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 : MSD
Address : Kumagaya, Saitama Prefecture, Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : 1-908-423-6000

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

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

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 and personal protective equipment recommendations.

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.

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 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.

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

<table>
<thead>
<tr>
<th></th>
<th>TWA (Inhalable particulate matter)</th>
<th>5 mg/m3</th>
<th>ACGIH</th>
</tr>
</thead>
</table>
Glyceryl monostearate 123-94-4 TWA (Inhalable particulate matter) 10 mg/m³ ACGIH

betamethasone 378-44-9 TWA 1 µg/m³ (OEB 4) Internal

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 (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>ACL</td>
<td>0.1 ppm</td>
<td>JP OEL ISHL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>OEL-M</td>
<td>0.1 ppm, 0.12 mg/m³</td>
<td>JP OEL JSOH</td>
</tr>
</tbody>
</table>

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

|                | OEL-C       | 0.2 ppm, 0.24 mg/m³            | JP OEL JSOH |

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

|                | TWA         | 0.1 ppm                         | ACGIH |
|                | STEL        | 0.3 ppm                          | ACGIH |

**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.

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.

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
- Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
  Method: OECD Test Guideline 402
  Assessment: The substance or mixture has no acute dermal
**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 (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

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

Species: Rabbit  
Result: No skin irritation

Remarks: Based on data from similar materials

Species: Rabbit  
Method: OECD Test Guideline 404  
Result: Corrosive after 1 to 4 hours of exposure

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

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
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:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Name</th>
<th>Species</th>
<th>Application Route</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</td>
<td>Rat</td>
<td>Ingestion</td>
<td>OECD Test Guideline 422</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Effects on foetal development</td>
<td>Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test</td>
<td>Rat</td>
<td>Ingestion</td>
<td>OECD Test Guideline 422</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

4-Chloro-3-methylphenol:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Name</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on fertility</td>
<td>Test Type: One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
<tr>
<td>Effects on foetal development</td>
<td>Test Type: Reproduction/Developmental toxicity screening test</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

Betamethasone:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Name</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>LOAEL</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Effects on foetal development</td>
<td>Species: Rabbit</td>
<td></td>
<td>Intramuscular</td>
<td>Fetotoxicity, Malformations were observed.</td>
<td>0.05 mg/kg body weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Rat</td>
<td>Subcutaneous</td>
<td>Developmental Toxicity: LOAEL: 0.42 mg/kg body weight</td>
<td>Malformations were observed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Species: Mouse</td>
<td>Intramuscular</td>
<td>Developmental Toxicity: LOAEL: 1 mg/kg body weight</td>
<td>Malformations were observed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Reproductive toxicity - Assessment

Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure

Not classified based on available information.
Components:

4-Chloro-3-methylphenol:
Assessment: May cause respiratory irritation.

STOT - repeated exposure
Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Components:
betamethasone:
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

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
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
NOEL (Pseudokirchneriella subcapitata (green algae)): >= 100 mg/l
Exposure time: 72 h
### Test substance: Water Accommodated Fraction
- Method: OECD Test Guideline 201
- Remarks: Based on data from similar materials

### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
- NOEC (Daphnia magna (Water flea)): 10 mg/l
- Exposure time: 21 d
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials

### 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: 7 d

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

### 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
### 4-Chloro-3-methylphenol:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to fish</strong></td>
<td>LC50 (Onchorhynchus mykiss (rainbow trout)): 917 µg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): 1.5 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>48 h</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>ErC50 (Chlorella pyrenoidosa (aglae)): 15 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td><strong>M-Factor (Acute aquatic toxicity)</strong></td>
<td>1</td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOEC (Onchorhynchus mykiss (rainbow trout)): 0.15 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Daphnia magna (Water flea)): 0.32 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>21 d</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC50: 22.86 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>60 h</td>
</tr>
</tbody>
</table>

### betamethasone:

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Americamysis): &gt; 50 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>96 h</td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 34 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td><strong>Remarks</strong></td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>72 h</td>
</tr>
<tr>
<td><strong>Toxicity to microorganisms</strong></td>
<td>EC10 (Pseudomonas putida): &gt; 1 mg/l</td>
</tr>
<tr>
<td>Exposure time</td>
<td>18 h</td>
</tr>
</tbody>
</table>

**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
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility
Based on data from similar materials

**Remarks:** No toxicity at the limit of solubility
Based on data from similar materials

**Toxicity to algae/aquatic plants:**

EC10 (Chlorella pyrenoidosa (aglae)): 2.3 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

**Remarks:** No toxicity at the limit of solubility
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>4.0</td>
<td>2020/03/23</td>
<td>1682148-00007</td>
<td>2019/09/13</td>
<td>2017/05/17</td>
</tr>
</tbody>
</table>

**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

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

**Toxicity to fish:**
- LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l
  - Exposure time: 96 h

**Toxicity to daphnia and other aquatic invertebrates:**
- EC50 (Daphnia magna (Water flea)): 1.5 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202

**Toxicity to algae/aquatic plants:**
- ErC50 (Chlorella pyrenoidosa (algae)): 15 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- EC10 (Chlorella pyrenoidosa (algae)): 2.3 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

**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

**Persistence and degradability**

**Components:**

**Petrolatum:**

<table>
<thead>
<tr>
<th>Biodegradability</th>
<th>Result: Not readily biodegradable.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodegradation</td>
<td>31 %</td>
</tr>
<tr>
<td>Exposure time</td>
<td>28 d</td>
</tr>
</tbody>
</table>
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

**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

**4-Chloro-3-methylphenol:**
Biodegradability: Result: Readily biodegradable.
Biodegradation: 78%
Exposure time: 15 d

**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

**4-Chloro-3-methylphenol:**
Bioaccumulation: Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 5.5 - 13
Partition coefficient: n-octanol/water: log Pow: 0.477
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: 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
  - Subsidiary risk: ENVIRONM.
  - Packing group: III
  - Labels: 9 (ENVIRONM.)
  - 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>
</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

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 / TWA : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / STEL : Short-term exposure limit
JP OEL ISHL : Administrative Control level
JP OEL JSOH / OEL-M : Occupational Exposure Limit-Mean
JP OEL JSOH / OEL-C : Occupational Exposure Limit-Ceiling

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 System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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 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; SADT - 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 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