SAFETY DATA SHEET
Betamethasone Cream Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Betamethasone Cream Formulation

Manufacturer or supplier’s details
Company : Organon & Co.
Address : Rua Treze de Maio, 1161
Campinas, São Paulo, Brazil B-2220

Telephone : 551-430-6000
Emergency telephone : 215-631-6999
E-mail address : EHSSTEWARD@organon.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard
Reproductive toxicity : Category 1B
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard : Category 3
Long-term (chronic) aquatic hazard : Category 1

GHS label elements in accordance with ABNT NBR 14725 Standard
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.
H402 Harmful to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements :
Prevention:
P201 Obtain special instructions before use.
P264 Wash skin thoroughly after handling.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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

Other hazards which do not result in classification
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>Aspiration hazard, Category 1 Long-term (chronic) aquatic hazard, Category 4</td>
<td>&gt;= 10 &lt; 20</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>Acute toxicity (Oral), Category 5 Eye irritation, Category 2A Short-term (acute) aquatic hazard, Category 2</td>
<td>&gt;= 5 &lt; 10</td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td>Acute toxicity (Oral), Category 4 Skin corrosion, Category 1C Serious eye damage, Category 1 Skin sensitization, Sub-category 1B Specific target organ toxicity - single exposure, Category 3 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 3</td>
<td>&gt;= 1 &lt; 2,5</td>
</tr>
<tr>
<td>4-Chloro-3-methylphenol</td>
<td>59-50-7</td>
<td>Acute toxicity (Oral), Category 4 Skin corrosion, Category 1C Serious eye damage, Category 1 Skin sensitization, Sub-category 1B Specific target organ toxicity - single exposure, Category 3 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 3</td>
<td>&gt;= 0,1 &lt; 0,25</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>Acute toxicity (Inhalation), Category 2 Reproductive toxicity,</td>
<td>&gt;= 0,025 &lt; 0,1</td>
</tr>
</tbody>
</table>
**SAFETY DATA SHEET**

**Betamethasone Cream Formulation**

Version 5.2  
Revision Date: 09.04.2021  
SDS Number: 1841218-00010  
Date of last issue: 10.10.2020  
Date of first issue: 19.07.2017

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### SECTION 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.

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### SECTION 5. FIRE-FIGHTING MEASURES

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

- **Unsuitable extinguishing media**: None known.

- **Specific hazards during firefighting**: Vapors may form explosive mixtures with air. Exposure to combustion products may be a hazard to health.

- **Hazardous combustion products**: Carbon oxides
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 fire-fighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

SECTION 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. Prevent spreading over a wide area (e.g., by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Soak up with inert absorbent material. For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSOAL 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 vapors. 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.

Conditions for safe storage:
- Keep in properly labeled 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
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients 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>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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

Engineering measures:
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- Essentially no open handling permitted.
- Use closed processing systems or containment technologies.
- If handled in a laboratory, use a properly designed biosafety cabinet, fume hood, or other containment device if the potential exists for aerosolization. If this potential does not exist, handle over lined trays or benchtops.

Personal protective equipment:
- Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the
Filter type
Hand protection

Material
Hand protection

Remarks
Eye protection

Skin and body protection

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance
Color
Odor
Odor Threshold
pH
Melting point/freezing point
Initial boiling point and boiling range
Flash point
Evaporation rate
Flammability (solid, gas)
Flammability (liquids)
Upper explosion limit / Upper flammability limit
Lower explosion limit / Lower flammability limit
Vapor pressure
Relative vapor density
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : No data available
Partition coefficient: n-octanol/water : Not applicable
Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.
Particle size : Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions :
Vapors may form explosive mixture with air.
Can react with strong oxidizing agents.
Conditions to avoid : None known.
Incompatible materials : Oxidizing agents
Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity : Acute toxicity estimate: > 5.000 mg/kg
Method: Calculation method

Components:
Petrolatum:
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

**Method:** OECD Test Guideline 402
**Assessment:** The substance or mixture has no acute dermal toxicity
**Remarks:** Based on data from similar materials

**Paraffin oil:**
- **Acute oral toxicity**
  LD50 (Rat): > 5,000 mg/kg
- **Acute dermal toxicity**
  LD50 (Rabbit): > 2,000 mg/kg
  **Assessment:** The substance or mixture has no acute dermal toxicity
  **Remarks:** Based on data from similar materials

**Hexadecan-1-ol. Ethoxylated:**
- **Acute oral toxicity**
  LD50 (Rat): 2,500 mg/kg

**4-Chloro-3-methylphenol:**
- **Acute oral toxicity**
  LD50 (Mouse): 600 mg/kg
- **Acute inhalation toxicity**
  LC50 (Rat): > 2,871 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
- **Acute dermal toxicity**
  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:**
- **Species**
  Rabbit
- **Method**
  OECD Test Guideline 404
- **Result**
  No skin irritation
- **Remarks**
  Based on data from similar materials

**Paraffin oil:**
- **Species**
  Rabbit
- **Result**
  No skin irritation
4-Chloro-3-methylphenol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: Corrosive after 1 to 4 hours of exposure

Betamethasone:
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

Paraffin oil:
Species: Rabbit
Result: No eye irritation

Hexadecan-1-ol. Ethoxylated:
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on data from similar materials

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

Betamethasone:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

Petrolatum:
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative

Remarks: Based on data from similar materials

4-Chloro-3-methylphenol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Assessment: Probability or evidence of low to moderate skin sensitization rate in humans

Betamethasone:
Routes of exposure: 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

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 fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Skin contact
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 fetal development : Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative

Betamethasone:
Effects on fetal 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 y

Paraffin oil:
Species : Rat, female  
LOAEL : 161 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

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

**Betamethasone**:  
**Species**: Rabbit  
**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.

**Components:**  
**Paraffin oil:**  
The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

**Experience with human exposure**  
**Components:**

**Betamethasone:**  
**Inhalation**: Target Organs: Adrenal gland  
**Skin contact**: Symptoms: Redness, pruritis, Irritation

**SECTION 12. ECOLOGICAL INFORMATION**

**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

Paraffin oil:  
Toxicity to fish  
LL50 (Scophthalmus maximus (turbot)): > 100 mg/l  
Exposure time: 96 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates  
EL50 (Acartia tonsa): > 100 mg/l  
Exposure time: 48 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants  
EL50 (Skeletonema costatum (marine diatom)): > 100 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

Hexadecan-1-ol. Ethoxylated:  
Toxicity to fish  
LC50: > 1 - 10 mg/l  
Exposure time: 96 h  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates  
EC50: > 1 - 10 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants  
EC50: > 10 - 100 mg/l  
Exposure time: 72 h
### 4-Chloro-3-methylphenol:

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

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

#### Toxicty to algae/aquatic plants
- **ErC50 (Chlorella pyrenoidosa)**: 15 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201
- **EC10 (Chlorella pyrenoidosa)**: 2,3 mg/l  
  Exposure time: 72 h  
  Method: OECD Test Guideline 201

#### M-Factor (Acute aquatic toxicity)
- **NOEC (Oncorhynchus mykiss (rainbow trout))**: 0,15 mg/l  
  Exposure time: 28 d  
  Method: OECD Test Guideline 204

#### Toxicty 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

#### Toxicty to microorganisms
- **EC50**: 22,86 mg/l  
  Exposure time: 60 h

### Betamethasone:

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

#### Toxicty 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.

#### Toxicty 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

Remarks: Based on data from similar materials
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

Hexadecan-1-ol. Ethoxylated:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 99 %
Exposure time: 19 d

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

Bioaccumulative potential

Components:

Paraffin oil:
Partition coefficient: n-octanol/water: log Pow: > 4
Remarks: Calculation

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

Mobility in soil
No data available

Other adverse effects
No data available
SECTION 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.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (Betamethasone)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Betamethasone)
Class: 9
Packing group: III
Labels: 9
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.

Domestic regulation

ANTT
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone)
Class: 9
Packing group : III
Labels : 9
Hazard Identification Number : 90

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.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
National List of Carcinogenic Agents for Humans - (LINACH) : Not applicable
Brazil. List of chemicals controlled by the Federal Police : Not applicable

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

SECTION 16. OTHER INFORMATION

Further information

Full text of other abbreviations
ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; 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 con-
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