Section 1: Identification

Product name : Betamethasone / Clotrimazole Cream Formulation

Manufacturer or supplier's details
Company : Organon & Co.
Address : 30 Hudson Street, 33rd floor
          Jersey City, New Jersey, U.S.A 07302
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

Section 2: Hazard 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)

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.
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 mist or vapours.
                           P264 Wash skin thoroughly after handling.
                           P270 Do not eat, drink or smoke when using this product.
                           P281 Use personal protective equipment as required.
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Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

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.

Section 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;= 10 - &lt; 30</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.01 - &lt; 0.3</td>
</tr>
</tbody>
</table>

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).
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 fire-fighting
- 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 firefighters
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

Hazchem Code
- 3Z

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 spills cannot be contained.

Methods and materials for containment and cleaning up
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked 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/PERSONAL PROTECTION section.

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

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe mist or vapours.
- 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 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

Section 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>WES-TWA (Mist)</td>
<td>5 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Further information: Sampled by a method that does not collect vapour.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-STEEL (Mist)</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>WES-TWA (particulate)</td>
<td>10 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-TWA (Vapour and</td>
<td>150 ppm 474 mg/m³</td>
<td>NZ OEL</td>
</tr>
</tbody>
</table>
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tion

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| particulates) | WES-TWA (Mist) | 5 mg/m³ | NZ OEL | WES-TEL (Mist) | 10 mg/m³ | NZ OEL | TWA (Inhalable particu-
late matter) | 5 mg/m³ | ACGIH |
<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>TWA</td>
<td>1 µg/m³ (OEB 4)</td>
<td>Internal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Further information: Sampled by a method that does not collect vapour.

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 recommended guidelines, use respiratory protection.

Filter type: Combined particulates and organic vapour type

Hand protection: 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.

Section 9: Physical and chemical properties:

Appearance: cream
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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>
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<tr>
<td>4.6</td>
<td>10.10.2020</td>
<td>412907-00014</td>
<td>23.03.2020</td>
<td>14.12.2015</td>
</tr>
</tbody>
</table>

- Colour: white to off-white
- 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: No data available
- Evaporation rate: No data available
- Flammability (solid, gas): Not applicable
- Flammability (liquids): No data available
- 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: No data available
- Relative density: No data available
- Density: No data available
- Solubility(ies):
  - Water solubility: No data available
- Partition coefficient: n-octanol/water: No data available
- 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
Section 10: Stability and reactivity

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: 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

Exposure routes:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity
Not classified based on available information.

Product:

Acute oral toxicity:
- Acute toxicity estimate: > 2,000 mg/kg
- Method: Calculation method

Acute dermal toxicity:
- Acute toxicity estimate: > 2,000 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

Propylene glycol:

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

Acute inhalation toxicity:
- LC50 (Rabbit): > 159 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist

Acute dermal toxicity:
- LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity
White mineral oil (petroleum):
Acute oral toxicity: LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity:
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Assessment: The substance or mixture has no acute inhalation toxicity
Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

Clotrimazole:
Acute oral toxicity:
  LD50 (Rat): 708 mg/kg
  LD50 (Mouse): 761 mg/kg
  LD50 (Rabbit): > 1,000 mg/kg
Acute inhalation toxicity:
  LC50 (Rat): > 0.73 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity: LD50 (Mouse): 923 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

Propylene glycol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
White mineral oil (petroleum):
Species: Rabbit
Result: No skin irritation

Clotrimazole:
Species: Rabbit
Result: No skin irritation

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

Propylene glycol:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405

White mineral oil (petroleum):
Species: Rabbit
Result: No eye irritation

Clotrimazole:
Species: Rabbit
Result: Mild eye irritation

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

Propylene glycol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

White mineral oil (petroleum):
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

betamethasone:
Exposure routes: Dermal
Species: Guinea pig
Result: Weak sensitizer

Chronic toxicity
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

Propylene glycol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Genotoxicity in vivo:
Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

White mineral oil (petroleum):
Genotoxicity in vitro:
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: Mouse
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: in vitro micronucleus test
Result: negative

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

Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)
Species: Hamster
Result: negative

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

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

Propylene glycol:
Species: Rat
Application Route: Ingestion
Exposure time: 2 Years
Result: negative

White mineral oil (petroleum):
Species: Rat
Application Route: Ingestion
Exposure time: 24 Months
Result: negative

clotrimazole:
Species: Rat
Application Route: Oral
Exposure time: 78 weeks
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

Propylene glycol:  
Effects on fertility:  
Test Type: Three-generation reproduction toxicity study  
Species: Mouse  
Application Route: Ingestion  
Result: negative

White mineral oil (petroleum):  
Effects on fertility:  
Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Skin contact  
Result: negative

Effects on foetal development:  
Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Ingestion  
Result: negative

Clotrimazole:  
Effects on fertility:  
Test Type: Fertility/early embryonic development  
Species: Rat  
Application Route: Oral  
Fertility: LOAEL: 50 mg/kg body weight  
Result: Effects on fertility

Effects on foetal development:  
Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 50 mg/kg body weight  
Result: Embryo-foetal toxicity, No teratogenic effects

Test Type: Embryo-foetal development  
Species: Mouse  
Application Route: Oral
Developmental Toxicity: NOAEL: 200 mg/kg body weight
Result: No effects on foetal development

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 180 mg/kg body weight
Result: No effects on foetal development

Reproductive toxicity - Assessment: Some evidence of adverse effects on sexual function and fertility, based on animal experiments. Some evidence of adverse effects on development, based on animal experiments.

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.

STOT - repeated exposure
Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Components:
clotrimazole:
Target Organs: Liver, Kidney, Adrenal gland
Assessment: May cause damage to organs through prolonged or repeated exposure.

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

**Propylene glycol:**
- **Species:** Rat, male
- **NOAEL:** 1,700 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 2 yr

**White mineral oil (petroleum):**
- **Species:** Rat
- **LOAEL:** 160 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days
- **Species:** Rat
- **LOAEL:** >= 1 mg/l
- **Application Route:** Inhalation (dust/mist/fume)
- **Exposure time:** 4 Weeks
- **Method:** OECD Test Guideline 412

**Clotrimazole:**
- **Species:** Rabbit
- **LOAEL:** 5 - 40 mg/kg
- **Application Route:** Skin contact
- **Exposure time:** 3 Weeks
- **Target Organs:** Skin
- **Symptoms:** Oedema, Fissuring, Necrosis, Redness

**Betamethasone:**
- **Species:** Rat
- **LOAEL:** 10 mg/kg
- **Application Route:** Oral
- **Exposure time:** 18 Months
- **Target Organs:** Liver, Kidney, Adrenal gland

**Species:** Dog
- **LOAEL:** 25 mg/kg
- **Application Route:** Oral
- **Exposure time:** 6 - 12 Months
- **Target Organs:** Adrenal gland
- **Symptoms:** Salivation, Lachrymation, Vomiting
### Species and LOAEL Data

**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:**

- **clotrimazole:**  
  - Skin contact: Symptoms: Rash, Itching, Blistering, Oedema, Redness  
  - Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea

- **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 |
|----------------------------------|------------------------------------------------------------------|

**Propylene glycol:**

| Toxicity to fish                  | LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l  
Exposure time: 96 h |
|----------------------------------|------------------------------------------------------------------|

| Toxicity to daphnia and other aquatic invertebrates | EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l  
Exposure time: 48 h |
|----------------------------------|------------------------------------------------------------------|

| Toxicity to algae/aquatic plants | ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201 |
|----------------------------------|------------------------------------------------------------------|

| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l  
Exposure time: 7 d |
|------------------------------------------------------------------|------------------------------------------------------------------|

| Toxicity to microorganisms | NOEC (Pseudomonas putida): > 20,000 mg/l  
Exposure time: 18 h |
|------------------------------------------------------------------|------------------------------------------------------------------|

**White mineral oil (petroleum):**

| Toxicity to fish (Chronic toxicity) | NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l  
Exposure time: 28 d |
|----------------------------------|------------------------------------------------------------------|

| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | NOEC (Daphnia magna (Water flea)): 1,000 mg/l  
Exposure time: 21 d |
|------------------------------------------------------------------|------------------------------------------------------------------|
clotrimazole:
Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 0.29 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.02 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l
Exposure time: 72 h
NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity) : NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.01 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Toxicity to microorganisms : EC50: > 10,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

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
ic toxicity) Method: OECD Test Guideline 211

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

Propylene glycol:
Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

White mineral oil (petroleum):
Biodegradability : Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d

Clotrimazole:
Stability in water : Hydrolysis: 50 %(242 d)

Bioaccumulative potential

Components:

Propylene glycol:
Partition coefficient: n-octanol/water : log Pow: -1.07

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.
Section 14: Transport information

International Regulations

**UNRTDG**
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, 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. (clotrimazole, 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. (clotrimazole, 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.

**National Regulations**

**NZS 5433**
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, betamethasone)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z
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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

Section 16: Other information

Further information
Date format: dd.mm.yyyy

Full text of other abbreviations
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants
- ACGIH / TWA: 8-hour, time-weighted average
- NZ OEL / WES-TWA: Workplace Exposure Standard - Time Weighted average
- NZ OEL / WES-STEL: Workplace Exposure Standard - Short-Term Exposure Limit

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 concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; 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; TSGA - 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

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.

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