SAFETY DATA SHEET
Betamethasone Cream Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone Cream Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: 30 Hudson Street, 33nd floor
         Jersey City, New Jersey, U.S.A 07302
Telephone: 551-430-6000
Emergency telephone: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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)
Short-term (acute) aquatic hazard: Category 3
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms:

Signal Word: Danger
Hazard Statements:
H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.
H402 Harmful to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements:
Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe vapors.
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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical name</td>
<td>CAS-No.</td>
</tr>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</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.
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.

SECTION 5. FIRE-FIGHTING MEASURES

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

Unsuitable extinguishing media:
- None known.

Specific hazards during fire fighting:
- Vapors may form explosive mixtures with air.
- 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 fire-fighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

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).

Environmental precautions:
- Avoid release to the environment.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g., by containment or oil barriers).
- 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:
- Soak up with inert absorbent material.
- For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- 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 breathe vapors. 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 labeled 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
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>CMP (Mist)</td>
<td>5 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Sampled by a method which does not include vapour, lung</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT (Mist)</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: lung</td>
<td></td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>CMP (Mist)</td>
<td>5 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>CMP - CPT</td>
<td>10 mg/m³</td>
<td>AR OEL</td>
</tr>
<tr>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Betamethasone Cream Formulation**

**Version** 4.2  **Revision Date:** 09.04.2021  **SDS Number:** 1842148-00010  **Date of last issue:** 10.10.2020

**TWA** (Inhalable particulate matter)  5 mg/m³  ACGIH

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

**Further information:** Skin

**Wipe limit**  10 µg/100 cm²  Internal

**Engineering measures**: 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. If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

**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 vapor type

**Hand protection**: Chemical-resistant gloves

**Material**: 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 such as disposable suits should be used based upon the task being performed (e.g., sleevelets, apron, gauntlet, disposable 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 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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: cream
### SAFETY DATA SHEET

**Betamethasone Cream Formulation**

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Color</strong></td>
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</tr>
<tr>
<td><strong>Odor</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
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</tr>
<tr>
<td><strong>pH</strong></td>
<td>5</td>
</tr>
<tr>
<td><strong>Melting point/freezing point</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flash point</strong></td>
<td>&gt; 93.3 °C</td>
</tr>
<tr>
<td><strong>Evaporation rate</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Flammability (liquids)</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Upper explosion limit / Upper flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Lower explosion limit / Lower flammability limit</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Vapor pressure</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Relative vapor density</strong></td>
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</tr>
<tr>
<td><strong>Relative density</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Density</strong></td>
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</tr>
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<td><strong>Solubility</strong></td>
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</tr>
<tr>
<td><strong>Water solubility</strong></td>
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</tr>
<tr>
<td><strong>Partition coefficient: n-octanol/water</strong></td>
<td>Not applicable</td>
</tr>
<tr>
<td><strong>Autoignition temperature</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
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</tr>
<tr>
<td><strong>Viscosity</strong></td>
<td>Not explosive</td>
</tr>
<tr>
<td><strong>Viscosity, kinematic</strong></td>
<td>No data available</td>
</tr>
<tr>
<td><strong>Explosive properties</strong></td>
<td>Not explosive</td>
</tr>
<tr>
<td><strong>Oxidizing properties</strong></td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td><strong>Particle size</strong></td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

*Date of last issue: 10.10.2020*

*Date of first issue: 19.07.2017*
### SECTION 10. STABILITY AND REACTIVITY

| Reactivity | Not classified as a reactivity hazard. |
| Chemical stability | Stable under normal conditions. |
| Possibility of hazardous reactions | Vapors may form explosive mixture with air. 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

#### Information on likely routes of exposure
- Inhalation
- Skin contact
- Ingestion
- Eye contact

#### Acute toxicity
Not classified based on available information.

#### Product:
- **Acute oral toxicity**: Acute toxicity estimate: > 5.000 mg/kg
  - Method: Calculation method

#### 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

**Paraffin oil:**
- **Acute oral toxicity**: LD50 (Rat): > 5.000 mg/kg

**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

### Betamethasone:
- **Acute Oral Toxicity**
  - **LD50 (Rat):** > 5,000 mg/kg
  - **LD50 (Mouse):** > 4,500 mg/kg
- **Acute Inhalation Toxicity**
  - **LC50 (Rat):** 0,4 mg/l
  - **Exposure time:** 4 h

### Skin Corrosion/Irritation
Not classified based on available information.

### Components:

#### Petrolatum:
- **Species:** Rabbit
- **Method:** OECD Test Guideline 404
- **Result:** No skin irritation
- **Remarks:** Based on data from similar materials

#### Paraffin Oil:
- **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

#### Betamethasone:
- **Species:** Rabbit
- **Result:** Mild skin irritation

### Serious Eye Damage/Eye Irritation
Not classified based on available information.

### Components:

#### Petrolatum:
- **Species:** Rabbit
- **Result:** No eye irritation
- **Method:** OECD Test Guideline 405
- **Remarks:** Based on data from similar materials
Paraffin oil:
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
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

Betamethasone:
Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Petrolatum:
Test Type : Buehler Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative
Remarks : Based on data from similar materials

4-Chloro-3-methylphenol:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Assessment : Probability or evidence of low to moderate skin sensitization rate in humans

Betamethasone:
Routes of exposure : Dermal
Species : Guinea pig
Result : Weak sensitizer

Germ cell mutagenicity
Not classified based on available information.
Components:

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

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

Betamethasone:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: In vitro mammalian cell gene mutation test
Result: negative
Test Type: Chromosome aberration test in vitro
Result: positive
Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Oral
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

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

4-Chloro-3-methylphenol:
Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on fetal development : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative

Betamethasone:
Effects on fetal 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 : Clear evidence of adverse effects on development, based on animal experiments.

STOT-single exposure
Not classified based on available information.
COMPONENTS:

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

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

COMPONENTS:

Betamethasone:
Target Organs: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

COMPONENTS:

Petrolatum:
Species: Rat
NOAEL: 5.000 mg/kg
Application Route: Ingestion
Exposure time: 2 y

Paraffin oil:
Species: Rat, female
LOAEL: 161 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

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

Betamethasone:
Species: Rabbit
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 10 - 30 d
Target Organs: Pituitary gland, Immune system, muscle

Species: Rat
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland
Species: Mouse
LOAEL: 0.1%
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland

Species: Dog
LOAEL: 0.05 mg/kg
Application Route: Oral
Exposure time: 28 d
Target Organs: Blood, thymus gland, Adrenal gland

**Aspiration toxicity**
Not classified based on available information.

**Components:**

**Paraffin oil:**
The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

**Experience with human exposure**

**Components:**

**Betamethasone:**
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
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

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

**Betamethasone Cream Formulation**

**Paraffin oil:**

Toxicity to fish:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity Value</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>LL50 (Scophthalmus maximus (trobto))</td>
<td>&gt; 100 mg/l</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity Value</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EL50 (Acartia tonsa)</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity Value</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EL50 (Skeletonema costatum (marine diatom))</td>
<td>&gt; 100 mg/l</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

Toxicity to fish:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity Value</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50</td>
<td>&gt; 1 - 10 mg/l</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity Value</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>&gt; 1 - 10 mg/l</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity Value</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50</td>
<td>&gt; 10 - 100 mg/l</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

Toxicity to fish:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity Value</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>LC50 (Oncorhynchus mykiss (rainbow trout))</td>
<td>917 µg/l</td>
<td>96 h</td>
<td></td>
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</tbody>
</table>

Toxicity to daphnia and other aquatic invertebrates:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity Value</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>EC50 (Daphnia magna (Water flea))</td>
<td>1,5 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
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</tbody>
</table>

Toxicity to algae/aquatic plants:

<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity Value</th>
<th>Exposure Time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>ErC50 (Chlorella pyrenoidosa)</td>
<td>15 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
<tr>
<td>EC10 (Chlorella pyrenoidosa)</td>
<td>2,3 mg/l</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity): 1

Toxicity to fish (Chronic toxicity): NOEC (Onchorhynchus mykiss (rainbow trout)): 0,15 mg/l 
Exposure time: 28 d  
Method: OECD Test Guideline 204

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 0,32 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211

Toxicity to microorganisms: EC50: 22,86 mg/l  
Exposure time: 60 h

Betamethasone:

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
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:
Paraffin oil:
Partition coefficient: n-octanol/water: log Pow: > 4 Remarks: Calculation

4-Chloro-3-methylphenol:
Bioaccumulation: Species: Cyprinus carpio (Carp) Bioconcentration factor (BCF): 5,5 - 13 Partition coefficient: n-octanol/water: log Pow: 0,477

Betamethasone:
Partition coefficient: n-octanol/water: log Pow: 2,11

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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)  
Class : 9  
Packing group : III  
Labels : 9  

IATA-DGR  
UN/ID No. : UN 3082  
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s. (Betamethasone)  
Class : 9  
Packing group : III  
Labels : Miscellaneous  
Packing instruction (cargo aircraft) : 964  
Packing instruction (passenger aircraft) : 964  
Environmentally hazardous : yes  

IMDG-Code  
UN number : UN 3082  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)  
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.  

SECTION 15. REGULATORY INFORMATION  

Safety, health and environmental regulations/legislation specific for the substance or mixture  
Argentina. Carcinogenic Substances and Agents Registry : Not applicable  

Control of precursors and essential chemicals for the preparation of drugs : Not applicable  

International Regulations  
The ingredients of this product are reported in the following inventories:
SAFETY DATA SHEET

Betamethasone Cream Formulation

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH / TWA : USA. ACGIH Threshold Limit Values (TLV)
AR OEL / CMP : Argentina. Occupational Exposure Limits

AICS - Australian Inventory of Industrial Chemicals; ANTI - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; Q SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SDAT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.