1. PRODUCT AND COMPANY IDENTIFICATION

   Chemical product name : Betamethasone (0.05%) Cream Formulation

   Supplier’s company name, address and phone number

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

   Recommended use of the chemical and restrictions on use

   Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

   GHS classification of chemical product

   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 |

<table>
<thead>
<tr>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 20 - &lt;= 30</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&lt; 10</td>
<td>2-234</td>
</tr>
<tr>
<td></td>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>3</td>
<td>2-669</td>
</tr>
<tr>
<td></td>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>0.1</td>
<td>3-900</td>
</tr>
<tr>
<td></td>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>0.064</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Alcohols, C16-18, ethoxylated</td>
<td>68439-49-6</td>
<td>0.05</td>
<td></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.

May damage the unborn child.

Causes damage to organs through prolonged or repeated exposure.

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).

Treat symptomatically and supportive.

Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

None known.

Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.
Carbon oxides
Silicon oxides
Formaldehyde

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.

In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Avoid release to the environment.
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.

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.
7. HANDLING AND STORAGE

Handling

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 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.

Avoidance of contact : Oxidizing agents
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.

Storage

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

Packaging material : Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

<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>OEL-M (Mist)</td>
<td>3 mg/m3</td>
<td>JP OEL JSOH</td>
</tr>
</tbody>
</table>

Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans
SAFETY DATA SHEET

Betamethasone (0.05%) Cream Formulation

Version: 5.0   Revision Date: 2020/10/10   SDS Number: 1682148-00008   Date of last issue: 2020/03/23
   Date of first issue: 2017/05/17

<table>
<thead>
<tr>
<th>Component</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glyceryl monostearate</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>betamethasone</td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

<table>
<thead>
<tr>
<th>Component</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
</table>
| Occupational exposure limits of decomposition products
| Components                      | CAS-No.                        | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis         |
| Formaldehyde                     | 50-00-0                        | ACL                            | 0.1 ppm                                      | JP OEL ISHL   |
|                                  |                                | OEL-M                          | 0.1 ppm                                      | JP OEL JSOH   |
|                                  |                                |                                | 0.12 mg/m3                                    |               |
|                                  |                                |                                |                                              |               |
|                                  |                                | OEL-C                          | 0.2 ppm                                      | JP OEL JSOH   |
|                                  |                                |                                | 0.24 mg/m3                                    |               |
|                                  |                                |                                |                                              |               |
|                                  |                                | TWA                            | 0.1 ppm                                      | ACGIH         |
|                                  |                                | STEL                           | 0.3 ppm                                      | ACGIH         |

Further information: Airway sensitizing agent; Group 2 substances which probably induce allergic reactions in humans., Skin sensitizing agent; Group 1 substances which induce allergic reactions in humans, Group 2A: probably carcinogenic to humans.

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
Eye protection: Consider double gloving. 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: cream

Colour: white

Odour: No data available

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: No data available

Flammability (solid, gas): Not classified as a flammability hazard

Flammability (liquids): Not applicable

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Flash point: > 93.3 °C

Decomposition temperature: No data available

pH: No data available

Evaporation rate: Not applicable

Auto-ignition temperature: No data available

Viscosity

Viscosity, kinematic: Not applicable
### Solubility(ies)
- **Water solubility**: No data available

### Partition coefficient: n-octanol/water
- Not applicable

### Vapour pressure
- No data available

### Density and / or relative density
- **Relative density**: No data available
- **Density**: No data available
- **Relative vapour density**: Not applicable

### Explosive properties
- Not explosive

### Oxidizing properties
- The substance or mixture is not classified as oxidizing.

### Particle characteristics
- **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.
- Hazardous decomposition products will be formed at elevated temperatures.

**Conditions to avoid**: None known.

**Incompatible materials**: Oxidizing agents

**Hazardous decomposition products**
- Thermal decomposition: 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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Acute dermal toxicity</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td></td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td>LC50 (Rabbit): &gt; 159 mg/l Exposure time: 4 h Test atmosphere: dust/mist</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td></td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td>LC50 (Rabbit): &gt; 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity</td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td></td>
<td>LD50 (Mouse): 600 mg/kg</td>
<td>LC50 (Rabbit): &gt; 2.871 mg/l Exposure time: 4 h Test atmosphere: dust/mist</td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td></td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td>LC50 (Rabbit): 0.4 mg/l Exposure time: 4 h</td>
<td></td>
</tr>
<tr>
<td>Alcohols, C16-18, ethoxylated</td>
<td></td>
<td>LD50 (Rat): &gt; 2,000 mg/kg Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Skin corrosion/irritation
Not classified based on available information.
SAFETY DATA SHEET
Betamethasone (0.05%) Cream Formulation

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

Alcohols, C16-18, ethoxylated:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

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

Alcohols, C16-18, ethoxylated:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

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
**SAFETY DATA SHEET**

**Betamethasone (0.05%) 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>
</tr>
</thead>
<tbody>
<tr>
<td>5.0</td>
<td>2020/10/10</td>
<td>1682148-00008</td>
<td>2020/03/23</td>
<td>2017/05/17</td>
</tr>
</tbody>
</table>

### 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

### Alcohols, C16-18, ethoxylated:
- **Test Type**: Buehler Test
- **Exposure routes**: Skin contact
- **Species**: Guinea pig
- **Method**: OECD Test Guideline 406
- **Result**: negative
- **Remarks**: Based on data from similar materials

### 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
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.

Alcohols, C16-18, ethoxylated:
Genotoxicity in vitro : 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
                        Method: OECD Test Guideline 476
                        Result: negative
                        Remarks: Based on data from similar materials
                        Test Type: Chromosome aberration test in vitro
                        Method: OECD Test Guideline 473
                        Result: negative
                        Remarks: Based on data from similar materials
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:
- 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.

Alcohols, C16-18, ethoxylated:

Effects on fertility:
- Test Type: Two-generation reproduction toxicity study
- Species: Rat
- Application Route: Skin contact
- Result: negative
- Remarks: Based on data from similar materials

Effects on foetal development:
- Test Type: Two-generation reproduction toxicity study
- Species: Rat
- Application Route: Skin contact
- Result: negative
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

Propylene glycol:
Species: Rat, male
NOAEL: 1,700 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

Glycerol 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 (0.05%) Cream Formulation

### betamethasone:

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>0.05 %</td>
<td>Skin contact</td>
<td>10 - 30 d</td>
<td>Pituitary gland, Immune system, muscle</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.05 %</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>0.1 %</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<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>

### Alcohols, C16-18, ethoxylated:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt; 100 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td>OECD Test Guideline 408</td>
<td>Based on data from similar materials</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

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity**

**Components:**

**Petrolatum:**

- Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Test substance</th>
<th>EC50 (Daphnia magna (Water flea)): &gt; 10,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
<tr>
<td>Test substance</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 203</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Test substance</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Daphnia magna (Water flea)): 10 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td>Test substance</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Propylene glycol:

<table>
<thead>
<tr>
<th>Test substance</th>
<th>LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>7 d</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Test substance</th>
<th>NOEC (Pseudomonas putida): &gt; 20,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>18 h</td>
</tr>
</tbody>
</table>

### Glyceryl monostearate:

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

<table>
<thead>
<tr>
<th>Test substance</th>
<th>EL50 (Daphnia magna (Water flea)): &gt; 32 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>47 h</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test substance</th>
<th>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td>Test substance</td>
<td>Water Accommodated Fraction</td>
</tr>
<tr>
<td>Remarks</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td></td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
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

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

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

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

### 4-Chloro-3-methylphenol:

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

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

<table>
<thead>
<tr>
<th>Toxicity to algae/aquatic plants</th>
<th>ErC50 (Chlorella pyrenoidosa (algae)): 15 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>EC10 (Chlorella pyrenoidosa (algae)): 2.3 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

| M-Factor (Acute aquatic toxicity) | 1 |

<table>
<thead>
<tr>
<th>Toxicity to fish (Chronic toxicity)</th>
<th>NOEC (Oncorhynchus mykiss (rainbow trout)): 0.15 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 28 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 204</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>NOEC (Daphnia magna (Water flea)): 0.32 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Toxicity to microorganisms</th>
<th>EC50: 22.86 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 60 h</td>
</tr>
</tbody>
</table>
**Betamethasone (0.05%) Cream Formulation**

**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

**Alcohols, C16-18, ethoxylated**
- LC50 (Leuciscus idus (Golden orfe)): > 1 - 10 mg/l
  - Exposure time: 96 h

**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

**Toxicity to daphnia and other aquatic invertebrates**
- EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
  - 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 301F

Alcohols, C16-18, ethoxylated:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 60%
Exposure time: 28 d
Method: OECD Test Guideline 301B
Remarks: Based on data from similar materials

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

Alcohols, C16-18, ethoxylated:
Bioaccumulation: Species: Fish
    Bioconcentration factor (BCF): < 500
    Remarks: Based on data from similar materials
Partition coefficient: n-octanol/water: log Pow: > 4

Mobility in soil
No data available
Hazardous to the ozone layer
Not applicable
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 handling 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

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
Refer to section 15 for specific national regulation.
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

Related Regulations

Fire Service Law
Designated Flammable Substances, Flammable solid, (3000 kilogram)

Chemical Substance Control Law

Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propane-1,2-diol</td>
<td>106</td>
</tr>
<tr>
<td>[alpha-(Alkyl(C=16-18))-omega-hydroxypoly(oxyethane-1,2-diyl) or alkenyl(C=16-18))-omega-hydroxypoly(oxyethane-1,2-diyl)]</td>
<td>250</td>
</tr>
</tbody>
</table>

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names
Article 57-2 (Enforcement Order Table 9)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
<td>&gt;=20 - &lt;30</td>
</tr>
</tbody>
</table>

Substances Subject to be Indicated Names
Article 57 (Enforcement Order Article 18)

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mineral oil</td>
<td>168</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable
Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Noxious liquid substance (Category Y)
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

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 : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-
SAFETY DATA SHEET
Betamethasone (0.05%) Cream Formulation

Version: 5.0   Revision Date: 2020/10/10   SDS Number: 1682148-00008   Date of last issue: 2020/03/23
Date of first issue: 2017/05/17

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

Date format: yyyy/mm/dd

Full text of other abbreviations:
ACGIH: USA, ACGIH Threshold Limit Values (TLV)
JP OEL ISHL: Japan, Administrative Control Levels

ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
JP OEL ISHL / ACL: Administrative Control Level
JP OEL JSOH / OEL-M: Occupational Exposure Limit-Mean
JP OEL JSOH / OEL-C: Occupational Exposure Limit-Ceiling

AcIIC - 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 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 System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Civil Aviation Organization; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organisation for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SAFETY DATA SHEET - self-accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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 mate-
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.

JP / EN