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

1.1 Product identifier
   Trade name : Betamethasone (0.05%) 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.
              30 Hudson Street, 33nd floor
              07302 Jersey City, New Jersey, U.S.A
   Telephone : 551-430-6000
   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:
Betamethasone (0.05%) Cream Formulation

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 components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).

Ecological information: 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.

Toxicological information: 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 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>200-431-6</td>
<td>604-014-00-3</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>0,1</td>
</tr>
</tbody>
</table>
Betamethasone (0.05%) Cream Formulation

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
Silicon oxides
Formaldehyde

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 method: Use extinguishing measures that are appropriate to local cir-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

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<table>
<thead>
<tr>
<th>Version</th>
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<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.5</td>
<td>09.04.2021</td>
<td>1685836-00009</td>
<td>10.10.2020</td>
<td>17.05.2017</td>
</tr>
</tbody>
</table>

ods 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.
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

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

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures:
See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation:
If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling:
Do not get on skin or clothing.
Do not breathe dust, fume, gas, mist, vapours or spray.
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

### Occupational Exposure Limits

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Vapour)</td>
<td>50 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist and particles)</td>
<td>1 mg/m³</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>TWA</td>
<td>25 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>79 mg/m³</td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: Skin
Wipe limit
10 µg/100 cm²

### Occupational exposure limits of decomposition products

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>TWA</td>
<td>0,5 ppm</td>
<td>FOR-2011-12-06-1358</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0,6 mg/m³</td>
<td></td>
</tr>
</tbody>
</table>

Further information: Substances considered to be carcinogenic, Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin.
Further information: Substances considered to be carcinogenic, Substances considered to evoke allergies when coming into touch with the eyes or airways or evoking allergies after coming into contact with the skin, Ceiling value is an instantaneous value which indicates the maximum concentration of a chemical in the breathing zone that should not be exceeded.

<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>Decamethylcyclopentasiloxane</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>97.3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Acute systemic effects</td>
<td>62 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>24.2 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>17.3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>4.3 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>5 mg/kg bw/day</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>168 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term local effects</td>
<td>10 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>50 mg/m³</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>6,289 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>3,567 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>1,551 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>1,783 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Ingestion</td>
<td>Long-term systemic effects</td>
<td>0.892 mg/kg bw/day</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance name</th>
<th>Environmental Compartment</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>Oral (Secondary Poisoning)</td>
<td>9.33 mg/kg food</td>
</tr>
<tr>
<td>Decamethylcyclopentasiloxane</td>
<td>Sewage treatment plant</td>
<td>10 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>11 mg/kg</td>
</tr>
</tbody>
</table>
### 8.2 Exposure controls

**Engineering measures**

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Essentially no open handling permitted.

Use closed processing systems or containment technologies.

**Personal protective equipment**

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

- **Hand protection**
  - **Material**: Chemical-resistant gloves

- **Remarks**: Consider double gloving.

- **Skin and body protection**
  - **Material**: 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.
SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- **Physical state**: cream
- **Colour**: white
- **Odour**: No data available
- **Odour Threshold**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flammability (solid, gas)**: Not classified as a flammability hazard
- **Flammability (liquids)**: Not applicable
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Flash point**: > 93.3 °C
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **pH**: No data available
- **Viscosity**: Not applicable
- **Solubility(ies)**: No data available
- **Water solubility**: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Vapour pressure**: No data available
- **Relative density**: No data available
- **Density**: No data available
- **Relative vapour density**: Not applicable
- **Particle characteristics**: Not applicable
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9.2 Other information

Explosives: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate: 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. Hazardous decomposition products will be formed at elevated temperatures.

10.4 Conditions to avoid
Conditions to avoid: None known.

10.5 Incompatible materials
Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products
Thermal decomposition: Formaldehyde

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008
Information on likely routes of exposure:
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Components:

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
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<thead>
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</tr>
</tbody>
</table>

**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

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

- **Acute inhalation toxicity**
  - **LC50 (Rat)**: 8.67 mg/l
  - **Exposure time**: 4 h
  - **Test atmosphere**: dust/mist
  - **Method**: OECD Test Guideline 403

- **Acute dermal toxicity**
  - **LD50 (Rabbit)**: > 2.000 mg/kg
  - **Assessment**: The substance or mixture has no acute dermal toxicity

**Skin corrosion/irritation**
Not classified based on available information.

**Components**:

**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

**Decamethylcyclopentasiloxane**:
- **Species**: Rabbit
- **Result**: No skin irritation

**Serious eye damage/eye irritation**
Not classified based on available information.

**Components**:

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

**Betamethasone:**
- Species: Rabbit
- Result: No eye irritation

**Decamethylcyclopentasiloxane:**
- 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

**Decamethylcyclopentasiloxane:**
- Test Type: Local lymph node assay (LLNA)
- Exposure routes: Skin contact
- Species: Mouse
- Result: negative

**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.

Decamethylcyclopentasiloxane:

Genotoxicity in vitro:

- Test Type: Bacterial reverse mutation assay (AMES)
  Method: OECD Test Guideline 471
  Result: negative

- Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative

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

Genotoxicity in vivo:

- Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Rat
  Application Route: Inhalation (vapour)
  Method: OECD Test Guideline 474
  Result: negative

- Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
  Species: Rat
  Application Route: Inhalation
  Method: OECD Test Guideline 486
  Result: negative

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:
Species: Rat
Application Route: Ingestion
Result: negative

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

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.

Decamethylcyclopentasiloxane:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: inhalation (vapour)
Method: OPPTS 870.3800
Result: negative

Effects on foetal development: Test Type: Two-generation reproduction toxicity study
Species: Rat
Application Route: inhalation (vapour)
Method: OPPTS 870.3800
Result: negative

STOT - single exposure
Not classified based on available information.

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

**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

**Decamethylcyclopentasiloxane:**
Species: Rat
NOAEL: 1.000 mg/kg
LOAEL: > 1.000 mg/kg
Application Route: Ingestion
Betamethasone (0.05%) Cream Formulation

Method:
OECD Test Guideline 408

Aspiration toxicity
Not classified based on available information.

11.2 Information on other hazards
Endocrine disrupting properties

Product:
Assessment: 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.

Experience with human exposure

Components:

betamethasone:

Inhalation: Target Organs: Adrenal gland
Skin contact: Symptoms: Redness, pruritus, Irritation

SECTION 12: Ecological information

12.1 Toxicity

Components:

4-Chloro-3-methylphenol:

Toxicity to fish: 
LC50 (Oncorhynhus mykiss (rainbow trout)): 917 µg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 1,5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

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

EC10 (Chlorella pyrenoidosa (aglae)): 2,3 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity):
1

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

Toxicity to fish (Chronic toxicity):
NOEC: 0,15 mg/l
<table>
<thead>
<tr>
<th>Toxicity Category</th>
<th>Endpoint</th>
<th>NOEC/EC50 (mg/l)</th>
<th>Exposure Time</th>
<th>Species</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>NOEC: 32 mg/l</td>
<td>21 days</td>
<td>Oncorhynchus mykiss (rainbow trout)</td>
<td>OECD Test Guideline 204</td>
<td></td>
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<tr>
<td>betamethasone:</td>
<td></td>
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<td></td>
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<tr>
<td>Toxicity to fish</td>
<td>NOEC: 0.052 mg/l</td>
<td>32 days</td>
<td>Pimephales promelas (fathead minnow)</td>
<td>OECD Test Guideline 210</td>
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<td></td>
<td>NOEC: 0.07 µg/l</td>
<td>219 days</td>
<td>Oryzias latipes (Japanese medaka)</td>
<td>OECD Test Guideline 229</td>
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<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>NOEC: 8 mg/l</td>
<td>21 days</td>
<td>Daphnia magna (Water flea)</td>
<td>OECD Test Guideline 211</td>
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<tr>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>1.000</td>
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<tr>
<td>Decamethylcyclopentasiloxane:</td>
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<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 16 µg/l</td>
<td>96 h</td>
<td></td>
<td>No toxicity at the limit of solubility</td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 2.9 µg/l</td>
<td>48 h</td>
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<td>No toxicity at the limit of solubility</td>
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<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>ErC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 12</td>
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</tbody>
</table>
plants µg/l
Exposure time: 96 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

EC10 (Pseudokirchneriella subcapitata (green algae)): > 12 µg/l
Exposure time: 96 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to microorganisms: EC50: > 2.000 mg/l
Exposure time: 3 h
Method: 88/302/EC

Toxicity to fish (Chronic toxicity): NOEC: 14 µg/l
Exposure time: 90 d
Species: Oncorhynchus mykiss (rainbow trout)
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 15 µg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

12.2 Persistence and degradability

Components:

4-Chloro-3-methylphenol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 78 %
Exposure time: 15 d
Method: OECD Test Guideline 301

Decamethylcyclopentasiloxane:
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 0,14 %
Exposure time: 28 d
Method: OECD Test Guideline 310

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 (0.05%) Cream Formulation**

### SAFETY DATA SHEET

**According to Regulation (EC) No. 1907/2006**

**Betamethasone (0.05%) 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>
<tbody>
<tr>
<td>3.5</td>
<td>09.04.2021</td>
<td>1685836-00009</td>
<td>10.10.2020</td>
<td>17.05.2017</td>
</tr>
</tbody>
</table>

---

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

**Product:**

Assessment: This substance/mixture contains components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB).

**Components:**

**Decamethylcyclopentasiloxane:**

Assessment:

- This substance is considered to be persistent, bioaccumulating and toxic (PBT).
- This substance is considered to be very persistent and very bioaccumulating (vPvB).

---

**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.
SECTION 14: Transport information

14.1 UN number or ID number

<p>| | | |</p>
<table>
<thead>
<tr>
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<tr>
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<tr>
<td>IATA</td>
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<td>UN 3077</td>
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14.2 UN proper shipping name

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<tr>
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<th>ENVIROMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)</th>
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<tr>
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<td>IMDG</td>
<td>:</td>
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<tr>
<td>IATA</td>
<td>:</td>
<td>Environmentally hazardous substance, solid, n.o.s. (betamethasone)</td>
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14.3 Transport hazard class(es)

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<td>IMDG</td>
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</tr>
<tr>
<td>IATA</td>
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</table>

14.4 Packing group

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<tr>
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<td>Tunnel restriction code</td>
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SAFETY DATA SHEET
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Betamethasone (0.05%) Cream Formulation

Version 3.5 Revision Date: 09.04.2021 SDS Number: 1685836-00009 Date of last issue: 10.10.2020
Date of first issue: 17.05.2017

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

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

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

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

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
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 Maritime transport in bulk according to IMO instruments
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)

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).
REACH - List of substances subject to authorisation (Annex XIV)

Conditions of restriction for the following entries should be considered:
Decamethylcyclopentasiloxane (Number on list 70)

Decamethylcyclopentasiloxane
Not applicable
Not applicable
Not applicable
Not applicable


Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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

AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H302: Harmful if swallowed.
H312: Harmful in contact with skin.
H314: Causes severe skin burns and eye damage.
H317: May cause an allergic skin reaction.
H318: Causes serious eye damage.
H330: Fatal if inhaled.
H335: May cause respiratory irritation.
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Betamethasone (0.05%) Cream Formulation

Version: 3.5
Revision Date: 09.04.2021
SDS Number: 1685836-0009
Date of last issue: 10.10.2020
Date of first issue: 17.05.2017

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>H360D</td>
<td>May damage the unborn child.</td>
</tr>
<tr>
<td>H372</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life.</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects.</td>
</tr>
<tr>
<td>H412</td>
<td>Harmful to aquatic life with long lasting effects.</td>
</tr>
</tbody>
</table>

Full text of other abbreviations:

- Acute Tox.: Acute toxicity
- Aquatic Acute: Short-term (acute) aquatic hazard
- Aquatic Chronic: Long-term (chronic) aquatic hazard
- Eye Dam.: Serious eye damage
- 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
- FOR-2011-12-06-1358: Norway. Occupational Exposure limits
- 2004/37/EC: Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
- FOR-2011-12-06-1358 / TWA: Ceiling

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;
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SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bio-accumulative

Further information

Classification of the mixture:

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<thead>
<tr>
<th>Category</th>
<th>Code</th>
<th>Calculation method</th>
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<td>Repr. 1B</td>
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<tr>
<td>STOT RE 1</td>
<td>H372</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
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<td>Calculation method</td>
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</table>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

NO / EN