SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Betamethasone Cream Formulation

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 : MSD
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   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:
betamethasone

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

<table>
<thead>
<tr>
<th>Components</th>
<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>
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<tbody>
<tr>
<td></td>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>232-384-2</td>
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<td>Asp. Tox. 1; H304</td>
<td>&gt;= 1 - &lt; 10</td>
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<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
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<td>Eye Irrit. 2; H319</td>
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<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>200-431-6</td>
<td>604-014-00-3</td>
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<td>Eye Dam. 1; H318</td>
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<td>Skin Sens. 1B; H317</td>
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<td>Aquatic Acute 1; H400</td>
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<td>Aquatic Chronic 3; H412</td>
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<td>M-Factor (Acute aquatic toxicity):</td>
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<td>378-44-9</td>
<td>206-825-4</td>
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<td>Acute Tox. 2; H330</td>
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<td></td>
<td></td>
<td></td>
<td>STOT RE 1; H372</td>
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</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/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 mist or 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
7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
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<tr>
<td>Components</td>
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<td>betamethasone</td>
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<td></td>
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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>
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<tr>
<td>Alcohols, C16-18</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>237.76 mg/m^3</td>
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<td>Workers</td>
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<td>Acute systemic effects</td>
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<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
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<td>Workers</td>
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<td>Acute local effects</td>
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<tr>
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<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>200 mg/kg bw/day</td>
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<td>Workers</td>
<td>Skin contact</td>
<td>Acute systemic effects</td>
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<td>Skin contact</td>
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<td>Consumers</td>
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<td>Consumers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>118.9 mg/m^3</td>
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<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
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<td>Consumers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
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<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>100 mg/kg bw/day</td>
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<td>Skin contact</td>
<td>Acute systemic effects</td>
<td>200 mg/kg bw/day</td>
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<tr>
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<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term local effects</td>
<td>0.562 mg/cm^2</td>
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<tr>
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<td>Skin contact</td>
<td>Acute local effects</td>
<td>0.562 mg/cm^2</td>
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<td>Consumers</td>
<td>Ingestion</td>
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<td>Ingestion</td>
<td>Acute systemic effects</td>
<td>75 mg/kg bw/day</td>
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Betamethasone Cream Formulation

<table>
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<tr>
<th>Paraffin oil</th>
<th>Workers</th>
<th>Inhalation</th>
<th>Long-term systemic effects</th>
<th>5 mg/m³</th>
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<td>Long-term local effects</td>
<td>5 mg/m³</td>
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<tr>
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<td>Workers</td>
<td>Inhalation</td>
<td>Acute local effects</td>
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<td>4-Chloro-3-methylphenol</td>
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<td>Long-term systemic effects</td>
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<td>Ingestion</td>
<td>Long-term systemic effects</td>
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Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

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<th>Value</th>
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<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
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<td>Alcohols, C16-18</td>
<td>Fresh water</td>
<td>0.13 mg/l</td>
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<td>Marine water</td>
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<td>Sewage treatment plant</td>
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<td>Fresh water sediment</td>
<td>13.61 mg/kg dry weight (d.w.)</td>
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<td></td>
<td>Marine sediment</td>
<td>1.361 mg/kg dry weight (d.w.)</td>
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<tr>
<td></td>
<td>Soil</td>
<td>100 mg/kg dry weight (d.w.)</td>
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<tr>
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<td>Oral (Secondary Poisoning)</td>
<td>86.7 mg/kg food</td>
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<td>4-Chloro-3-methylphenol</td>
<td>Fresh water</td>
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<td>Intermittent use/release</td>
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<td>Sewage treatment plant</td>
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<td>Fresh water sediment</td>
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<tr>
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<td>Soil</td>
<td>6.399 mg/kg dry weight (d.w.)</td>
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</tbody>
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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.
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

**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

- **Appearance**: cream
- **Colour**: No data available
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: 5
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: > 93.3 °C
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
- **Relative density**: No data available
Betamethasone Cream Formulation

Density
Solubility(ies)
  Water solubility
Partition coefficient: n-octanol/water
Auto-ignition temperature
Decomposition temperature
Viscosity
  Viscosity, kinematic
Explosive properties
Oxidizing properties

9.2 Other information
  Flammability (liquids)
  Particle size

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
Betamethasone Cream Formulation

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 Cream Formulation

version 5.1

Revision Date: 10.10.2020

SDS Number: 1842138-00009

Date of last issue: 24.04.2020

Date of first issue: 19.07.2017

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
### Betamethasone Cream Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paraffin oil</td>
<td>Skin contact</td>
<td>10 - 30 d</td>
<td>Pituitary gland, Immune system, muscle</td>
</tr>
<tr>
<td>Mouse</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
<tr>
<td></td>
<td>Oral</td>
<td>28 d</td>
<td>Blood, thymus gland, Adrenal gland</td>
</tr>
</tbody>
</table>

**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)): > 1,028 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): > 3,193 mg/l
### aquatic invertebrates

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</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>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

NOELR (Skeletonema costatum (marine diatom)): 993 mg/l
Exposure time: 72 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

### Hexadecan-1-ol. Ethoxylated:

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Toxicity to fish

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

LC50 : > 1 - 10 mg/l
Exposure time: 96 h
Remarks: Based on data from similar materials

### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

EC50 : > 1 - 10 mg/l
Exposure time: 48 h
Remarks: Based on data from similar materials

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

EC50 : > 10 - 100 mg/l
Exposure time: 72 h
Remarks: Based on data from similar materials

### 4-Chloro-3-methylphenol:

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>96 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l
Exposure time: 96 h | Method: OECD Test Guideline 204

### Toxicity to fish

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>48 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

EC50 (Daphnia magna (Water flea)): 1.5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

ErC50 (Chlorella pyrenoidosa (algae)): 15 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>72 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

### M-Factor (Acute aquatic toxicity)

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>60 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

1

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
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</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>60 h</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

EC50 : 22.86 mg/l
Exposure time: 60 h

### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Test substance</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Accommodated Fraction</td>
<td>28 d</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

NOEC: 0.15 mg/l
Species: Oncorhynchus mykiss (rainbow trout) Method: OECD Test Guideline 204
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

Betamethasone:

- NOEC: 0.32 mg/l
- Exposure time: 21 d
- Species: Daphnia magna (Water flea)
- Method: OECD Test Guideline 211

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:**

**Paraffin oil:**

- Biodegradability: Result: Readily biodegradable.
- Biodegradation: 82%
- Exposure time: 24 d
- Method: OECD Test Guideline 301F
- Remarks: Based on data from similar materials

**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

betamethasone:
Partition coefficient: n-octanol/water: log Pow: 2.11

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 3082
ADR: UN 3082
RID: UN 3082
Betamethasone Cream Formulation

14.2 UN proper shipping name

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

14.3 Transport hazard class(es)

<table>
<thead>
<tr>
<th></th>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</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
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
Betamethasone Cream Formulation

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

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quantity 1</td>
<td>100 t</td>
</tr>
<tr>
<td>Quantity 2</td>
<td>200 t</td>
</tr>
</tbody>
</table>

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
H302 : Harmful if swallowed.
H304 : May be fatal if swallowed and enters airways.
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 : Harmful 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
according to Regulation (EC) No. 1907/2006

Betamethasone Cream Formulation

Version 5.1  Revision Date: 10.10.2020  SDS Number: 1842138-00009  Date of last issue: 24.04.2020  Date of first issue: 19.07.2017

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

Further information

Classification of the mixture: Classification procedure:
Repr. 1B H360D Calculation method
STOT RE 1 H372 Calculation method
Aquatic Chronic 1 H410 Calculation method
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