SAFETY DATA SHEET
Betamethasone (0.05%) Cream Formulation

Version 2.7 Revision Date: 2021/04/09 SDS Number: 1682151-00009 Date of last issue: 2020/10/10 Date of first issue: 2017/05/17

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Betamethasone (0.05%) Cream Formulation

Manufacturer or supplier’s details
Company: Organon & Co.
Address: JL Raya Pandaan KM. 48
Pandaan, Jawa Timur - Indonesia
Telephone: 551-430-6000
Emergency telephone number: 215-631-6999
E-mail address: EHSSTEWARD@organon.com

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

2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity: Category 1B
Specific target organ toxicity - repeated exposure: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) 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.

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>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.
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 (see section 7) and personal protective equipment recommendations (see section 8).

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.

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

Technical measures:
- See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation:
- If sufficient ventilation is unavailable, use with local exhaust ventilation.
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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.

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

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>NAB (Mist)</td>
<td>5 mg/m3</td>
<td>ID OEL</td>
</tr>
<tr>
<td>Glyceryl monostearate</td>
<td>123-94-4</td>
<td>NAB</td>
<td>10 mg/m3</td>
<td>ID OEL</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>PSD</td>
<td>0.3 ppm</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

Further information:
- Sampled by a method that does not collect vapour.
- Not classified as carcinogenic to humans. Not enough data to classify these materials as carcinogenic to humans or animals.
- Skin Wipe limit 10 µg/100 cm²

Occupational exposure limits of decomposition products

<table>
<thead>
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<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formaldehyde</td>
<td>50-00-0</td>
<td>PSD</td>
<td>0.3 ppm</td>
<td>ID OEL</td>
</tr>
</tbody>
</table>

Further information: Skin Wipe limit 10 µg/100 cm²

Internal
Engineering measures:

Further information: Dermal Sensitization, Respiratory Sensitization, Suspected human carcinogen

<table>
<thead>
<tr>
<th></th>
<th>TWA</th>
<th>STEL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.1 ppm</td>
<td>0.3 ppm</td>
</tr>
</tbody>
</table>

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

Hand protection

Material: Chemical-resistant gloves

Remarks: Consider double gloving.

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.

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.

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

Appearance: cream

Colour: white
10. STABILITY AND REACTIVITY

Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: > 93.3 °C
Evaporation rate: Not applicable
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
Vapour pressure: No data available
Relative vapour density: Not applicable
Relative density: No data available
Density: No data available
Solubility(ies)
  Water solubility: No data available
Partition coefficient: n-octanol/water: Not applicable
Auto-ignition temperature: No data available
Decomposition temperature: No data available
Viscosity
  Viscosity, kinematic: Not applicable
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
Particle size: Not applicable
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

Information on likely routes of exposure:
- Skin contact
- Ingestion
- Eye contact

### Acute toxicity
Not classified based on available information.

**Components:**

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

**Glyceryl monostearate:**
- Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
  Method: OECD Test Guideline 401
  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
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:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

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

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:**
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

**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

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
- 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
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

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 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) 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

Glyceryl monostearate:
Betamethasone (0.05%) Cream Formulation

Species: Rat
NOAEL: >= 12,500 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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 10 mg/l
Exposure time: 21 d
Test substance: Water Accommodated Fraction
Remarks: Based on data from similar materials

Glyceryl monostearate:
Toxicity to fish : LL50 (Leuciscus idus (Golden orfe)): > 100 mg/l
Exposure time: 48 h
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 (Oncomorhynchus mykiss (rainbow trout)): 917 µg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:

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

Toxicity to algae/aquatic plants:

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

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

M-Factor (Acute aquatic toxicity):

1

Toxicity to fish (Chronic toxicity):

NOEC (Oncomorhynchus 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

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

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:

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
Partition coefficient: n-octanol/water  
betamethasone:  
Partition coefficient: n-octanol/water  
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
Packing group: III
Labels: 9
15. REGULATORY INFORMATION

**Safety, health and environmental regulations/legislation specific for the substance or mixture**

Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health

- Hazardous substances that must be registered: Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances

- Hazardous substances approved for use: Not applicable
- Prohibited substances: Not applicable
- Restricted substances: Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials

Type of Hazardous Materials Restricted to Import, Distribution and Supervision: Not applicable

**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**

Sources of key data used to: Internal technical data, data from raw material SDSs, OECD
SAFETY DATA SHEET
Betamethasone (0.05%) Cream Formulation

Version: 2.7  
Revision Date: 2021/04/09  
SDS Number: 1682151-00009  
Date of last issue: 2020/10/10  
Date of first issue: 2017/05/17

Full text of other abbreviations:
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
ID OEL: Indonesia. Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
ACGIH / STEL: Short-term exposure limit
ID OEL / NAB: Long term exposure limit
ID OEL / PSD: Short term exposure limit

Date format: yyyy/mm/dd

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.