SAFETY DATA SHEET
Betamethasone (0.05%) Cream Formulation

Version 2.4  Revision Date: 09/13/2019  SDS Number: 1682160-00006  Date of last issue: 24.04.2019  Date of first issue: 17.05.2017

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone (0.05%) 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 dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.
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

 Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</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>Propylene glycol</td>
<td>57-55-6</td>
<td>&lt; 10</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>

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.

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
Silicon oxides
Formaldehyde

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: 2Z

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not swallow.
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></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA (particulate)</td>
<td>10 mg/m3</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Total (vapour and particles))</td>
<td>150 ppm 474 mg/m3</td>
<td>AU OEL</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica

<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></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable fraction)</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>
</tbody>
</table>

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

Occupational exposure limits of decomposition products

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
</table>

4 / 21
Formaldehyde

<table>
<thead>
<tr>
<th>Form of exposure</th>
<th>TWA</th>
<th>STEL</th>
<th>permissible concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-00-0</td>
<td>1 ppm</td>
<td>2 ppm</td>
<td>1.2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>1 ppm</td>
<td>2.5 mg/m³</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Further information: Category 2 (Carc. 2) Suspected human carcinogen, Sensitiser

Engineering measures:
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Essentially no open handling permitted. Use closed processing systems or containment technologies.

Personal protective equipment

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

Filter type: Combined particulates, inorganic gas/vapour 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 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

Colour: white
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**Betamethasone (0.05%) Cream Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
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<th>Date of first issue:</th>
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<tbody>
<tr>
<td>2.4</td>
<td>09/13/2019</td>
<td>1682160-00006</td>
<td>24.04.2019</td>
<td>17.05.2017</td>
</tr>
</tbody>
</table>

- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: > 93.3 °C
- **Evaporation rate**: Not applicable
- **Flammability (solid, gas)**: Not classified as a flammability hazard
- **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**: Not applicable
- **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**: Not applicable
- **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.
- Hazardous decomposition products will be formed at elevated temperatures.

### Conditions to avoid
None known.

### Incompatible materials
- Oxidizing agents

### Hazardous decomposition products
- Thermal decomposition: Formaldehyde

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Exposure routes
- 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

- **Propylene glycol**
  - **Acute oral toxicity**: LD50 (Rat): > 5,000 mg/kg
  - **Acute inhalation toxicity**: LC50 (Rabbit): > 159 mg/l
    - Exposure time: 4 h
    - Test atmosphere: dust/mist
  - **Acute dermal toxicity**: LD50 (Rabbit): > 2,000 mg/kg
    - Assessment: The substance or mixture has no acute dermal toxicity

- **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 (Mouse): > 4,500 mg/kg
   LD50 (Rat): > 5,000 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

Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

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

Propylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

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

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
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 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

Propylene glycol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Glyceryl monostearate:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
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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
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Propylene glycol:
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

**Propylene glycol:**
- **Effects on fertility:** Test Type: Three-generation reproduction toxicity study  
  Species: Mouse  
  Application Route: Ingestion  
  Result: negative

- **Effects on foetal development:** Test Type: Embryo-foetal development  
  Species: Mouse  
  Application Route: Ingestion  
  Result: negative

**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**

**betamethasone:**
Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative

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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>Rat, male</td>
<td>1,700 mg/kg</td>
<td>Ingestion</td>
<td>2 yr</td>
<td></td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>Rat</td>
<td>&gt;= 12,500 mg/kg</td>
<td>Ingestion</td>
<td>84 Days</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>Rat</td>
<td>200 mg/kg</td>
<td>Ingestion</td>
<td>28 Days</td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td>Rabbit</td>
<td>0.05 %</td>
<td>Skin contact</td>
<td>10 - 30 d</td>
<td>Pituitary gland, Immune system, muscle</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>0.05 %</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
<tr>
<td></td>
<td>Mouse</td>
<td>0.1 %</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
<tr>
<td></td>
<td>Dog</td>
<td>0.05 mg/kg</td>
<td>Oral</td>
<td>28 d</td>
<td>Blood, thymus gland, Adrenal gland</td>
</tr>
</tbody>
</table>

**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

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Petrolatum:
Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
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
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
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
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Propylene glycol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
Exposure time: 21 d
Remarks: Based on data from similar materials

Toxicity to microorganisms: NOEC (Pseudomonas putida): > 20,000 mg/l
Exposure time: 18 h
### Glyceryl monostearate:

<table>
<thead>
<tr>
<th><strong>Toxicity to fish</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>LL50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to daphnia and other aquatic invertebrates</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>EL50 (Daphnia magna (Water flea)): &gt; 32 mg/l</td>
<td>Exposure time: 47 h</td>
</tr>
<tr>
<td>Remarks:</td>
<td>No toxicity at the limit of solubility Backed on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to algae/aquatic plants</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Remarks:</td>
<td>No toxicity at the limit of solubility Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to fish (Chronic toxicity)</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>NOELR (Oryzias latipes (Japanese medaka)): &gt; 1 mg/l</td>
<td>Exposure time: 14 d</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 204</td>
<td></td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>NOEC (Daphnia magna (Water flea)): &gt; 0.22 mg/l</td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 211</td>
<td></td>
</tr>
<tr>
<td>Remarks:</td>
<td>No toxicity at the limit of solubility Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to microorganisms</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>EC10 (Pseudomonas putida): &gt; 1 mg/l</td>
<td>Exposure time: 18 h</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Remarks:</td>
<td>Based on data from similar materials</td>
<td></td>
</tr>
</tbody>
</table>

### 4-Chloro-3-methylphenol:

<table>
<thead>
<tr>
<th><strong>Toxicity to fish</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l</td>
<td>Exposure time: 96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to daphnia and other aquatic invertebrates</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>EC50 (Daphnia magna (Water flea)): 1.5 mg/l</td>
<td>Exposure time: 48 h</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 202</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Toxicity to algae/aquatic plants</strong></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>:</td>
<td>ErC50 (Chlorella pyrenoidosa (aglae)): 15 mg/l</td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td>Method:</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
</tbody>
</table>

| :                                  | EC10 (Chlorella pyrenoidosa (aglae)): 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

Propylene glycol:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

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

Components:

Propylene glycol:
Partition coefficient: n-octanol/water : log Pow: -1.07

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

Mobility in soil
No data available

Other adverse effects

Product:
Results of PBT and vPvB assessment : This substance/mixture contains components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).

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 han-
SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Class : 9
Packing group : III
Labels : 9

IATA-DGR
UN/ID No. : UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (betamethasone)
Class : 9
Packing group : III
Labels : Miscellaneous
Packing instruction (cargo aircraft) : 956
Packing instruction (passenger aircraft) : 956
Environmentally hazardous : yes

IMDG-Code
UN number : UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Class : 9
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.

National Regulations

ADG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : 2Z
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:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

SECTION 16. OTHER INFORMATION

Further information

Revision Date : 09/13/2019
Date format : dd.mm.yyy

Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH</td>
<td>USA. ACGIH Threshold Limit Values (TLV)</td>
</tr>
<tr>
<td>AU OEL</td>
<td>Australia. Workplace Exposure Standards for Airborne Contaminants.</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>AU OEL / TWA</td>
<td>Exposure standard - time weighted average</td>
</tr>
<tr>
<td>AU OEL / STEL</td>
<td>Exposure standard - short term exposure limit</td>
</tr>
</tbody>
</table>

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 x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-
SAFETY DATA SHEET

Betamethasone (0.05%) Cream Formulation

Version 2.4    Revision Date: 09/13/2019

SDS Number: 1682160-00006    Date of last issue: 24.04.2019

Date of first issue: 17.05.2017

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.

AU / EN