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

1.1 Product identifier
   Trade name: Betamethasone 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: Organon & Co.
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone: 44 1 670 59 30 00
   E-mail address of person responsible for the SDS: EHSSTEWARD@organon.com

1.4 Emergency telephone number
   215-631-6999

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   Reproductive toxicity, Category 1B
   Specific target organ toxicity - repeated exposure, Category 1
   Long-term (chronic) aquatic hazard, Category 1
   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.

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:
betamethasone

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

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<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>Paraffin oil</td>
<td>8012-95-1</td>
<td>232-384-2</td>
<td></td>
<td></td>
<td>Asp. Tox. 1; H304 Aquatic Chronic 4; H413</td>
<td>&gt;= 2.5 - &lt; 10</td>
</tr>
<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 SE 3; H335 Aquatic Acute 1; H400 Aquatic Chronic 3; H412</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>206-825-4</td>
<td></td>
<td></td>
<td>Acute Tox. 2; H330 Repr. 1B; H360D STOT RE 1; H372</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

Unsuitable extinguishing media:
- None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting:
- Vapours may form explosive mixtures with air.
- 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 (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate contain-
ment to keep material from spreading. If dyked 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.

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/PERSOAL 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 vapours. 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.
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
SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
</tr>
<tr>
<td>betamethasone</td>
</tr>
</tbody>
</table>

Further information: Skin Wipe limit 10 µg/100 cm² Internal

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>Workers</td>
<td>Inhalation</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>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>
</tbody>
</table>

7.3 Specific end use(s)

Specific use(s): No data available
Paraffin oil  | Workers | Inhalation | Long-term systemic effects | 5 mg/m3  
---|---|---|---|---
| Workers | Inhalation | Short-term exposure | 5 mg/m3  
| Workers | Inhalation | Local effects | 5 mg/m3  
| Workers | Inhalation | Acute local effects | 5 mg/m3  
4-Chloro-3-methylphenol  | Workers | Inhalation | Long-term systemic effects | 6.289 mg/m3  
| Workers | Skin contact | Long-term systemic effects | 3.567 mg/kg bw/day  
| Consumers | Inhalation | Long-term systemic effects | 1.551 mg/m3  
| Consumers | Skin contact | Long-term systemic effects | 1.783 mg/kg bw/day  
| Consumers | Ingestion | Long-term systemic effects | 0.892 mg/kg bw/day  

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>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></td>
<td>Oral (Secondary Poisoning)</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**
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**
Eye protection: Wear safety glasses with side shields or goggles.
Betamethasone Cream Formulation

| Material | Chemical-resistant gloves |
| Remarks | Consider double gloving. |
| 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. |
| Respiratory protection | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387 |
| 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>5</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>$&gt; 93.3 \degree C$</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Not applicable</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>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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 : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
  Particle size : Not applicable

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 : Vapours may form explosive mixture with air.
  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
    Inhalation
    Skin contact
    Ingestion
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Betamethasone Cream Formulation

Version 6.0
Revision Date: 09.04.2021
SDS Number: 1842138-00010
Date of last issue: 10.10.2020
Date of first issue: 19.07.2017

Eye contact

Acute toxicity
Not classified based on available information.

Components:

Paraffin oil:
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
- 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: Acute toxicity estimate: 1,100 mg/kg
  Method: Expert judgement
  Remarks: Based on harmonised classification in EU regulation 1272/2008, Annex VI

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:

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:

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
Method: OECD Test Guideline 405
Result: Irreversible effects on the eye

betamethasone:
Species: Rabbit
Result: No eye irritation

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

betamethasone:
Exposure routes: Dermal
Species: Guinea pig
Result: Weak sensitizer
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

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.

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

betamethasone:
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:  
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 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:

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**
- 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**

**12.1 Toxicity**

**Components:**

- **Paraffin oil:**
  - **Toxicity to fish**
    - LL50 (Scophthalmus maximus (turbot)): > 100 mg/l
    - Exposure time: 96 h
    - Test substance: Water Accommodated Fraction
    - Remarks: Based on data from similar materials

  - **Toxicity to daphnia and other**
    - EL50 (Acartia tonsa): > 100 mg/l
### Aquatic Invertebrates
- **Toxicity to algae/aquatic plants**: Exposure time: 48 h
- Test substance: Water Accommodated Fraction
- Remarks: Based on data from similar materials

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

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

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

### 4-Chloro-3-methylphenol:
- **Toxicity to fish**: LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l
  - Exposure time: 96 h

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

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

  EC10 (Chlorella pyrenoidosa (algae)): 2.3 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

- **M-Factor (Acute aquatic toxicity)**: 1

- **Toxicity to 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

**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: 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:**

|-----------------------------|---------------------------------------------------------------------------------------------|

<table>
<thead>
<tr>
<th>4-Chloro-3-methylphenol:</th>
<th>Biodegradability: Result: Readily biodegradable. Biodegradation: 78 % Exposure time: 15 d</th>
</tr>
</thead>
</table>
12.3 Bioaccumulative potential

**Components:**

- **Paraffin oil:**
  - Partition coefficient: n-octanol/water: \( \log P \) > 4
  - Remarks: Calculation

- **4-Chloro-3-methylphenol:**
  - Bioaccumulation: Species: Cyprinus carpio (Carp)
  - Bioconcentration factor (BCF): 5.5 - 13
  - Partition coefficient: n-octanol/water: \( \log P \) = 0.477

- **Betamethasone:**
  - Partition coefficient: n-octanol/water: \( \log P \) = 2.11

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

**Product:**

- Assessment: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

**Product:**

- Endocrine disrupting potential: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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.
**SECTIONS 14: Transport information**

### 14.1 UN number

<table>
<thead>
<tr>
<th>ADN</th>
<th>: UN 3082</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>: UN 3082</td>
</tr>
<tr>
<td>RID</td>
<td>: UN 3082</td>
</tr>
<tr>
<td>IMDG</td>
<td>: UN 3082</td>
</tr>
<tr>
<td>IATA</td>
<td>: UN 3082</td>
</tr>
</tbody>
</table>

### 14.2 UN proper shipping name

<table>
<thead>
<tr>
<th>ADN</th>
<th>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)</td>
</tr>
<tr>
<td>IATA</td>
<td>Environmentally hazardous substance, liquid, n.o.s. (betamethasone)</td>
</tr>
</tbody>
</table>

### 14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th>ADN</th>
<th>: 9</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
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</tr>
<tr>
<td>RID</td>
<td>: 9</td>
</tr>
<tr>
<td>IMDG</td>
<td>: 9</td>
</tr>
<tr>
<td>IATA</td>
<td>: 9</td>
</tr>
</tbody>
</table>

### 14.4 Packing group

**ADN**

- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9

**ADR**

- Packing group: III
- Classification Code: M6
- Hazard Identification Number: 90
- Labels: 9
- Tunnel restriction code: (-)
RID
Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

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

IATA (Cargo)
Packing instruction (cargo aircraft) : 964
Packing instruction (LQ) : Y964
Packing group : III
Labels : Miscellaneous

IATA (Passenger)
Packing instruction (passenger aircraft) : 964
Packing instruction (LQ) : Y964
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)
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
REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)
  Conditions of restriction for the following entries should be considered:
  Number on list 3

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
  Not applicable

REACH - List of substances subject to authorisation (Annex XIV)
  Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer
  Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast)
  Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals
  Not applicable


Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

- 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

<table>
<thead>
<tr>
<th>H</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>H302</td>
<td>Harmful if swallowed.</td>
</tr>
<tr>
<td>H304</td>
<td>May be fatal if swallowed and enters airways.</td>
</tr>
<tr>
<td>H312</td>
<td>Harmful in contact with skin.</td>
</tr>
<tr>
<td>H314</td>
<td>Causes severe skin burns and eye damage.</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction.</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage.</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation.</td>
</tr>
<tr>
<td>H330</td>
<td>Fatal if inhaled.</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation.</td>
</tr>
<tr>
<td>H360D</td>
<td>May damage the unborn child.</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**  
according to Regulation (EC) No. 1907/2006

## Betamethasone Cream Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
<th>Date of first issue</th>
</tr>
</thead>
</table>

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 : Harmful to aquatic life with long lasting effects.
H413 : May cause long lasting harmful effects to aquatic life.

### Full text of other abbreviations

- **Acute Tox.** : Acute toxicity
- **Aquatic Acute** : Short-term (acute) aquatic hazard
- **Aquatic Chronic** : Long-term (chronic) aquatic hazard
- **Asp. Tox.** : Aspiration 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; AIIC - Australian Inventory of Industrial Chemicals; 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 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; 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
Betamethasone Cream Formulation

Version 6.0  Revision Date: 09.04.2021  SDS Number: 1842138-00010  Date of last issue: 10.10.2020
Date of first issue: 19.07.2017


Classification of the mixture:

<table>
<thead>
<tr>
<th>Class</th>
<th>Code</th>
<th>Classification procedure</th>
</tr>
</thead>
<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>
</tr>
</tbody>
</table>

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

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.

GB / EN