SAFETY DATA SHEET
according to GB/T 16483 and GB/T 17519

Clotrimazole / Gentamicin / Betamethasone
(0.1%) Formulation

Version 5.5  Revision Date: 2020/03/23  SDS Number: 808841-00013  Date of last issue: 2019/09/13
Date of first issue: 2016/07/22

1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Manufacturer or supplier’s details
Company: MSD
Address: No. 485 Jing Tai Road
Pu Tuo District - Shanghai - China 200331
Telephone: 908-740-4000
Emergency telephone number: 86-571-87268110
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product

2. HAZARDS IDENTIFICATION

Emergency Overview
Appearance: liquid
Colour: No data available
Odour: No data available

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

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

GHS label elements
Hazard pictograms:

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

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

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

Storage:
P405 Store locked up.

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

Physical and chemical hazards
Not classified based on available information.

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

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chemical name</td>
</tr>
<tr>
<td>Mixture</td>
<td>White mineral oil (petroleum)</td>
</tr>
<tr>
<td></td>
<td>clotrimazole</td>
</tr>
<tr>
<td></td>
<td>Gentamicin</td>
</tr>
<tr>
<td></td>
<td>betamethasone</td>
</tr>
</tbody>
</table>
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4. FIRST AID MEASURES

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

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

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

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

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

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

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

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media : None known.

Specific hazards during firefighting : 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.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment : Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions:
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- 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 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.

7. HANDLING AND STORAGE

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

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

Advice on safe handling:
- Do not get on skin or clothing.
- Do not breathe vapours or spray mist.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact:
- Oxidizing agents

Storage
Conditions for safe storage:
- Keep in properly labelled containers.
- Store locked up.
- Keep tightly closed.
- Store in accordance with the particular national regulations.

Materials to avoid:
- Do not store with the following product types:
  - Strong oxidizing agents
Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

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>White mineral oil (petroleum)</td>
<td>8042-47-5</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 particulates and organic vapour type
Eye/face protection: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleeves, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

Hand protection

Material: Chemical-resistant gloves
Remarks: Consider double gloving.
Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>liquid</td>
</tr>
<tr>
<td>Colour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour</td>
<td>No data available</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
</tbody>
</table>
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.

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: > 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:
White mineral oil (petroleum):
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<thead>
<tr>
<th>Route of Administration</th>
<th>Acute oral toxicity</th>
<th>Acute inhalation toxicity</th>
<th>Acute dermal toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LD50 (Rat): &gt; 5,000 mg/kg</td>
<td>LC50 (Rat): &gt; 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
<tr>
<td><strong>clotrimazole:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute oral toxicity</td>
<td>LD50 (Rat): 708 mg/kg</td>
<td>LD50 (Mouse): 761 mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50 (Rabbit): &gt; 1,000 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 0.73 mg/l Exposure time: 4 h Test atmosphere: dust/mist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Mouse): 923 mg/kg</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| 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 |                       |
|                                  | LD50 (Mouse): 30 mg/kg Application Route: Intravenous |                       |                       |

| 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 |                             |                       |
Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

**Skin corrosion/irritation**

Not classified based on available information.

**Components:**

**White mineral oil (petroleum):**
- **Species**: Rabbit
- **Result**: No skin irritation

**Clotrimazole:**
- **Species**: Rabbit
- **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:**

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

**Clotrimazole:**
- **Species**: Rabbit
- **Result**: Mild eye irritation

**Gentamicin:**
- **Species**: Rabbit
- **Result**: Mild eye irritation

**Betamethasone:**
- **Species**: Rabbit
- **Result**: No eye irritation
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Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

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

Gentamicin:
Remarks: No data available

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

Germ cell mutagenicity
Not classified based on available information.

Components:

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
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| 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.  

### 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:**

### 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

### Gentamicin:
- **Carcinogenicity - Assessment:** No data available

**Reproductive toxicity**
May damage the unborn child.

### 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: Rat
  - 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
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**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.

**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 foetal development:**  
**Test Type:** Embryo-foetal development  
**Species:** Rabbit  
**Developmental Toxicity:** NOAEL: 3.6 mg/kg body weight  
**Result:** No embryo-foetal toxicity

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

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

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

**Reproductive toxicity - Assessment:** Positive evidence of adverse effects on development from human epidemiological studies.
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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 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:
White mineral oil (petroleum):
Species: Rat
LOAEL: 160 mg/kg
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</tbody>
</table>

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

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

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
## Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

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</tbody>
</table>

**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.

**Experience with human exposure**

**Components:**

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

**Gentamicin:**  
**Ingestion** : Target Organs: Kidney  
Target Organs: inner ear
Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

White mineral oil (petroleum):

Toxicity to fish:

\[
\text{LC50 (Oncorhynchus mykiss (rainbow trout)): } > 100 \text{ mg/l} \\
\text{Exposure time: 96 h} \\
\text{Method: OECD Test Guideline 203}
\]

Toxicity to daphnia and other aquatic invertebrates:

\[
\text{EC50 (Daphnia magna (Water flea)): } > 100 \text{ mg/l} \\
\text{Exposure time: 48 h} \\
\text{Method: OECD Test Guideline 202}
\]

Toxicity to algae/aquatic plants:

\[
\text{NOEC (Pseudokirchneriella subcapitata (green algae)): } 100 \text{ mg/l} \\
\text{Exposure time: 72 h} \\
\text{Method: OECD Test Guideline 201}
\]

Toxicity to fish (Chronic toxicity):

\[
\text{NOEC (Oncorhynchus mykiss (rainbow trout)): } 1,000 \text{ mg/l} \\
\text{Exposure time: 28 d}
\]

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

\[
\text{NOEC (Daphnia magna (Water flea)): } 1,000 \text{ mg/l} \\
\text{Exposure time: 21 d}
\]

Clotrimazole:

Toxicity to fish:

\[
\text{LC50 (Brachydanio rerio (zebrafish)): } > 0.29 \text{ mg/l} \\
\text{Exposure time: 96 h} \\
\text{Method: OECD Test Guideline 203}
\]

Toxicity to daphnia and other aquatic invertebrates:

\[
\text{EC50 (Daphnia magna (Water flea)): } 0.02 \text{ mg/l} \\
\text{Exposure time: 48 h}
\]

Toxicity to algae/aquatic plants:

\[
\text{EC50 (Desmodesmus subspicatus (green algae)): } 0.268 \text{ mg/l} \\
\text{Exposure time: 72 h} \\
\text{NOEC (Desmodesmus subspicatus (green algae)): } 0.017 \text{ mg/l} \\
\text{Exposure time: 72 h}
\]

M-Factor (Acute aquatic toxicity):

\[
\text{10}
\]

Toxicity to fish (Chronic toxicity):

\[
\text{NOEC (Oncorhynchus mykiss (rainbow trout)): } 0.025 \text{ mg/l} \\
\text{Exposure time: 32 d} \\
\text{Method: OECD Test Guideline 210}
\]
Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

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

**Gentamicin:**

Toxicity to daphnia and other aquatic invertebrates:

- EC50 (Daphnia magna (Water flea)): 86 mg/l
- Exposure time: 48 h
- Method: OECD Test Guideline 202

- LC50 (Americamysis): 30 mg/l
- Exposure time: 96 h

Toxicity to algae/aquatic plants:

- EC50 (Pseudokirchneriella subcapitata (green algae)): 10 µg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

- NOEC (Pseudokirchneriella subcapitata (green algae)): 1.5 µg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

- EC50 (Anabaena flos-aquae (cyanobacterium)): 4.7 µg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

- NOEC (Anabaena flos-aquae (cyanobacterium)): 1.6 µg/l
- Exposure time: 72 h
- Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity):

- 100

M-Factor (Chronic aquatic toxicity):

- 1

Toxicity to microorganisms:

- EC50: 288.7 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

<table>
<thead>
<tr>
<th>Compound</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae))</th>
<th>Exposure time (h)</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotrimazole</td>
<td>&gt; 34 mg/l</td>
<td>72</td>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>34 mg/l</td>
<td>72</td>
<td>OECD Test Guideline 201</td>
<td>No toxicity at the limit of solubility</td>
</tr>
</tbody>
</table>

### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOEC (Pimephales promelas (fathead minnow))</th>
<th>Exposure time (d)</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotrimazole</td>
<td>0.052 mg/l</td>
<td>32</td>
<td>OECD Test Guideline 210</td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td>0.07 µg/l</td>
<td>219</td>
<td>OECD Test Guideline 229</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Compound</th>
<th>NOEC (Daphnia magna (Water flea))</th>
<th>Exposure time (d)</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotrimazole</td>
<td>8 mg/l</td>
<td>21</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

### M-Factor (Chronic aquatic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotrimazole</td>
<td>1,000</td>
</tr>
</tbody>
</table>

### Persistence and degradability

#### Components:

**White mineral oil (petroleum):**

- Biodegradability: Result: Not readily biodegradable. Biodegradation: 31 % Exposure time: 28 d

**Clotrimazole:**

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

**Gentamicin:**

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

### Bioaccumulative potential

#### Components:

**Gentamicin:**

- Partition coefficient: n-octanol/water: log Pow: < -2
Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

**betamethasone:**
Partition coefficient: n-octanol/water: \[ \text{log Pow: 2.11} \]

**Mobility in soil**
No data available

**Other adverse effects**
No data available

13. DISPOSAL CONSIDERATIONS

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

14. TRANSPORT INFORMATION

**International Regulations**

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

GB 6944/12268
UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(clotrimazole, Gentamicin)
Class : 9
Packing group : III
Labels : 9

Special precautions for user
The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

15. REGULATORY INFORMATION

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

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

16. OTHER INFORMATION

Further information
Date format : yyyy/mm/dd

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

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

Disclaimer
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.