SAFETY DATA SHEET
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Clotrimazole / Gentamicin / Betamethasone (0.05%) 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 2
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.
H401 Toxic 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>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td></td>
<td>&gt;= 10 &lt;- 20</td>
</tr>
<tr>
<td></td>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>Aspiration hazard, Long-term (chronic) aquatic hazard, Category 4</td>
<td>&gt;= 5 &lt;- 10</td>
</tr>
<tr>
<td></td>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td>Acute toxicity (Oral), Eye irritation, Short-term (acute) aquatic hazard, Category 2</td>
<td>&gt;= 1 &lt;- 2.5</td>
</tr>
<tr>
<td></td>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>Acute toxicity (Oral), Acute toxicity (Dermal), Eye irritation, Reproductive toxicity, Specific target organ toxicity - repeated exposure (Oral) (Liver, Kidney, Adrenal gland), Category 2 Short-term (acute) aquatic hazard, Category 1</td>
<td>&gt;= 1 &lt;- 2.5</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).

Notes to physician: Treat symptomatically and supportively.

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: 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 spills 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/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 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>Clotrimazole</td>
<td>23593-75-1</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m³ (OEB 2)</td>
<td>Internal</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 recommended guidelines, use respiratory protection.

Filter type: Combined particulaties and organic vapor 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**: liquid

**Color**: No data available

**Odor**: No data available

**Odor 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

**Vapor pressure**: No data available

**Relative vapor 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**: 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: 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

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

Acute dermal 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

Hexadecan-1-ol. Ethoxylated:
Acute oral toxicity : LD50 (Rat): 2.500 mg/kg

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

Benzyl alcohol:
Acute oral toxicity : LD50 (Rat): 1.620 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 4,178 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

Gentamicin:
Acute oral toxicity : LD50 (Rat): 8.000 - 10.000 mg/kg
LD50 (Mouse): 10.000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 0,2 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: No mortality observed at this dose.
Acute toxicity (other routes of administration) : LD50 (Rat): 67 - 96 mg/kg
Application Route: Intravenous
LD50 (Rat): 371 - 384 mg/kg
Application Route: Intramuscular
LDLo (Monkey): 30 mg/kg
Application Route: Intravenous
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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

Clotrimazole:
Species: Rabbit
Result: No skin irritation

Benzyl alcohol:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Gentamicin:
Species: Rabbit
Result: Mild 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

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

clotrimazole:
Species: Rabbit
Result: Mild eye irritation

Benzyl alcohol:
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

Gentamicin:
Species: Rabbit
Result: Mild eye irritation

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

Benzyl alcohol:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
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Method: OECD Test Guideline 406
Result: negative

Gentamicin:
Remarks: No data available

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:
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

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

Benzyl alcohol:
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

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

Test Type: Chromosome aberration test in vitro
Result: equivocal

Genotoxicity in vivo: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intravenous injection
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
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Application Route: Ingestion
Exposure time: 2 Years
Result: negative

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

Benzyl alcohol:
Species: Mouse
Application Route: Ingestion
Exposure time: 103 weeks
Method: OECD Test Guideline 451
Result: negative

Gentamicin:
Carcinogenicity - Assessment: No data available
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

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

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

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

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

Benzyl alcohol:
Effects on fertility: Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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

Gentamicin:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat
Fertility: NOAEL: 20 mg/kg body weight
Result: No significant adverse effects were reported

Effects on fetal development: Test Type: Embryo-fetal development
Species: Rabbit
Developmental Toxicity: NOAEL: 3,6 mg/kg body weight
Result: No embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 75 mg/kg body weight
Result: Embryo-fetal toxicity.

Test Type: Embryo-fetal development
Species: Mouse
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: Fetal mortality., No malformations were observed.

Test Type: Embryo-fetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: Fetal mortality., No malformations were observed.

Reproductive toxicity - Assessment : Positive evidence of adverse effects on development from human epidemiological studies.

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.

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.

Gentamicin:
Target Organs : Kidney, inner ear
Assessment: Causes 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 y

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

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

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

Benzy alcohol:
Species: Rat
NOAEL: 1,072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

Gentamicin:
Species: Dog
LOAEL: 3 mg/kg
Application Route: Intramuscular
Exposure time: 12 Months
Target Organs: Kidney
Symptoms: Vomiting, Salivation

Species: Monkey
LOAEL: 50 mg/kg
Application Route: Subcutaneous
Exposure time: 3 Weeks
Target Organs: Kidney, inner ear

Species: Monkey
LOAEL: 6 mg/kg
Application Route: Intramuscular
Exposure time: 3 Weeks
Target Organs: Blood, Kidney, inner ear, Liver

Species: Rat
NOAEL: 5 mg/kg
LOAEL: 10 mg/kg
Application Route: Intramuscular
Exposure time: 52 Weeks
Target Organs: Kidney, Blood

Species: Rat
NOAEL: 12.5 mg/kg
LOAEL: 50 mg/kg
Application Route: Intramuscular
Exposure time: 13 Weeks
Target Organs: Kidney

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:**

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

**Gentamicin:**
- **Ingestion:** Target Organs: Kidney
  - Target Organs: inner ear
  - Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

**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
Toxicity to algae/aquatic plants:

- **NOEL** (Pseudokirchneriella subcapitata (green algae)): \( \geq \) 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
    - Remarks: Based on data from similar materials

**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

M-Factor (Acute aquatic toxicity):
: 10

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

M-Factor (Chronic aquatic toxicity):
: 10

Toxicity to microorganisms:
EC50: > 10.000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**Benzyl alcohol:**
Toxicity to fish:
LC50 (Pimephales promelas (fathead minnow)): 460 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 230 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
EC50 (Pseudokirchneriella subcapitata (green algae)): 770 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 310 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 51 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

**Gentamicin:**
Toxicity to daphnia and other:
EC50 (Daphnia magna (Water flea)): 86 mg/l
## Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

<table>
<thead>
<tr>
<th>Component</th>
<th>Aquatic Invertebrates</th>
<th>Toxicity to Algae/Aquatic Plants</th>
<th>Toxicity to Microorganisms</th>
<th>Betamethasone:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td>EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l</td>
<td>EC50: 288.7 mg/l</td>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 202</td>
<td>Method: OECD Test Guideline 201</td>
<td>Test Type: Respiration inhibition</td>
<td>EC50 (Americamysis): &gt; 50 mg/l</td>
</tr>
<tr>
<td></td>
<td>LC50 (Americamysis): 30 mg/l</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l</td>
<td>Method: OECD Test Guideline 201</td>
<td>Exposure time: 96 h</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td>EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l</td>
<td>Method: OECD Test Guideline 201</td>
<td>Method: OECD Test Guideline 201</td>
</tr>
<tr>
<td></td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
<td>M-Factor (Acute aquatic toxicity)</td>
<td>: 100</td>
<td>NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td>M-Factor (Chronic aquatic toxicity)</td>
<td>: 1</td>
<td>Exposure time: 32 d</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: No toxicity at the limit of solubility.</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Remarks

- No toxicity at the limit of solubility.
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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

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

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

Benzy alcohol:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 92 - 96 %
Exposure time: 14 d

Gentamicin:
Biodegradability: Result: rapidly degradable
Biodegradation: 100 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Bioaccumulative potential

Components:

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

Benzyl alcohol:
SAFETY DATA SHEET
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 5.2  Revision Date: 09.04.2021  SDS Number: 610533-00014  Date of last issue: 10.10.2020
Date of first issue: 29.04.2016

Partition coefficient: n-octanol/water : log Pow: 1.05

**Gentamicin:**
Partition coefficient: n-octanol/water : log Pow: < -2

**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, clotrimazole)
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, clotrimazole)
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.
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Version 5.2  Revision Date: 09.04.2021  SDS Number: 610533-00014  Date of last issue: 10.10.2020  Date of first issue: 29.04.2016

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, clotrimazole)
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
Sources of key data used to : Internal technical data, data from raw material SDSs, OECD
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 5.2  Revision Date: 09.04.2021  SDS Number: 610533-00014  Date of last issue: 10.10.2020  Date of first issue: 29.04.2016


Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

AIIIC - 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; 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

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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