Betamethasone (0.05%) Cream Formulation

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone (0.05%) Cream Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 199 Wenhai North Road
          HEDA, Hangzhou - Zhejiang Province - CHINA 310018
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance: cream
Colour: white
Odour: No data available

May damage the unborn child. Causes damage to organs through prolonged or repeated exposure. Very toxic to aquatic life with long lasting effects.

GHS Classification
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms: 

Signal word: Danger
Hazard statements: H360D May damage the unborn child.
H372 Causes damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements:

Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P391 Collect spillage.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Physical and chemical hazards
Not classified based on available information.

Health hazards
May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

Environmental hazards
Very toxic to aquatic life with long lasting effects.

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 20 - &lt;= 30</td>
</tr>
<tr>
<td>Decamethylcyclopentasiloxane</td>
<td>541-02-6</td>
<td>7</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>3</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>0.1</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>0.064</td>
</tr>
</tbody>
</table>

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
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When symptoms persist or in all cases of doubt seek medical advice.

If inhaled: If inhaled, remove to fresh air. Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: May damage the unborn child. Causes damage to organs through prolonged or repeated exposure.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

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

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spills cannot be contained.

Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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 swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact: Oxidizing agents

Storage
Conditions for safe storage: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Materials to avoid: Do not store with the following product types: Strong oxidizing agents

Packaging material: Unsuitable material: None known.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
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Glyceryl monostearate  123-94-4  TWA (Inhalable particulate matter)  10 mg/m³  ACGIH
betamethasone  378-44-9  TWA  1 µg/m³ (OEB 4)  Internal

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

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 / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>MAC</td>
<td>0.5 mg/m³</td>
<td>GBZ 2.1-2007</td>
</tr>
</tbody>
</table>

Further information: G1 - Carcinogenic to humans, Sensitizing TWA 0.1 ppm ACGIH STEL 0.3 ppm ACGIH

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

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Combined particulates, inorganic gas/vapour and organic vapour type

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

Skin and body protection: Work uniform or laboratory coat. Additional body garments 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.

Hand protection

Material: Chemical-resistant gloves
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Remarks: Consider double gloving.

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

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

10. STABILITY AND REACTIVITY
Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions:
  Vapours may form explosive mixture with air.
  Can react with strong oxidizing agents.
  Hazardous decomposition products will be formed at elevated temperatures.
Conditions to avoid: None known.
Incompatible materials: Oxidizing agents

Hazardous decomposition products:
  Thermal decomposition: Formaldehyde

11. TOXICOLOGICAL INFORMATION
Exposure routes:
  Skin contact
  Ingestion
  Eye contact

Acute toxicity:
Not classified based on available information.

Product:
Acute inhalation toxicity: Acute toxicity estimate: > 10 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: Calculation method

Components:
Petrolatum:
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  Method: OECD Test Guideline 401
### Acute dermal toxicity

- **Betamethasone (0.05%) Cream Formulation**

  - **LD50 (Rat):** > 2,000 mg/kg
  - **Method:** OECD Test Guideline 402
  - **Assessment:** The substance or mixture has no acute dermal toxicity
  - **Remarks:** Based on data from similar materials

#### 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

#### Glyceryl monostearate:

- **Acute oral toxicity:**
  - **LD50 (Rat):** > 5,000 mg/kg
  - **Method:** OECD Test Guideline 401
  - **Remarks:** Based on data from similar materials

- **Acute dermal toxicity:**
  - **LD50 (Rat):** > 2,000 mg/kg
  - **Remarks:** Based on data from similar materials

#### 4-Chloro-3-methylphenol:

- **Acute oral toxicity:**
  - **LD50 (Mouse):** 600 mg/kg

- **Acute inhalation toxicity:**
  - **LC50 (Rat):** > 2.871 mg/l
  - **Exposure time:** 4 h
  - **Test atmosphere:** dust/mist

- **Acute dermal toxicity:**
  - **LD50 (Rat):** > 5,000 mg/kg

#### betamethasone:

- **Acute oral toxicity:**
  - **LD50 (Rat):** > 5,000 mg/kg
  - **LD50 (Mouse):** > 4,500 mg/kg

- **Acute inhalation toxicity:**
  - **LC50 (Rat):** 0.4 mg/l
  - **Exposure time:** 4 h

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Petrolatum:
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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Version: 3.3
Revision Date: 2020/03/23
SDS Number: 1682154-00007
Date of last issue: 2019/09/13
Date of first issue: 2017/05/17

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

Decamethylcyclopentasiloxane:
Species: Rabbit
Result: No skin irritation

Glyceryl monostearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Corrosive after 1 to 4 hours of exposure

Betamethasone:
Species: Rabbit
Result: Mild skin irritation

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

Components:

Petrolatum:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

Decamethylcyclopentasiloxane:
Species: Rabbit
Result: No eye irritation

Glyceryl monostearate:
Species: Rabbit
Result: No eye irritation
Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:
Species: Rabbit
Result: Irreversible effects on the eye
Method: OECD Test Guideline 405
Betamethasone (0.05%) Cream Formulation

Version: 3.3  Revision Date: 2020/03/23  SDS Number: 1682154-00007  Date of last issue: 2019/09/13
Date of first issue: 2017/05/17

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:

Petrolatum:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

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

Glyceryl monostearate:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

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:

Petrolatum:
Genotoxicity in vitro:
- Test Type: Chromosome aberration test in vitro
  - Result: negative
  - Remarks: Based on data from similar materials

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

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

Glyceryl monostearate:
Genotoxicity in vitro:
- Test Type: Chromosome aberration test in vitro
  - Method: OECD Test Guideline 473
  - Result: negative
  - Remarks: Based on data from similar materials

  Test Type: Bacterial reverse mutation assay (AMES)
  - Method: OECD Test Guideline 471
  - Result: negative
  - Remarks: Based on data from similar materials

  Test Type: In vitro mammalian cell gene mutation test
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Result: negative
Remarks: Based on data from similar materials

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

Betamethasone:
Genotoxicity in vitro:
: Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative

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

: Test Type: Chromosome aberration test in vitro
  Result: positive

Genotoxicity in vivo:
: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Oral
  Result: equivocal

Germ cell mutagenicity:
Assessment:
: Weight of evidence does not support classification as a germ cell mutagen.

Carcinogenicity:
Not classified based on available information.

Components:
Petrolatum:
Species:
: Rat
Application Route:
: Ingestion
Exposure time:
: 2 Years
Result:
: negative

Reproductive toxicity:
May damage the unborn child.

Components:
Petrolatum:
Effects on fertility:
: Test Type: Reproduction/Developmental toxicity screening test
  Species: Rat
  Application Route: Ingestion
  Result: negative
  Remarks: Based on data from similar materials

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

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

Glyceryl monostearate:
Effects on fertility : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

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

Effects on 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:**

Petrolatum:
Species: Rat
NOAEL: 5,000 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

Decamethylcyclopentasiloxane:
Species: Rat
NOAEL: 1,000 mg/kg
LOAEL: > 1,000 mg/kg
Application Route: Ingestion
Method: OECD Test Guideline 408

Glyceryl monostearate:
Species: Rat
SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

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Version: 3.3
Revision Date: 2020/03/23
SDS Number: 1682154-00007
Date of last issue: 2019/09/13
Date of first issue: 2017/05/17

NOAEL: \( \geq 12,500 \text{ mg/kg} \)
Application Route: Ingestion
Exposure time: 84 Days
Remarks: Based on data from similar materials

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

betamethasone:
Species: Rabbit
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 10 - 30 d
Target Organs: Pituitary gland, Immune system, muscle
Species: Rat
LOAEL: 0.05 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland
Species: Mouse
LOAEL: 0.1 %
Application Route: Skin contact
Exposure time: 8 Weeks
Target Organs: thymus gland
Species: Dog
LOAEL: 0.05 mg/kg
Application Route: Oral
Exposure time: 28 d
Target Organs: Blood, thymus gland, Adrenal gland

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

betamethasone:
Inhalation: Target Organs: Adrenal gland
Skin contact: Symptoms: Redness, pruritis, Irritation
12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Petrolatum:

Toxicity to fish: LL50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h
Test substance: Water Accommodated Fraction
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 10,000 mg/l
Exposure time: 48 h
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

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

Decamethylcyclopentasiloxane:

Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 16 µg/l
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 fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): 14 µg/l
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<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>
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<td>3.3</td>
<td>2020/03/23</td>
<td>1682154-00007</td>
<td>2019/09/13</td>
<td>2017/05/17</td>
</tr>
</tbody>
</table>

**Glyceryl monostearate:**

Toxicity to fish:

- **LL50** (Leuciscus idus (Golden orfe)): > 100 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 210
  - Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:

- **EL50** (Daphnia magna (Water flea)): > 32 mg/l
  - Exposure time: 47 h
  - Remarks: No toxicity at the limit of solubility
  - Based on data from similar materials

Toxicity to algae/aquatic plants:

- **EL50** (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

  - **NOELR** (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
    - Exposure time: 72 h
    - Test substance: Water Accommodated Fraction
    - Method: OECD Test Guideline 201
    - Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity):

- **NOELR** (Oryzias latipes (Japanese medaka)): > 1 mg/l
  - Exposure time: 14 d
  - Method: OECD Test Guideline 204
  - Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- **NOEC** (Daphnia magna (Water flea)): > 0.22 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211
  - Remarks: No toxicity at the limit of solubility
  - Based on data from similar materials

Toxicity to microorganisms:

- **EC10** (Pseudomonas putida): > 1 mg/l
  - Exposure time: 18 h
  - Remarks: Based on data from similar materials
### 4-Chloro-3-methylphenol:

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

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

- **Toxicity to algae/aquatic plants**
  - EC50 (Chlorella pyrenoidosa (aglae)): 15 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

  - ErC50: 22.86 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201

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

- **Toxicity to fish (Chronic toxicity)**
  - NOEC (Oncorhynchus mykiss (rainbow trout)): 0.15 mg/l
  - Exposure time: 28 d
  - Method: OECD Test Guideline 204

- **Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**
  - NOEC (Daphnia magna (Water flea)): 0.32 mg/l
  - Exposure time: 21 d
  - Method: OECD Test Guideline 211

- **Toxicity to microorganisms**
  - EC50: 22.86 mg/l
  - Exposure time: 60 h

### Betamethasone:

- **Toxicity to daphnia and other aquatic invertebrates**
  - EC50 (Americamysis): > 50 mg/l
  - Exposure time: 96 h

- **Toxicity to algae/aquatic plants**
  - EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

  - NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: No toxicity at the limit of solubility

- **Toxicity to fish (Chronic toxicity)**
  - NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l
  - Exposure time: 32 d
  - Method: OECD Test Guideline 210

  - NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l
  - Exposure time: 219 d
  - Method: OECD Test Guideline 229
Betamethasone (0.05%) Cream Formulation

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 8 mg/l
- Exposure time: 21 d
- Method: OECD Test Guideline 211

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

Persistence and degradability

Components:

Petrolatum:
- Biodegradability: Result: Not readily biodegradable.
- Biodegradation: 31 %
- Exposure time: 28 d
- Method: OECD Test Guideline 301F
- Remarks: Based on data from similar materials

Decamethylcyclopentasiloxane:
- Biodegradability: Result: Not readily biodegradable.
- Biodegradation: 0.14 %
- Exposure time: 28 d
- Method: OECD Test Guideline 310

Glyceryl monostearate:
- Biodegradability: Result: Readily biodegradable.
- Remarks: Based on data from similar materials

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

Bioaccumulative potential

Components:

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

Glyceryl monostearate:
- Partition coefficient: n-octanol/water: log Pow: 6.1

4-Chloro-3-methylphenol:
- Bioaccumulation: Species: Cyprinus carpio (Carp)
  Bioconcentration factor (BCF): 5.5 - 13
Betamethasone (0.05%) Cream Formulation

Partition coefficient: n-octanol/water
betamethasone: log Pow: 0.477

Mobility in soil
No data available

Other adverse effects
No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Dispose of in accordance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3077
Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (betamethasone)
Class: 9
Packing group: III
Labels: Miscellaneous,
Packing instruction (cargo aircraft): 956
Packing instruction (passenger aircraft): 956
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3077
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Class: 9
Subsidiary risk: ENVIRONM.
Betamethasone (0.05%) Cream Formulation

Version 3.3  Revision Date: 2020/03/23  SDS Number: 1682154-00007  Date of last issue: 2019/09/13  Date of first issue: 2017/05/17

Packing group: III  Labels: 9 (ENVIRONM.)  EmS Code: F-A, S-F  Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

GB 6944/12268
UN number: UN 3077  Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (betamethasone)
Class: 9  Packing group: III  Labels: 9

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.

15. REGULATORY INFORMATION

National regulatory information
Law on the Prevention and Control of Occupational Diseases

The components of this product are reported in the following inventories:
AICS: not determined  DSL: not determined  IECSC: not determined

16. OTHER INFORMATION

Further information
Date format: yyyy/mm/dd

Full text of other abbreviations
Betamethasone (0.05%) Cream Formulation

ACGIH / TWA : 8-hour, time-weighted average
ACGIH / STEL : Short-term exposure limit
GBZ 2.1-2007 / MAC : Maximum allowable concentration

AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemicals and Chemical Substances; IECSC - Inventory of Existing Chemicals and Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

Disclaimer
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.