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

Betamethasone (0.05%) Cream Formulation

Version 3.5  Revision Date: 09.04.2021  SDS Number: 1685840-00009  Date of last issue: 10.10.2020

Date of first issue: 17.05.2017

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:
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>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</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></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 M-Factor (Acute aquatic toxicity): 1</td>
</tr>
</tbody>
</table>

Concentration (% w/w): 0.1
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Betamethasone (0.05%) Cream Formulation  

Acute toxicity estimate  
Acute dermal toxicity: 1,100 mg/kg  

betamethasone  
378-44-9  
206-825-4  

Acute Tox. 2; H330  
Repr. 1B; H360D  
STOT RE 1; H372  
(Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)  
Aquatic Chronic 1; H410  

M-Factor (Chronic aquatic toxicity): 1,000  

specific concentration limit  
STOT RE 1; H372  
>= 0.01 %  
Repr. 1B; H360D  
>= 0.01 %  

PBT and vPvB substance :  
Decamethylcyclopentasiloxane  
541-02-6  
208-764-9  

For explanation of abbreviations see section 16.  

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 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. 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

<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>OELV - 8 hrs (TWA) (inhalable fraction)</td>
<td>5 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>OELV - 8 hrs (TWA) (particles)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA) (total (vapour and particles))</td>
<td>150 ppm 470 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>OELV - 8 hrs (TWA)</td>
<td>10 mg/m³</td>
<td>IE OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Further information: Where no specific short-term exposure limit is listed, a figure three times the long-term exposure limit value should be used.</td>
<td></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>
<tr>
<td></td>
<td></td>
<td>Further information: Skin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>
### 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>OELV - 15 min (STEL)</td>
<td>0.6 ppm</td>
<td>0.738 mg/m3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>OELV - 8 hrs (TWA)</td>
<td>0.3 ppm</td>
<td>0.37 mg/m3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL</td>
<td>0.6 ppm</td>
<td>0.74 mg/m3</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>0.3 ppm</td>
<td>0.37 mg/m3</td>
</tr>
</tbody>
</table>

Further information: Chemical agents which following exposure may cause sensitisation of the respiratory tract and lead to asthma, rhinitis or extrinsic allergic alveolitis, Carc 1B - Substances presumed to have carcinogenic potential for humans.

### 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>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>
</tbody>
</table>
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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>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>
<tr>
<td></td>
<td>Marine sediment</td>
<td>1.1 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>3.77 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Oral (Secondary Poisoning)</td>
<td>13 mg/kg food</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>Fresh water</td>
<td>260 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>26 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>183 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>20000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>572 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>57.2 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>50 mg/kg</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>Fresh water</td>
<td>0.015 mg/l</td>
</tr>
<tr>
<td></td>
<td>Intermittent use/release</td>
<td>0.015 mg/l</td>
</tr>
<tr>
<td></td>
<td>Marine water</td>
<td>0.002 mg/l</td>
</tr>
<tr>
<td></td>
<td>Sewage treatment plant</td>
<td>2.286 mg/l</td>
</tr>
<tr>
<td></td>
<td>Fresh water sediment</td>
<td>13.981 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Marine sediment</td>
<td>13.981 mg/kg dry weight (d.w.)</td>
</tr>
<tr>
<td></td>
<td>Soil</td>
<td>6.399 mg/kg dry weight (d.w.)</td>
</tr>
</tbody>
</table>

8.2 Exposure controls

Engineering measures
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., vacuum conveying from a closed system, packout head with inflatable seal from stationary container, ventilated enclosure, etc.).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Essentially no open handling permitted.
Use closed processing systems or containment technologies.

Personal protective equipment

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

Hand protection

Material : Chemical-resistant gloves
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 I.S. EN 14387
Filter type: Combined particulates, inorganic gas/vapour and organic vapour type (AB-P)

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
  Decomposition temperature: No data available
pH: No data available
Viscosity
  Viscosity, kinematic: Not applicable
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
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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
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
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
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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:
- 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.

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:
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:
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
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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
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, pruritis, Irritation

SECTION 12: Ecological information

12.1 Toxicity
Components:
4-Chloro-3-methylphenol:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 917 µg/l
Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 1.5 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants: ErC50 (Chlorella pyrenoidosa (aglae)): 15 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
EC10 (Chlorella pyrenoidosa (aglae)): 2.3 mg/l
Exposure time: 72 h
**Betamethasone (0.05%) Cream Formulation**

<table>
<thead>
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<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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<td>1685840-00009</td>
<td>10.10.2020</td>
<td>17.05.2017</td>
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**M-Factor (Acute aquatic toxicity):**

<table>
<thead>
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<th>Method: OECD Test Guideline 201</th>
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<tbody>
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<td>1</td>
</tr>
</tbody>
</table>

**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 |

**Decamethylcyclopentasiloxane:**

**Toxicity to fish:**

| LC50 (Oncorhynchus mykiss (rainbow trout)): > 16 µg/l |
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Exposure time: 96 h
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 2.9 µg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: No toxicity at the limit of solubility

Toxicity to algae/aquatic plants:
ErC50 (Pseudokirchneriella subcapitata (green algae)): > 12 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:**

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

**Decamethylcyclopentasiloxane:**

- **Bioaccumulation:** Species: *Pimephales promelas* (fathead minnow)
  Bioconcentration factor (BCF): 7,060 - 13,300
  Method: OECD Test Guideline 305

- **Partition coefficient: n-octanol/water:** log Pow: 8.023

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 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.

12.7 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 or ID number

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<th>Code</th>
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<td>ADN</td>
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<td>IMDG</td>
<td>UN 3077</td>
</tr>
<tr>
<td>IATA</td>
<td>UN 3077</td>
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</table>

14.2 UN proper shipping name

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<td>ADN</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)</td>
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<tr>
<td>ADR</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)</td>
</tr>
<tr>
<td>RID</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)</td>
</tr>
<tr>
<td>IMDG</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)</td>
</tr>
<tr>
<td>IATA</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>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
</tr>
</tbody>
</table>

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

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

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

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

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

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

### 14.5 Environmental hazards

**ADN**
- Environmentally hazardous: yes

**ADR**
- Environmentally hazardous: yes

**RID**
- Environmentally hazardous: yes

**IMDG**
- Marine pollutant: yes

**IATA (Passenger)**
- Environmentally hazardous: yes

**IATA (Cargo)**
- Environmentally hazardous: yes
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according to Regulation (EC) No. 1907/2006

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Date of first issue: 17.05.2017

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Decamethylcyclopentasiloxane

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


<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
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<tr>
<td>100 t</td>
<td>200 t</td>
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</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
SAFETY DATA SHEET
generated by Regulation (EC) No. 1907/2006

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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.
H360D: Causes damage to organs through prolonged or repeated exposure.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.
H412: Hazardous to aquatic life with long lasting effects.

Full text of other abbreviations:

Acute Tox.: Acute toxicity
Aquatic Acute: Short-term (acute) aquatic hazard
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
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
IE OEL: Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
2004/37/EC / STEL: Short term exposure limit
2004/37/EC / TWA: Long term exposure limit
IE OEL / OELV - 8 hrs (TWA): Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL): Occupational exposure limit value (15-minute reference period)

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
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- 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


Classification of the mixture:

<table>
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<th>Classification procedure:</th>
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<tbody>
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<td>Repr. 1B</td>
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<tr>
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<td>H372</td>
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<tr>
<td>Aquatic Chronic 1</td>
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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.

IE / EN