SAFETY DATA SHEET

Betamethasone (0.025%) Cream Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
   Trade name : Betamethasone (0.025%) Cream Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
   Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
   Company : MSD
   117 16th Road
   07033 Halfway house, Midrand, South Africa
   Telephone : +27 11 655 3000
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Reproductive toxicity, Category 1B : H360D: May damage the unborn child.
   Specific target organ toxicity - repeated exposure, Category 1 : H372: Causes damage to organs through prolonged or repeated exposure.
   Long-term (chronic) aquatic hazard, Category 1 : H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
   Labelling (REGULATION (EC) No 1272/2008)
   Hazard pictograms :
   Signal word : Danger
   Hazard statements : H360D May damage the unborn child.
   H372 Causes damage to organs through prolonged or repeated exposure.
   H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- 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.

Hazardous components which must be listed on the label:
9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate

**Additional Labelling**
EUH208 Contains 4-Chloro-3-methylphenol. May produce an allergic reaction.

### 2.3 Other hazards
None known.

### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td></td>
<td></td>
<td></td>
<td>Eye Irrit.2; H319</td>
<td>&gt;= 1 - &lt; 10</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>200-431-6</td>
<td>604-014-00-3</td>
<td></td>
<td>Acute Tox.4; H302 Acute Tox.4; H312 Skin Corr.1C; H314 Eye Dam.1; H318 Skin Sens.1B; H317 STOT SE3; H335 Aquatic Acute1; H400 Aquatic Chronic3; H412</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>218-439-3</td>
<td></td>
<td></td>
<td>Acute Tox.2; H330 Repr.1B; H360D STOT RE1; H372 Aquatic Chronic1; H410</td>
<td>&gt;= 0,025 - &lt; 0,1</td>
</tr>
</tbody>
</table>
SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

May produce an allergic reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Betamethasone (0.025%) Cream Formulation

Version 1.1  Revision Date: 09/13/2019  SDS Number: 4375610-00002  Date of last issue: 03.06.2019
Date of first issue: 03.06.2019

5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting:
- Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
- Carbon oxides

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

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.

SECTION 6: Accidental release measures

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

6.2 Environmental precautions
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.

6.3 Methods and material for containment and cleaning up
Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.
SECTION 7: Handling and storage

7.1 Precautions for safe handling

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

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

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

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.

7.2 Conditions for safe storage, including any incompatibilities

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

Advice on common storage: Do not store with the following product types: Strong oxidizing agents Organic peroxides Explosives Gases

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione</td>
<td>2152-44-5</td>
<td>TWA</td>
<td>1 µg/m3 (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohols, C16-18</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>237.76 mg/m³</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Acute systemic effects</td>
<td>237.76 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>6.52 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>6.52 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>200 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>400 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>1,124 mg/cm²</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>1,124 mg/cm²</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>118.88 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>118.9 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>0.652 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
<td>0.652 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>100 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>200 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>0.562 mg/cm²</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Acute local effects</td>
<td>0.562 mg/cm²</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>75 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>75 mg/kg bw/day</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>6.289 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>3.567 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1.551 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1.783 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.892 mg/kg bw/day</td>
</tr>
</tbody>
</table>

### Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
</tr>
<tr>
<td>Substance</td>
<td>Exposure Medium</td>
<td>Concentration</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>----------------------------------------</td>
<td>---------------------</td>
</tr>
<tr>
<td>Alcohols, C16-18</td>
<td>Fresh water</td>
<td>0.13 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.12 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>1000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>13.61 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>1.361 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>100 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td>Oral (Secondary Poisoning)</td>
<td></td>
<td>86.7 mg/kg food</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>Fresh water</td>
<td>0.015 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.015 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.002 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2.286 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>13.981 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>13.981 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>6.399 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

### 8.2 Exposure controls

**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**

**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.

**Hand protection**

- Material: Chemical-resistant gloves

**Skin and body protection**

- Remarks: Consider double gloving.
- 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.

**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 (A-P)
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>cream</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

9.2 Other information

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Components:

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: Acute toxicity estimate: 1.100 mg/kg
Method: Expert judgement
Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI
### Acute oral toxicity

<table>
<thead>
<tr>
<th>Compound</th>
<th>LD50 (Rat)</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate</td>
<td>&gt; 5.000 mg/kg</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>LD50 (Mouse): &gt; 4.500 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

### Acute inhalation toxicity

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50 (Rat)</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate</td>
<td>0.4 mg/l</td>
<td>4 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Skin corrosion/irritation

Not classified based on available information.

### Components

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 404</td>
<td>Corrosive after 1 to 4 hours of exposure</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>Mild skin irritation</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

#### Hexadecan-1-ol. Ethoxylated:

<table>
<thead>
<tr>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Irritation to eyes, reversing within 21 days</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Method</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>OECD Test Guideline 405</td>
<td>Irreversible effects on the eye</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Species</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rabbit</td>
<td>No eye irritation</td>
<td>Based on data from similar materials</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:

**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:**

**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.

### Reproductive toxicity

May damage the unborn child.

**Components:**

**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 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:**

**4-Chloro-3-methylphenol:**
Betamethasone (0.025%) Cream Formulation

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

12.1 Toxicity

Components:

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: EC50 > 1 - 10 mg/l
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**Betamethasone (0.025%) Cream Formulation**

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<td>09/13/2019</td>
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**Aquatic Invertebrates**
- 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)**
- 1

**Toxicity to Microorganisms**
- EC50: 22.86 mg/l
- Exposure time: 60 h

**Toxicity to Fish (Chronic Toxicity)**
- NOEC: 0.15 mg/l
- Exposure time: 28 d
- Species: Oncorhynchus mykiss (rainbow trout)
- Method: OECD Test Guideline 204

**Toxicity to Daphnia and Other Aquatic Invertebrates (Chronic Toxicity)**
- NOEC: 0.32 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

**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: 0.052 mg/l
  Exposure time: 32 d
  Species: Pimephales promelas (fathead minnow)
  Method: OECD Test Guideline 210
- NOEC: 0.07 µg/l
  Exposure time: 219 d
  Species: Oryzias latipes (Japanese medaka)
  Method: OECD Test Guideline 229

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

M-Factor (Chronic aquatic toxicity):
- 1.000

12.2 Persistence and degradability

Components:

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

12.3 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

12.4 Mobility in soil
- No data available

12.5 Results of PBT and vPvB assessment
- Not relevant
12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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.

SECTION 14: Transport information

14.1 UN number
ADN : UN 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name
ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate)
ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate)
RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate)
IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate)
IATA : Environmentally hazardous substance, solid, n.o.s. (9-Fluoro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3,20-dione 17-valerate)

14.3 Transport hazard class(es)
ADN : 9
ADR : 9
14.4 Packing group

**ADN**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

**ADR**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)

**RID**
- Packing group: III
- Classification Code: M7
- Hazard Identification Number: 90
- Labels: 9

**IMDG**
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F

**IATA (Cargo)**
- Packing instruction (cargo aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

**IATA (Passenger)**
- Packing instruction (passenger aircraft): 956
- Packing instruction (LQ): Y956
- Packing group: III
- Labels: Miscellaneous

14.5 Environmental hazards

**ADN**
- Environmentally hazardous: yes

**ADR**
- Environmentally hazardous: yes

**RID**
- Environmentally hazardous: yes

**IMDG**
- Marine pollutant: yes

**IATA (Passenger)**
SAFETY DATA SHEET

Betamethasone (0.025%) Cream Formulation

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Environmentally hazardous : yes

**IATA (Cargo)**
Environmentally hazardous : yes

### 14.6 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.

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

### SECTION 15: Regulatory information

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

The components of this product are reported in the following inventories:

- **AICS** : not determined
- **DSL** : not determined
- **IECSC** : not determined

#### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

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

**Full text of H-Statements**

- **H302** : Harmful if swallowed.
- **H312** : Harmful in contact with skin.
- **H314** : Causes severe skin burns and eye damage.
- **H317** : May cause an allergic skin reaction.
- **H318** : Causes serious eye damage.
- **H319** : Causes serious eye irritation.
- **H330** : Fatal if inhaled.
- **H335** : May cause respiratory irritation.
- **H360D** : May damage the unborn child.
- **H372** : Causes damage to organs through prolonged or repeated exposure.
- **H400** : Very toxic to aquatic life.
- **H410** : Very toxic to aquatic life with long lasting effects.
- **H412** : Hazardous to aquatic life with long lasting effects.

**Full text of other abbreviations**

- **Acute Tox.** : Acute toxicity
- **Aquatic Acute** : Short-term (acute) aquatic hazard
SAFETY DATA SHEET

Betamethasone (0.025%) Cream Formulation

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Aquatic Chronic: Long-term (chronic) aquatic hazard
Eye Dam.: Serious eye damage
Eye Irrit.: Eye irritation
Repr.: Reproductive toxicity
Skin Corr.: Skin corrosion
Skin Sens.: Skin sensitisation
STOT RE: Specific target organ toxicity - repeated exposure
STOT SE: Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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 Substance in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; ISHl - Industrial Safety and Health Law (Japan); KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; 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

Further information

Classification of the mixture:

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<th>Component</th>
<th>Classification</th>
<th>Classification procedure</th>
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<tbody>
<tr>
<td>Repr. 1B</td>
<td>H360D</td>
<td>Calculation method</td>
</tr>
<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
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</table>
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.

ZA / EN