1. PRODUCT AND COMPANY IDENTIFICATION

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

Manufacturer or supplier's details
Company: MSD
Address: Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone: +1-908-740-4000
Emergency telephone number: +1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Reproductive toxicity: Category 1A
Specific target organ toxicity - repeated exposure: Category 1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)
Short-term (acute) aquatic hazard: Category 1
Long-term (chronic) aquatic hazard: Category 1

GHS label elements
Hazard pictograms: 

Signal word: Danger
Hazard statements: H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through pro-
longed or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:

**Prevention:**
- P203 Obtain, read and follow all safety instructions before use.
- 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:**
- P318 IF exposed or concerned, get medical advice.
- P391 Collect spillage.

**Storage:**
- P405 Store locked up.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

**Components**

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (%)</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; 2.5</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>&gt;= 0.3 - &lt; 1</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.1 - &lt; 0.25</td>
</tr>
</tbody>
</table>

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.
## 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**

- **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 and emergency procedures**

- Use personal protective equipment.  
- Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**Environmental precautions**

- Avoid release to the environment.  
- Prevent further leakage or spillage if safe to do so.  
- Prevent spreading over a wide area (e.g. by containment or oil barriers).  
- Retain and dispose of contaminated wash water.  
- Local authorities should be advised if significant spillages cannot be contained.

**Methods and materials for containment and cleaning up**

- Soak up with inert absorbent material.  
- For large spills, provide 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 absorb-
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 5.5  Revision Date: 27.08.2021  SDS Number: 817858-00015  Date of last issue: 10.10.2020  Date of first issue: 22.07.2016

bent. 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

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

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

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

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

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 (Mist)</td>
<td>5 mg/m3</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m3</td>
<td>IN OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
<tr>
<td>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

**Hand protection**

  **Material**: Chemical-resistant gloves

  **Remarks**: Consider double gloving.

**Eye protection**

  **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**

  **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.

**Hygiene measures**

  **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

**Appearance**: liquid

**Colour**: No data available

**Odour**: No data available

**Odour Threshold**: No data available
### 10. STABILITY AND REACTIVITY

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability and reactivity</td>
<td>Does not react with strong oxidizing agents.</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Stable under normal conditions.</td>
</tr>
<tr>
<td>Density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Solubility(s)</td>
<td>Not applicable</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</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability</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>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>Not classified as oxidizing.</td>
</tr>
<tr>
<td>Particle size</td>
<td>Not applicable</td>
</tr>
</tbody>
</table>

**Reactivity:**

- Not classified as a reactivity hazard.

**Chemical stability:**

- Stable under normal conditions.

**Possibility of hazardous reac-**

- Can react with strong oxidizing agents.
SAFETY DATA SHEET

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Version 5.5  Revision Date: 27.08.2021  SDS Number: 817858-00015  Date of last issue: 10.10.2020
Date of first issue: 22.07.2016

Conditions to avoid: None known.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

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

**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

**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 5.5  Revision Date: 27.08.2021  SDS Number: 817858-00015  Date of last issue: 10.10.2020  Date of first issue: 22.07.2016

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

**clotrimazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

**Gentamicin:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Mild eye irritation</td>
</tr>
</tbody>
</table>

**betamethasone:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

**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):**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Buehler Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
</tbody>
</table>

**Gentamicin:**

<table>
<thead>
<tr>
<th>Remarks</th>
<th>No data available</th>
</tr>
</thead>
</table>

**betamethasone:**

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Result</td>
<td>Weak sensitizer</td>
</tr>
</tbody>
</table>

**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.

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 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
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.

betamethasone:
Effects on foetal development:
Species: Rabbit
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 0.05 mg/kg body weight
Result: Fetotoxicity, Malformations were observed.

Species: Rat
Application Route: Subcutaneous
Developmental Toxicity: LOAEL: 0.42 mg/kg body weight
Result: Malformations were observed.

Species: Mouse
Application Route: Intramuscular
Developmental Toxicity: LOAEL: 1 mg/kg body weight
Result: Malformations were observed.

Reproductive toxicity - Assessment: Clear evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

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

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

Betamethasone:
Target Organ                  : 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 Organ                  : Skin
Symptoms                      : Oedema, Fissuring, Necrosis, Redness

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

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

Gentamicin:
Species                       : Dog
LOAEL                          : 3 mg/kg
### SAFETY DATA SHEET

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

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5</td>
<td>27.08.2021</td>
<td>817858-00015</td>
<td>10.10.2020</td>
<td>22.07.2016</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intramuscular</td>
<td>12 Months</td>
<td>Kidney</td>
<td>Vomiting, Salivation</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intramuscular</td>
<td>3 Weeks</td>
<td>Kidney, Blood</td>
<td>Rat</td>
</tr>
</tbody>
</table>
| *NOAEL*: 5 mg/kg*  
| *LOAEL*: 10 mg/kg* |

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

**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
Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

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

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: 1,000 mg/l
Exposure time: 28 d
Species: Oncorhynchus mykiss (rainbow trout)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC: 1,000 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
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 microorganisms

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

Toxicity to fish (Chronic toxicity)

NOEC: 0.025 mg/l
Exposure time: 32 d
Species: Oncorhynchus mykiss (rainbow trout)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC: 0.01 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity): 10

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
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
**SAFETY DATA SHEET**

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

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue: 10.10.2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>5.5</td>
<td>27.08.2021</td>
<td>817858-00015</td>
<td>Date of first issue: 22.07.2016</td>
</tr>
</tbody>
</table>

- **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

- **Toxicity to microorganisms:**
  - **EC50:** 288.7 mg/l
  - Exposure time: 3 h
  - Test Type: Respiration inhibition
  - Method: OECD Test Guideline 209

- **M-Factor (Chronic aquatic toxicity):** 1

**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:** 0.052 mg/l
  - Exposure time: 32 d
  - Species: Pimephales promelas (fathead minnow)
  - Method: OECD Test Guideline 210

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

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

- **M-Factor (Chronic aquatic toxicity):** 1,000
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

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
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 5.5
Revision Date: 27.08.2021
SDS Number: 817858-00015
Date of last issue: 10.10.2020
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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 IMO instruments
Not applicable for product as supplied.

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

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

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

Clotrimazole / Gentamicin / Betamethasone (0.1%) Formulation

Version 5.5
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16. OTHER INFORMATION

Further information

Date format: dd.mm.yyyy

Full text of other abbreviations
ACGIH: USA. ACGIH Threshold Limit Values (TLV)
IN OEL: India. Permissible levels of certain chemical substances in work environment.

ACGIH / TWA: 8-hour, time-weighted average
IN OEL / TWA: Time-Weighted Average Concentration (TWA) (8 hrs.)
IN OEL / STEL: Short-term exposure Limit STEL (15 min)

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
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone
(0.1%) Formulation

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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.

IN / EN