SAFETY DATA SHEET

Betamethasone (0.025%) Cream Formulation

Version Revision Date: SDS Number: Date of last issue: 13.09.2019
1.2 23.03.2020 4375588-00003 Date of first issue: 03.06.2019

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone (0.025%) Cream Formulation

Manufacturer or supplier's details
Company : MSD
Address : 26 Talavera Road, Talavera Corp Centre, Macquarie Park New South Wales, 2113 Australia
Telephone : (61)-02-8988-8000
Emergency telephone number : (61)-02-8988-8000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

SECTION 2. HAZARDS IDENTIFICATION

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

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

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P281 Use personal protective equipment as required.
Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td></td>
<td>Petrolatum</td>
</tr>
<tr>
<td></td>
<td>White mineral oil (petroleum)</td>
</tr>
<tr>
<td></td>
<td>Hexadecan-1-ol. Ethoxylated</td>
</tr>
<tr>
<td></td>
<td>4-Chloro-3-methylphenol</td>
</tr>
<tr>
<td></td>
<td>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

General advice: In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution.
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).
SECTION 5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media
- None known.

Specific hazards during firefighting
- 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.

Hazchem Code
- 2Z

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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

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

SECTION 7. HANDLING AND STORAGE

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

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

Advice on safe handling
- Do not get on skin or clothing.
- Do not swallow.
- Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures:
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.
When using do not eat, drink or smoke.
Wash contaminated clothing before re-use.
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

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

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>AU OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable 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>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>AU 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>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>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**

: Combined particulates and organic vapour type

**Hand protection**

: Chemical-resistant gloves

**Remarks**

: Consider double gloving.

**Eye protection**

: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Skin and body protection**

: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**

: cream

**Colour**

: 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
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Vapour pressure : Not applicable
Relative vapour density : Not applicable
Relative density : No data available
Density : No data available
Solubility(ies)
  Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : Not applicable
Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.
Molecular weight : No data available
Particle size : No data available

SECTION 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.

SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes : Skin contact
  Ingestion
  Eye contact

Acute toxicity
Not classified based on available information.

Components:

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

### 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.

## Components:

### Petrolatum:

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>
### Betamethasone (0.025%) Cream Formulation

**SAFETY DATA SHEET**

**Version**: 1.2  
**Revision Date**: 23.03.2020  
**SDS Number**: 4375588-00003  
**Date of last issue**: 13.09.2019  
**Date of first issue**: 03.06.2019

<table>
<thead>
<tr>
<th>Remarks</th>
<th>Based on data from similar materials</th>
</tr>
</thead>
</table>

#### White mineral oil (petroleum):
- **Species**: Rabbit  
- **Result**: No skin 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

**Hexadecan-1-ol. Ethoxylated**:
- **Result**: Irritation to eyes, reversing within 21 days  
- **Remarks**: Based on data from similar materials

#### 4-Chloro-3-methylphenol:
- **Species**: Rabbit  
- **Method**: OECD Test Guideline 405  
- **Result**: Irreversible effects on the eye

#### 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-tri-hydroxy-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

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials

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

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

Genotoxicity in vitro: 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.
<table>
<thead>
<tr>
<th>Components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>4-Chloro-3-methylphenol:</td>
<td></td>
</tr>
<tr>
<td>Assessment</td>
<td>May cause respiratory irritation.</td>
</tr>
</tbody>
</table>

**STOT - single exposure**

Not classified based on available information.

<table>
<thead>
<tr>
<th>Components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate:</td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td>Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland</td>
</tr>
<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

**Repeated dose toxicity**

<table>
<thead>
<tr>
<th>Components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum:</td>
<td></td>
</tr>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>NOAEL</td>
<td>5,000 mg/kg</td>
</tr>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 yr</td>
</tr>
</tbody>
</table>

| 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

SECTION 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
### Betamethasone (0.025%) Cream Formulation

<table>
<thead>
<tr>
<th>Test Substance</th>
<th>Remarks</th>
<th>Method</th>
<th>Exposure Time</th>
<th>NOEL/EC50/LC50</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>NOEL (Pseudokirchneriella subcapitata (green algae)): $\geq$ 100 mg/l</td>
<td>OECD Test Guideline 201</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
<td>OECD Test Guideline 201</td>
<td>21 d</td>
<td>Based on data from similar materials</td>
<td></td>
</tr>
<tr>
<td><strong>White mineral oil (petroleum):</strong></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 100 mg/l</td>
<td>OECD Test Guideline 203</td>
<td>96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
<td>OECD Test Guideline 202</td>
<td>48 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l</td>
<td>OECD Test Guideline 201</td>
<td>72 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to fish (Chronic toxicity)</strong></td>
<td>NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l</td>
<td>OECD Test Guideline 201</td>
<td>28 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</strong></td>
<td>NOEC (Daphnia magna (Water flea)): 1,000 mg/l</td>
<td>OECD Test Guideline 201</td>
<td>21 d</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Hexadecan-1-ol. Ethoxylated:</strong></td>
<td>LC50: $&gt; 1 - 10$ mg/l</td>
<td>Based on data from similar materials</td>
<td>96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other aquatic invertebrates</strong></td>
<td>EC50: $&gt; 1 - 10$ mg/l</td>
<td>Based on data from similar materials</td>
<td>48 h</td>
<td></td>
<td></td>
</tr>
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<td><strong>Toxicity to algae/aquatic plants</strong></td>
<td>EC50: $&gt; 10 - 100$ mg/l</td>
<td>Based on data from similar materials</td>
<td>72 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>4-Chloro-3-methylphenol:</strong></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l</td>
<td>OECD Test Guideline 203</td>
<td>96 h</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Toxicity to daphnia and other</strong></td>
<td>EC50 (Daphnia magna (Water flea)): 1.5 mg/l</td>
<td>OECD Test Guideline 202</td>
<td>48 h</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Test substance:** Water Accommodated Fraction
### aquatic invertebrates
Exposure time: 48 h  
Method: OECD Test Guideline 202

### Toxicity to algae/aquatic plants
<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Chlorella pyrenoidosa (algae))</th>
<th>EC10 (Chlorella pyrenoidosa (algae))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>15 mg/l</td>
<td>2.3 mg/l</td>
</tr>
</tbody>
</table>
Exposure time: 72 h  
Method: OECD Test Guideline 201

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

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

### Toxicity to microorganisms
<table>
<thead>
<tr>
<th>Method</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>22.86 mg/l</td>
</tr>
</tbody>
</table>
Exposure time: 60 h

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

#### Toxicity to aquatic invertebrates
<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Americamysis)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 50 mg/l</td>
</tr>
</tbody>
</table>
Exposure time: 96 h

#### Toxicity to algae/aquatic plants
<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Pseudokircheriella subcapitata (green algae))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt; 34 mg/l</td>
</tr>
</tbody>
</table>
Exposure time: 72 h  
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Pseudokircheriella subcapitata (green algae))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>34 mg/l</td>
</tr>
</tbody>
</table>
Exposure time: 72 h  
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

#### Toxicity to fish (Chronic toxicity)
<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Pimephales promelas (fathead minnow))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.052 mg/l</td>
</tr>
</tbody>
</table>
Exposure time: 32 d  
Method: OECD Test Guideline 210

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

#### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)
<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Daphnia magna (Water flea))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8 mg/l</td>
</tr>
</tbody>
</table>
Exposure time: 21 d  
Method: OECD Test Guideline 211
Persistence and degradability

Components:

Petrolatum:
Biodegradability
Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

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-Flouro-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

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues
Dispose of in accordance with local regulations.
Contaminated packaging
Empty containers should be taken to an approved waste han-
SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
(9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate)
Class : 9
Packing group : III
Labels : 9

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
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

ADG
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
Betamethasone (0.025%) Cream Formulation

Version 1.2  Revision Date: 23.03.2020  SDS Number: 4375588-00003  Date of last issue: 13.09.2019  Date of first issue: 03.06.2019

Labels: 9  Hazchem Code: 2Z

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

SECTION 15. REGULATORY INFORMATION

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

Prohibition/Licensing Requirements: There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

SECTION 16. OTHER INFORMATION

Further information
Revision Date: 23.03.2020
Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
AU OEL: Australia. Workplace Exposure Standards for Airborne Contaminants.
ACGIH / TWA: 8-hour, time-weighted average
AU OEL / TWA: Exposure standard - time weighted average

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized Sys-
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

AU / EN