1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.025%) Cream Formulation

Manufacturer or supplier’s details
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture, Yicheng 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
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard : Category 3
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.
H402 Harmful to aquatic life.
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.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 10 - &lt; 20</td>
<td></td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 1 - &lt; 10</td>
<td></td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td>&gt;= 1 - &lt; 2.5</td>
<td></td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
<td>3-900</td>
</tr>
<tr>
<td>9-Fluoro-11β,17,21-trihydroxy-16β-</td>
<td>2152-44-5</td>
<td>&gt;= 0.025 - &lt; 0.1</td>
<td>9-321</td>
</tr>
<tr>
<td>methylpregna-1,4-diene-3,20-dione</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17-valerate</td>
<td></td>
<td></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.
## SAFETY DATA SHEET

**Betamethasone (0.025%) 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>1.1</td>
<td>09/13/2019</td>
<td>4375604-00002</td>
<td>2019/06/03</td>
<td>2019/06/03</td>
</tr>
</tbody>
</table>

- **Get medical attention if irritation develops and persists.**
- **If swallowed**: If swallowed, **DO NOT induce vomiting.** Get medical attention. Rinse mouth thoroughly with water.
- **Most important symptoms and effects, both acute and delayed**: May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.
- **Protection of first-aiders**: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- **Notes to physician**: Treat symptomatically and supportively.

### 5. FIREFIGHTING MEASURES

- **Suitable extinguishing media**: Water spray
  - Alcohol-resistant foam
  - Carbon dioxide (CO\(_2\))
  - Dry chemical
- **Unsuitable extinguishing media**: None known.
- **Specific hazards during firefighting**: Exposure to combustion products may be a hazard to health.
- **Hazardous combustion products**: Carbon oxides
- **Specific extinguishing methods**: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
  - Use water spray to cool unopened containers.
  - Remove undamaged containers from fire area if it is safe to do so.
  - Evacuate area.
- **Special protective equipment for firefighters**: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### 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.
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.
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</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>JSOH</td>
</tr>
<tr>
<td>Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable fraction)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>OEL-M (Mist)</td>
<td>3 mg/m³</td>
<td>JP OEL</td>
</tr>
</tbody>
</table>
Further information: Substance whose OEL is set based on non-carcinogenic health effects. See III, Group 1: carcinogenic to humans

TWA (Inhalable fraction) 5 mg/m³ ACGIH

Further information: Skin

Wipe limit 10 µg/100 cm² Internal

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 and organic vapour type

Hand protection: Chemical-resistant gloves

Eye protection: Consider double gloving.

Material: 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

Appearance: cream

Colour: No data available

Odour: No data available
10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: Can react with strong oxidizing agents.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity:
Not classified based on available information.

Components:

Petrolatum:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
   Method: OECD Test Guideline 401
   Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rat): > 2,000 mg/kg
   Method: OECD Test Guideline 402
   Assessment: The substance or mixture has no acute dermal toxicity
   Remarks: Based on data from similar materials

White mineral oil (petroleum):
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 5 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist
   Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
   Assessment: The substance or mixture has no acute dermal toxicity

Hexadecan-1-ol. Ethoxylated:
Acute oral toxicity: LD50 (Rat): 2,500 mg/kg

4-Chloro-3-methylphenol:
Acute oral toxicity: LD50 (Mouse): 600 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 2.871 mg/l
   Exposure time: 4 h
   Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Rat): > 5,000 mg/kg
SAFETY DATA SHEET
Betamethasone (0.025%) Cream Formulation

Version 1.1
Revision Date: 09/13/2019
SDS Number: 4375604-00002
Date of last issue: 2019/06/03
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9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Remarks: Based on data from similar materials
LD50 (Mouse): > 4,500 mg/kg
Acute inhalation toxicity: LC50 (Rat): 0.4 mg/l
Exposure time: 4 h
Remarks: Based on data from similar materials

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

White mineral oil (petroleum):
Species: Rabbit
Result: No eye irritation

4-Chloro-3-methylphenol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Corrosive after 1 to 4 hours of exposure

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:
Species: Rabbit
Result: Mild 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

White mineral oil (petroleum):
Species: Rabbit
Result: No eye irritation
<table>
<thead>
<tr>
<th>Hexadecan-1-ol. Ethoxylated:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
</tr>
<tr>
<td>Remarks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4-Chloro-3-methylphenol:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
</tr>
<tr>
<td>Result</td>
</tr>
<tr>
<td>Method</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
</tr>
<tr>
<td>Result</td>
</tr>
<tr>
<td>Remarks</td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

<table>
<thead>
<tr>
<th>Petrolatum:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type</td>
</tr>
<tr>
<td>Exposure routes</td>
</tr>
<tr>
<td>Species</td>
</tr>
<tr>
<td>Result</td>
</tr>
<tr>
<td>Remarks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>White mineral oil (petroleum):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type</td>
</tr>
<tr>
<td>Exposure routes</td>
</tr>
<tr>
<td>Species</td>
</tr>
<tr>
<td>Result</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4-Chloro-3-methylphenol:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Type</td>
</tr>
<tr>
<td>Exposure routes</td>
</tr>
<tr>
<td>Species</td>
</tr>
<tr>
<td>Assessment</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
</tr>
<tr>
<td>Species</td>
</tr>
<tr>
<td>Result</td>
</tr>
<tr>
<td>Remarks</td>
</tr>
</tbody>
</table>
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

White mineral oil (petroleum):
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:
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

White mineral oil (petroleum):
Species: Rat
Application Route: Ingestion
Exposure time: 24 Months
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

White mineral oil (petroleum):
Effects on fertility: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Skin contact
Result: negative

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

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

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:

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:

- May damage the unborn child.

**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:**

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:

**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
White mineral oil (petroleum):
Species : Rat
LOAEL  : 160 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat
LOAEL  : >= 1 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 4 Weeks
Method : OECD Test Guideline 412

4-Chloro-3-methylphenol:
Species : Rat
NOAEL  : 200 mg/kg
LOAEL  : 400 mg/kg
Application Route : Ingestion
Exposure time : 28 Days

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:
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:
9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:
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

White mineral oil (petroleum):
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 28 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 1,000 mg/l
Exposure time: 21 d

Hexadecan-1-ol. Ethoxylated:
Toxicity to fish: LC50: > 1 - 10 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50: > 1 - 10 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants: EC50: > 10 - 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

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

Toxicity to fish: LC50 (Onchorhynchus 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 (Onchorhynchus 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

**9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:**

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
**Toxicity to fish (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Pimephales promelas (fathead minnow))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.052 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Oryzias latipes (Japanese medaka))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.07 µg/l</td>
<td>219 d</td>
<td>OECD Test Guideline 229</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

**M-Factor (Chronic aquatic toxicity)**

- **Toxicity to fish (Chronic toxicity)**: NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**: NOEC (Daphnia magna (Water flea)): 8 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

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

**Persistence and degradability**

**Components:**

**Petrolatum:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Biodegradability</th>
<th>Biodegradation</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Result: Not readily biodegradable.</td>
<td>31 %</td>
<td>28 d</td>
<td>OECD Test Guideline 301F</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Biodegradability</th>
<th>Biodegradation</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>Result: Not readily biodegradable.</td>
<td>31 %</td>
<td>28 d</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Hexadecan-1-ol. Ethoxylated:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Biodegradability</th>
<th>Biodegradation</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>Result: Readily biodegradable.</td>
<td>78 %</td>
<td>15 d</td>
<td></td>
</tr>
</tbody>
</table>

**Bioaccumulative potential**

**Components:**

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Bioaccumulation</th>
<th>Species</th>
<th>Bioconcentration factor (BCF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>Species: Cyprinus carpio (Carp)</td>
<td>Bioconcentration factor (BCF): 5.5 - 13</td>
<td></td>
</tr>
</tbody>
</table>
Partition coefficient: n-octanol/water:

**9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:**

Partition coefficient: n-octanol/water:

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.
  (9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate)

- **Class:** 9
- **Packing group:** III
- **Labels:** Miscellaneous

#### IATA-DGR

- **UN/ID No.:** UN 3077
- **Proper shipping name:** Environmentally hazardous substance, solid, n.o.s.
  (9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate)

- **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 (0.025%) Cream Formulation

(9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate)

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
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Priority Assessment Chemical Substance

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>alpha-Alkyl(C=9-11)-omega-hydroxypoly(oxyethylene) (It is limited that a number-average molecular weight of the polymer is less than 1,000.)</td>
<td>188</td>
</tr>
<tr>
<td>alpha-Alkyl(C=12-15)-omega-hydroxypoly(oxyethylene) (It is limited that a number-average molecular weight of the polymer is less than 1,000.)</td>
<td>189</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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 57-2 (Enforcement Order Table 9)</td>
<td></td>
</tr>
</tbody>
</table>
Mineral oil | 168 | >=20 - <30

**Substances Subject to be Indicated Names**

<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 Z)
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 Sheet:


Date format: yyyy/mm/dd

#### Full text of other abbreviations

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **ACGIH / TWA**: 8-hour, time-weighted average
- **JP OEL JSOH / OEL-M**: Occupational Exposure Limit-Mean

**Abbreviations**

- 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 Chemical Substances in China
- IMDG - International Maritime Dangerous Goods
- IMO - International Maritime Organization
- IC50 - Lethal Concentration to 50% of a test population
- LD50 - Lethal Dose to 50% of a test population
- 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 - Organization 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
- 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