SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Section 1: Identification

Product name: Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Manufacturer or supplier’s details

Company: MSD
Address: 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone: 908-740-4000
Emergency telephone number: 1-908-423-6000
E-mail address: EHSDATASTEWARD@msd.com
Telefax: 908-735-1496

Recommended use of the chemical and restrictions on use

Recommended use: Pharmaceutical

Section 2: Hazard identification

GHS Classification

Reproductive toxicity: Repr.1B
Specific target organ toxicity - repeated exposure: STOT RE1 (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland)

GHS label elements

Hazard pictograms:

Signal word: Danger

Hazard statements: H360D May damage the unborn child.
H372 Causes damage to organs (Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland) through prolonged or repeated exposure.

Precautionary statements: Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product. 
P281 Use personal protective equipment as required.

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

Storage:
P405 Store locked up.

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

Other hazards which do not result in classification
None known.

Section 3: Composition/information on ingredients

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>&gt;= 10 -&lt; 30</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Hexadecan-1-ol. Ethoxylated</td>
<td>9004-95-9</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>&lt; 3</td>
</tr>
<tr>
<td>Benzyl alcohol</td>
<td>100-51-6</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>&lt; 0.3</td>
</tr>
<tr>
<td>betamethasone</td>
<td>378-44-9</td>
<td>&gt;= 0.01 -&lt; 0.3</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

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

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

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

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

If swallowed : If swallowed, DO NOT induce vomiting. 
               Get medical attention. 
               Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed:
- May damage the unborn child.
- Causes damage to organs through prolonged or repeated exposure.

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

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 firefighters:
- 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 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 deter-
mine 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 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.

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

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

Materials to avoid: Do not store with the following product types:
- Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Petrolatum</td>
<td>8009-03-8</td>
<td>WES-TWA (Mist)</td>
<td>5 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>WES-STEI (Mist)</td>
<td>10 mg/m3</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate)</td>
<td>5 mg/m3</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

Further information: Sampled by a method that does not collect vapour.
# SAFETY DATA SHEET

## Clotrimazole / Gentamicin / Betamethasone (0.05%) 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>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>late matter</th>
<th>WES-TWA (particulate)</th>
<th>WES-TWA (Vapour and particulates)</th>
<th>NZ OEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene glycol</td>
<td>57-55-6</td>
<td>10 mg/m³</td>
<td>150 ppm 474 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td>Paraffin oil</td>
<td>8012-95-1</td>
<td>5 mg/m³</td>
<td></td>
<td>NZ OEL</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>WES-STEI (Mist)</th>
<th>TWA (Inhalable particulate matter)</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clotrimazole</td>
<td>23593-75-1</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td></td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>0.1 mg/m³ (OEB 2)</td>
<td></td>
</tr>
<tr>
<td>Betamethasone</td>
<td>378-44-9</td>
<td>1 µg/m³ (OEB 4)</td>
<td></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

Material: Safety glasses with side shields or goggles.

Remarks: 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

Material: Work uniform or laboratory coat.

Remarks: 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
- **Colour**: No data available
- **Odour**: No data available
- **Odour Threshold**: No data available
- **pH**: No data available
- **Melting point/freezing point**: No data available
- **Initial boiling point and boiling range**: No data available
- **Flash point**: No data available
- **Evaporation rate**: No data available
- **Flammability (solid, gas)**: Not applicable
- **Flammability (liquids)**: No data available
- **Upper explosion limit / Upper flammability limit**: No data available
- **Lower explosion limit / Lower flammability limit**: No data available
- **Vapour pressure**: No data available
- **Relative vapour density**: No data available
- **Relative density**: No data available
- **Density**: No data available
- **Solubility(ies)**
  - Water solubility: No data available
- **Partition coefficient: n-octanol/water**: Not applicable
- **Auto-ignition temperature**: No data available
- **Decomposition temperature**: No data available
- **Viscosity**
  - Viscosity, kinematic: No data available
# SAFETY DATA SHEET

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</tr>
</thead>
</table>

- **Explosive properties**: Not explosive
- **Oxidizing properties**: The substance or mixture is not classified as oxidizing.
- **Particle size**: Not applicable

### Section 10: Stability and reactivity

- **Reactivity**: Not classified as a reactivity hazard.
- **Chemical stability**: Stable under normal conditions.
- **Possibility of hazardous reactions**: Can react with strong oxidizing agents.
- **Conditions to avoid**: None known.
- **Incompatible materials**: Oxidizing agents
- **Hazardous decomposition products**: No hazardous decomposition products are known.

### Section 11: Toxicological information

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

**Acute toxicity**
Not classified based on available information.

**Product**

<table>
<thead>
<tr>
<th>Type</th>
<th>Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>&gt; 2,000 mg/kg</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute inhalation toxicity</td>
<td>&gt; 5 mg/l</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>&gt; 2,000 mg/kg</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

#### Components

**Petrolatum**

<table>
<thead>
<tr>
<th>Type</th>
<th>Estimate</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>&gt; 5,000 mg/kg</td>
<td>OECD Test Guideline 401</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>&gt; 2,000 mg/kg</td>
<td>OECD Test Guideline 402</td>
<td>The substance or mixture has no acute dermal toxicity</td>
</tr>
</tbody>
</table>
Propylene glycol:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity : LC50 (Rabbit): > 159 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

Paraffin oil:
Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
  Assessment: The substance or mixture has no acute dermal toxicity

Hexadecan-1-ol. Ethoxylated:
Acute oral toxicity : LD50 (Rat): 2,500 mg/kg

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

Benzy alcohol:
Acute oral toxicity : LD50 (Rat): 1,620 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 4.178 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
  Method: OECD Test Guideline 403

Gentamicin:
Acute oral toxicity : LD50 (Rat): 8,000 - 10,000 mg/kg
  LD50 (Mouse): 10,000 mg/kg
Acute inhalation toxicity : LC50 (Rat): > 0.2 mg/l
  Exposure time: 4 h
  Test atmosphere: dust/mist
Remarks: No mortality observed at this dose.

Acute toxicity (other routes of administration):
- LD50 (Rat): 67 - 96 mg/kg
  Application Route: Intravenous
- LD50 (Rat): 371 - 384 mg/kg
  Application Route: Intramuscular
- LDLo (Monkey): 30 mg/kg
  Application Route: Intravenous

**betamethasone:**
- Acute oral toxicity
  - LD50 (Rat): > 5,000 mg/kg
- LD50 (Mouse): > 4,500 mg/kg
- Acute inhalation toxicity
  - LC50 (Rat): 0.4 mg/l
    - Exposure time: 4 h

**Skin corrosion/irritation**
Not classified based on available information.

**Components:**

**Petrolatum:**
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation
- Remarks: Based on data from similar materials

**Propylene glycol:**
- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation

**Paraffin oil:**
- Species: Rabbit
- Result: No skin irritation

**clotrimazole:**
- Species: Rabbit
- Result: No skin irritation

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

**Gentamicin:**
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Version 4.5  Revision Date: 23.03.2020  SDS Number: 610547-00012  Date of last issue: 13.09.2019
Date of first issue: 29.04.2016

Species: Rabbit
Result: Mild skin irritation

betamethasone:
Species: Rabbit
Result: Mild skin irritation

Serious eye damage/eye irritation
Not classified based on available information.

Components:

Petrolatum:
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

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

Paraffin oil:
Species: Rabbit
Result: No eye irritation

Hexadecan-1-ol. Ethoxylated:
Result: Irritation to eyes, reversing within 21 days
Remarks: Based on data from similar materials

clotrimazole:
Species: Rabbit
Result: Mild eye irritation

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

Gentamicin:
Species: Rabbit
Result: Mild eye irritation

betamethasone:
Species: Rabbit
Result: No eye irritation
Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

Petrolatum:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

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

Benzyl alcohol:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Gentamicin:
Remarks: No data available

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

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

Components:

Petrolatum:
Genotoxicity in vitro: Test Type: Chromosome aberration test in vitro
Result: negative
Remarks: Based on data from similar materials
Genotoxicity in vivo:
  Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Intraperitoneal injection
  Method: OECD Test Guideline 474
  Result: negative
  Remarks: Based on data from similar materials

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

Genotoxicity in vivo:
  Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Intraperitoneal injection
  Result: negative

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.

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

Genotoxicity in vivo:
  Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
  Species: Mouse
  Application Route: Intraperitoneal injection
  Result: negative
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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

Test Type: Chromosome aberration test in vitro
Result: equivocal

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

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

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

Test Type: Chromosome aberration test in vitro
Result: positive

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

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

Carcinogenicity
Not classified based on available information.

Components:

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

Propylene glycol:
Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative
clotrimazole:
Species: Rat
Application Route: Oral
Exposure time: 78 weeks
Result: negative

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

Gentamicin:
Carcinogenicity - Assessment: No data available
Reproductive toxicity: May damage the unborn child.

Components:
Petrolatum:
Effects on fertility: Test Type: Reproduction/Developmental toxicity screening test
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Skin contact
Result: negative
Remarks: Based on data from similar materials

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

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

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

Effect on foetal development:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>LOAEL: 100 mg/kg body weight</td>
<td>Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rat</td>
<td>Oral</td>
<td>NOAEL: 50 mg/kg body weight</td>
<td>Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Mouse</td>
<td>Oral</td>
<td>NOAEL: 200 mg/kg body weight</td>
<td>No effects on foetal development</td>
</tr>
<tr>
<td>Embryo-foetal development</td>
<td>Rabbit</td>
<td>Oral</td>
<td>NOAEL: 180 mg/kg body weight</td>
<td>No effects on foetal development</td>
</tr>
</tbody>
</table>

Reproductive toxicity - Assessment:

Some evidence of adverse effects on sexual function and fertility, based on animal experiments. Some evidence of adverse effects on development, based on animal experiments.

Benzyl alcohol:

Effect on fertility:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fertility/early embryonic development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Effect on foetal development:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Mouse</td>
<td>Ingestion</td>
<td>negative</td>
</tr>
</tbody>
</table>

Gentamicin:

Effect on fertility:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Fertility</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two-generation reproduction toxicity study</td>
<td>Rat</td>
<td>NOAEL: 20 mg/kg body weight</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

Effect on foetal development:

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Embryo-foetal development</td>
<td>Rabbit</td>
</tr>
</tbody>
</table>
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.
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Components:

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

**Gentamicin:**
Target Organs: Kidney, inner ear
Assessment: Causes damage to organs through prolonged or repeated exposure.

**betamethasone:**
Target Organs: Pituitary gland, Immune system, muscle, thymus gland, Blood, Adrenal gland
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

**Petrolatum:**
Species: Rat
NOAEL: 5,000 mg/kg
Application Route: Ingestion
Exposure time: 2 yr

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

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

**clotrimazole:**
Species: Rabbit
LOAEL: 5 - 40 mg/kg
Application Route: Skin contact
Exposure time: 3 Weeks
Target Organs: Skin
Symptoms: Oedema, Fissuring, Necrosis, Redness
Species: Rat
SAFETY DATA SHEET
Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

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

Benzyl alcohol:
Species: Rat
NOAEL: 1.072 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 28 Days
Method: OECD Test Guideline 412

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

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

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

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

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

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 4.5  Revision Date: 23.03.2020  SDS Number: 610547-00012  Date of last issue: 13.09.2019
Date of first issue: 29.04.2016

betamethasone:
Species : Rabbit
LOAEL : 0.05 %
Application Route : Skin contact
Exposure time : 10 - 30 d
Target Organs : Pituitary gland, Immune system, muscle

Species : Rat
LOAEL : 0.05 %
Application Route : Skin contact
Exposure time : 8 Weeks
Target Organs : thymus gland

Species : Mouse
LOAEL : 0.1 %
Application Route : Skin contact
Exposure time : 8 Weeks
Target Organs : thymus gland

Species : Dog
LOAEL : 0.05 mg/kg
Application Route : Oral
Exposure time : 28 d
Target Organs : Blood, thymus gland, Adrenal gland

Aspiration toxicity
Not classified based on available information.

Components:

Paraffin oil:
The substance or mixture is known to cause human aspiration toxicity hazards or has to be regarded as if it causes a human aspiration toxicity hazard.

Experience with human exposure

Components:
clotrimazole:
Skin contact : Symptoms: Rash, Itching, Blistering, 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
### Section 12: Ecological information

**Ecotoxicity**

**Components:**

**Petrolatum:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LL50 (Pimephales promelas (fathead minnow)): &gt; 100 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 203</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposition time: 96 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 10,000 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 203</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposition time: 48 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEL (Pseudokirchneriella subcapitata (green algae)): &gt;= 100 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposition time: 72 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEC (Daphnia magna (Water flea)): 10 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposition time: 21 d</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Propylene glycol:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposition time: 96 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>Component</th>
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<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposition time: 48 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to algae/aquatic plants</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposition time: 72 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposition time: 7 d</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to microorganisms</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NOEC (Pseudomonas putida): &gt; 20,000 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposition time: 18 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Paraffin oil:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Toxicity to fish</th>
<th>Test substance</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>LL50 (Scophthalmus maximus (turbot)): &gt; 1,028 mg/l</td>
<td>Water Accommodated Fraction</td>
<td>OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposition time: 96 h</td>
<td></td>
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</table>

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<tr>
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<tr>
<td></td>
<td>NOEC (Pseudomonas putida): &gt; 20,000 mg/l</td>
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</tr>
<tr>
<td></td>
<td>Exposition time: 18 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Toxicity to daphnia and other aquatic invertebrates:
- EL50 (Acartia tonsa): > 3,193 mg/l
  - Exposure time: 48 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
- EL50 (Skeletonema costatum (marine diatom)): > 3,200 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials

NOELR (Skeletonema costatum (marine diatom)): 993 mg/l
  - Exposure time: 72 h
  - Test substance: Water Accommodated Fraction
  - Remarks: Based on data from similar materials

Hexadecan-1-ol. Ethoxylated:
- LC50: > 1 - 10 mg/l
  - Exposure time: 96 h
  - Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
- EC50: > 1 - 10 mg/l
  - Exposure time: 48 h
  - Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
- EC50: > 10 - 100 mg/l
  - Exposure time: 72 h
  - Remarks: Based on data from similar materials

Clotrimazole:
- 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
### Benzyl alcohol:

**Toxicity to fish**
- **Test Type:** Respiration inhibition
- **Method:** OECD Test Guideline 209
- **Exposure time:** 3 h
- **LC50 (Pimephales promelas (fathead minnow)):** 460 mg/l
- **Exposure time:** 96 h

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

**Toxicity to algae/aquatic plants**
- **EC50 (Pseudokirchneriella subcapitata (green algae)):** 770 mg/l
- **Exposure time:** 72 h
- **Method:** OECD Test Guideline 201
- **NOEC (Pseudokirchneriella subcapitata (green algae)):** 310 mg/l
- **Exposure time:** 72 h
- **Method:** OECD Test Guideline 201

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

### Gentamicin:

**Toxicity to daphnia and other 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
- **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
Method: OECD Test Guideline 209

**betamethasone:**
Toxicity to daphnia and other aquatic invertebrates: EC50 (Americamysis): > 50 mg/l
Exposure time: 96 h

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

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

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

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

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

**Persistence and degradability**

**Components:**

**Petrolatum:**
Biodegradability: Result: Not readily biodegradable.
Biodegradation: 31 %
Exposure time: 28 d
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

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

**Paraffin oil:**
Biodegradability: Result: Readily biodegradable. Biodegradation: 82 % Exposure time: 24 d Method: OECD Test Guideline 301F Remarks: Based on data from similar materials

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

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

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

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

Bioaccumulative potential

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

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

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

Betamethasone:
Partition coefficient: n-octanol/water: log Pow: 2.11

Mobility in soil
No data available

Other adverse effects
No data available
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 4.5 Revision Date: 23.03.2020 SDS Number: 610547-00012 Date of last issue: 13.09.2019 Date of first issue: 29.04.2016

Section 13: Disposal considerations

Disposal methods

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

Section 14: Transport information

International Regulations

UNRTDG
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone, clotrimazole)
Class: 9
Packing group: III
Labels: 9

IATA-DGR
UN/ID No.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (betamethasone, clotrimazole)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environments hazardous: yes

IMDG-Code
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (betamethasone, clotrimazole)
Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable for product as supplied.

National Regulations

NZS 5433
UN number: UN 3082
Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
SAFETY DATA SHEET

Clotrimazole / Gentamicin / Betamethasone
(0.05%) Formulation

Version 4.5  Revision Date: 23.03.2020  SDS Number: 610547-00012  Date of last issue: 13.09.2019
Date of first issue: 29.04.2016

(betamethasone, clotrimazole)

Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z

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

Section 15: Regulatory information

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

HSNO Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

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

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

Section 16: Other information

Further information
Date format : dd.mm.yyyy

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

Clotrimazole / Gentamicin / Betamethasone (0.05%) Formulation

Version 4.5  Revision Date: 23.03.2020  SDS Number: 610547-00012  Date of last issue: 13.09.2019  Date of first issue: 29.04.2016

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.

NZ / EN