SAFETY DATA SHEET

Betamethasone (0.025%) Cream Formulation

Version 1.3  Revision Date: 10.10.2020  SDS Number: 4375608-00004  Date of last issue: 23.03.2020
                Date of first issue: 03.06.2019

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone (0.025%) Cream Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 50 Tuas West Drive
Singapore - Singapore 638408
Telephone: 908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

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

2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:
Signal word: Danger
Hazard statements: H360D May damage the unborn child. H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure. H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements: Prevention: P201 Obtain special instructions before use. P202 Do not handle until all safety precautions have been read and understood. P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td>Mixture</td>
</tr>
</tbody>
</table>

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

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.

5.1. Suitable extinguishing media:
Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

5.2. Unsuitable extinguishing media:
None known.

5.3. Specific hazards during firefighting:
Exposure to combustion products may be a hazard to health.

5.4. Hazardous combustion products:
Carbon oxides

5.5. 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.

5.6. Special protective equipment for firefighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2. Environmental precautions:
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.

6.3. 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

7.1. 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.

Conditions for safe storage: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>PEL (long term) (Mist)</td>
<td>5 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term) (Mist)</td>
<td>10 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>PEL (long term) (Mist)</td>
<td>5 mg/m³</td>
<td>SG OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>PEL (short term) (Mist)</td>
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<td>ACGIH</td>
</tr>
<tr>
<td>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate</td>
<td>2152-44-5</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin

- Wipe limit: 10 µg/100 cm² Internal

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 expo-
sure assessment demonstrates exposures outside the rec-
ommended guidelines, use respiratory protection.

**Filter type**: Combined particulates 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, dis-
posable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially
contaminated clothing.

**Hygiene measures**: If exposure to chemical is likely during typical use, provide
eye flushing systems and safety showers close to the work-
ing 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance**: cream

**Colour**: No data available

**Odour**: No data available

**Odour Threshold**: No data available

**pH**: No data available

**Melting point/freezing point**: No data available

**Initial boiling point and boiling range**: No data available
Flash point : Not applicable
Evaporation rate : Not applicable
Flammability (solid, gas) : No data available
Flammability (liquids) : No data available
Upper explosion limit / Upper flammability limit : No data available
Lower explosion limit / Lower flammability limit : No data available
Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies) : No data available
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity : Not applicable
Viscosity, kinematic : Not applicable
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : 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

**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.

<table>
<thead>
<tr>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum:</td>
</tr>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result: No skin irritation</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>White mineral oil (petroleum):</td>
</tr>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Result: No skin irritation</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol:</td>
</tr>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result: Corrosive after 1 to 4 hours of exposure</td>
</tr>
<tr>
<td>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:</td>
</tr>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Result: Mild skin irritation</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

Serious eye damage/eye irritation:
Not classified based on available information.

<table>
<thead>
<tr>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum:</td>
</tr>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Result: No eye irritation</td>
</tr>
<tr>
<td>Method: OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>White mineral oil (petroleum):</td>
</tr>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Result: No eye irritation</td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated:</td>
</tr>
<tr>
<td>Result: Irritation to eyes, reversing within 21 days</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>
4-Chloro-3-methylphenol:
Species : Rabbit
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:
Species : Rabbit
Result : No eye irritation
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

White mineral oil (petroleum):
Test Type : Buehler Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

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

9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:
Exposure routes : Dermal
Species : Guinea pig
Result : Weak sensitizer
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

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

Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
- Result: negative

Genotoxicity in vivo:
- Test Type: Chromosome aberration test in vitro
- Result: positive

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

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:

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

#### White mineral oil (petroleum):

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Ingestion</td>
<td>24 Months</td>
<td>negative</td>
</tr>
</tbody>
</table>

### Reproductive toxicity

May damage the unborn child.

#### Components:

#### Petrolatum:

- **Effects on fertility**: Test Type: Reproduction/Developmental toxicity screening test  
  Species: Rat  
  Application Route: Ingestion  
  Result: negative  
  Remarks: Based on data from similar materials

- **Effects on foetal development**: Test Type: Embryo-foetal development  
  Species: Rat  
  Application Route: Skin contact  
  Result: negative  
  Remarks: Based on data from similar materials

#### 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:  
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

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 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l
- Exposure time: 96 h

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

Toxicity to algae/aquatic plants
- ErC50 (Chlorella pyrenoidosa (aglae)): 15 mg/l
- Exposure time: 72 h
Method: OECD Test Guideline 201
- EC10 (Chlorella pyrenoidosa (aglae)): 2.3 mg/l
- Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity)
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

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
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility
Toxicity to fish (Chronic toxicity): 
NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l
Exposure time: 219 d
Method: OECD Test Guideline 229

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

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

Persistence and degradability

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

White mineral oil (petroleum):
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

Hexadecan-1-ol. Ethoxylated:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 99 %
Exposure time: 19 d

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

Bioaccumulative potential

Components:

4-Chloro-3-methylphenol:
Bioaccumulation: Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 5.5 - 13
Partition coefficient: n-octanol/water: log Pow: 0.477
9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:
Partition coefficient: n-octanol/water  :  log Pow: 3.9
Mobility in soil
No data available
Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues  :  Dispose of in accordance with local regulations.
Contaminated packaging  :  Empty containers should be taken to an approved waste 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
Packing instruction (cargo aircraft)  :  956
Packing instruction (passenger aircraft)  :  956
Environmentally hazardous  :  yes

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.
(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.

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations: This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.
Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations: Not applicable
Fire Safety (Petroleum and Flammable Materials) Regulations: Not applicable

The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

16. OTHER INFORMATION

Further information
Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
SG OEL: Singapore. Workplace Safety and Health Act - First Schedule Permissible Exposure Limits of Toxic Substances
ACGIH / TWA: 8-hour, time-weighted average
SG OEL / PEL (long term): Permissible Exposure Level (PEL) Long Term
SG OEL / PEL (short term): Permissible Exposure Level (PEL) Short Term
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.

SG / EN