Based on data from similar materials

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.

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
### 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

### Glyceryl Monostearate

#### Toxicity to Fish

**LL50 (Leuciscus idus (Golden orfe)):** > 100 mg/l  
**Exposure time:** 48 h  
**Remarks:** Based on data from similar materials

#### Toxicity to Daphnia and Other Aquatic Invertebrates

**EL50 (Daphnia magna (Water flea)):** > 32 mg/l  
**Exposure time:** 47 h  
**Remarks:** No toxicity at the limit of solubility based on data from similar materials

#### Toxicity to Algae/Aquatic Plants

**EL50 (Pseudokirchneriella subcapitata (green algae)):** > 100 mg/l  
**Exposure time:** 72 h  
**Test substance:** Water Accommodated Fraction  
**Method:** OECD Test Guideline 201  
**Remarks:** No toxicity at the limit of solubility

**NOELR (Pseudokirchneriella subcapitata (green algae)):** > 1 mg/l  
**Exposure time:** 72 h  
**Test substance:** Water Accommodated Fraction  
**Method:** OECD Test Guideline 201  
**Remarks:** No toxicity at the limit of solubility

#### Toxicity to Fish (Chronic toxicity)

**NOELR (Oryzias latipes (Japanese medaka)):** > 1 mg/l  
**Exposure time:** 14 d  
**Method:** OECD Test Guideline 204  
**Remarks:** Based on data from similar materials

#### Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic toxicity)

**NOEC (Daphnia magna (Water flea)):** > 0.22 mg/l  
**Exposure time:** 21 d
ic toxicity) Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility
Based on data from similar materials

Toxicity to microorganisms: EC10 (Pseudomonas putida): > 1 mg/l
Exposure time: 18 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 (aglae)): 15 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Chlorella pyrenoidosa (aglae)): 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: 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

M-Factor (Chronic aquatic toxicity): 1,000

Persistence and degradability

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

Glyceryl monostearate:
Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

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

Bioaccumulative potential

Glyceryl monostearate:
Partition coefficient: n-octanol/water: log Pow: 6.1

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
SAFETY DATA SHEET

Betamethasone (0.05%) Cream Formulation

Mobility in soil
No data available

Other adverse effects
No data available

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 han-
dling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

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 (passen-
ger aircraft) : 956
Environmentally hazardous : yes

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

Transport in bulk according to 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**

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


Date format:

- dd.mm.yyyy

**Full text of other abbreviations**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full text</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>SG OEL</td>
<td>Singapore, Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances</td>
</tr>
<tr>
<td>ACGIH / TWA</td>
<td>8-hour, time-weighted average</td>
</tr>
<tr>
<td>ACGIH / STEL</td>
<td>Short-term exposure limit</td>
</tr>
<tr>
<td>SG OEL / PEL (long term)</td>
<td>Permissible Exposure Level (PEL) Long Term</td>
</tr>
<tr>
<td>SG OEL / PEL (short term)</td>
<td>Permissible Exposure Level (PEL) Short Term</td>
</tr>
</tbody>
</table>

**Abbreviations:**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for
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.