SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

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

Manufacturer or supplier’s details
Company name of supplier : MSD
Address : Avenida 16 de Septiembre No. 301
          Xaltocan - Xochimilco Mexico 16090
Telephone : 52 55 57284444
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

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

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity : Category 1A
Specific target organ toxicity - repeated exposure : Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Liver, Kidney, Adrenal gland)

GHS label elements
Hazard pictograms :

Signal Word : Danger
Hazard Statements :
H360Df May damage the unborn child. Suspected of damaging fertility.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.
H373 May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

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 vapors.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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
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>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt;= 90 - &lt;= 100</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>&gt;= 1 - &lt; 5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>&gt;= 0.1 - &lt; 1</td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.1 - &lt; 1</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. Suspected of damaging fertility. 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 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 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 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 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 vapors 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.

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>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>VLE-PPT (Mist)</td>
<td>5 mg/m³</td>
<td>NOM-010-STPS-2014</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>23593-75-1</td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Gentamicin</td>
<td></td>
<td>TWA</td>
<td>0.1 mg/m³ (OEB)</td>
<td>Internal</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 5.3  Revision Date: 23.03.2020  SDS Number: 808849-00013  Date of last issue: 13.09.2019  Date of first issue: 22.07.2016

<table>
<thead>
<tr>
<th>Substance</th>
<th>CAS Number</th>
<th>TWA</th>
<th>OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>1 µg/m³ (OEL 4)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information: Skin Wipe limit</td>
<td></td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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 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 temperature: No data available
range

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:

White mineral oil (petroleum):

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

Acute inhalation toxicity: LC50 (Rat): > 5 mg/l
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
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

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

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:

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
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 5.3
Revision Date: 23.03.2020
SDS Number: 808849-00013
Date of last issue: 13.09.2019
Date of first issue: 22.07.2016

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

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Components:

White mineral oil (petroleum):
Test Type: Buehler Test
Routes of exposure: Skin contact
Species: Guinea pig
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:

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.

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. Suspected of damaging fertility.

Components:

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

- Effects on fetal development: Test Type: Embryo-fetal development  
  Species: Rat  
  Application Route: Ingestion
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
- 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.

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.
May cause damage to organs (Liver, Kidney, Adrenal gland) through prolonged or repeated exposure if swallowed.

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
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 : 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

Gentamicin:
Species : Dog
LOAEL : 3 mg/kg
### Application Route and Exposure Details

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure Time</th>
<th>Target Organs</th>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure Time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intramuscular</td>
<td>12 Months</td>
<td>Kidney</td>
<td>Monkey</td>
<td>50 mg/kg</td>
<td>Subcutaneous</td>
<td>3 Weeks</td>
<td>Kidney, inner ear</td>
</tr>
<tr>
<td>Intra.muscular</td>
<td>3 Weeks</td>
<td>Blood, Kidney, inner ear, Liver</td>
<td>Rat</td>
<td>5 mg/kg</td>
<td>Intramuscular</td>
<td>52 Weeks</td>
<td>Kidney</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Rat</td>
<td>10 mg/kg</td>
<td>Intramuscular</td>
<td>13 Weeks</td>
<td>Kidney</td>
</tr>
</tbody>
</table>

### LOAEL and NOAEL Details

<table>
<thead>
<tr>
<th>LOAEL</th>
<th>Species</th>
<th>Application Route</th>
<th>Exposure Time</th>
<th>Target Organs</th>
<th>NOAEL</th>
<th>Species</th>
<th>Application Route</th>
<th>Exposure Time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 mg/kg</td>
<td>Monkey</td>
<td>Subcutaneous</td>
<td>3 Weeks</td>
<td>Kidney, inner ear</td>
<td>6 mg/kg</td>
<td>Monkey</td>
<td>Intramuscular</td>
<td>52 Weeks</td>
<td>Blood, Kidney, inner ear, Liver</td>
</tr>
<tr>
<td>12.5 mg/kg</td>
<td>Rat</td>
<td>Intramuscular</td>
<td>13 Weeks</td>
<td>Kidney</td>
<td>5 mg/kg</td>
<td>Rat</td>
<td>Intramuscular</td>
<td>52 Weeks</td>
<td>Kidney</td>
</tr>
<tr>
<td>0.05 %</td>
<td>Rabbit</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>Pituitary gland, Immune system, muscle</td>
<td>0.05 %</td>
<td>Rat</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
<tr>
<td>0.1 %</td>
<td>Mouse</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
<td>0.05 %</td>
<td>Mouse</td>
<td>Skin contact</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
<tr>
<td>0.05 mg/kg</td>
<td>Dog</td>
<td>Oral</td>
<td>8 Weeks</td>
<td>thymus gland</td>
<td>0.05</td>
<td>Dog</td>
<td>Oral</td>
<td>8 Weeks</td>
<td>thymus gland</td>
</tr>
</tbody>
</table>

**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

---

**SAFETY DATA SHEET**

Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

**Version:** 5.3
**Revision Date:** 23.03.2020
**SDS Number:** 808849-00013
**Date of last issue:** 13.09.2019
**Date of first issue:** 22.07.2016
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 5.3  Revision Date: 23.03.2020  SDS Number: 808849-00013  Date of last issue: 13.09.2019  Date of first issue: 22.07.2016

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, 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**:

**White mineral oil (petroleum)**:
Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants: NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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 |

**Gentamicin:**

| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): 86 mg/l  
Exposure time: 48 h |
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Method: OECD Test Guideline 202</td>
<td></td>
</tr>
</tbody>
</table>
| LC50 (Americamysis): 30 mg/l  
Exposure time: 96 h |
| Method: US-EPA OPPTS 850.1035 |
| 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 |
| Toxicity to microorganisms | EC50: 288.7 mg/l  
Exposure time: 3 h |
| Test Type: Respiration inhibition |
Betamethasone:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Americamysis): > 50 mg/l
Exposure time: 96 h

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (green algae)): > 34 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

NOEC (Pseudokirchneriella subcapitata (green algae)): 34 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility.

Toxicity to fish (Chronic toxicity):
NOEC (Pimephales promelas (fathead minnow)): 0.052 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210

NOEC (Oryzias latipes (Japanese medaka)): 0.07 µg/l
Exposure time: 219 d
Method: OECD Test Guideline 229

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 8 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

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

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.
(clotrimazole, Gentamicin)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: 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: 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.

Domestic regulation

NOM-002-SCT
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.

SECTION 15. REGULATORY INFORMATION

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

Federal Law for the control of chemical precursors, essential chemical products and machinery for producing capsules, tablets and pills.

The ingredients of this product are reported in the following inventories:

AICS: not determined
DSL: not determined
IECSC: not determined

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NOM-010-STPS-2014: Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Control - Appendix 1 Occupational Exposure Limits
ACGIH / TWA: 8-hour, time-weighted average
Sources of key data used to compile the Material Safety Data Sheet:


Revision Date: 23.03.2020

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

MX / Z8