SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Mometasone / Clotrimazole / Gentamicin 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: Veterinary product

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification
Reproductive toxicity: Category 1A
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.
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.
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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td>White mineral oil (petroleum)</td>
</tr>
<tr>
<td></td>
<td>clotrimazole</td>
</tr>
<tr>
<td></td>
<td>Gentamicin</td>
</tr>
<tr>
<td></td>
<td>Mometasone</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. May cause damage to organs through prolonged or repeated exposure if swallowed.

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/PERSOANL 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></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>Mometasone</td>
<td>83919-23-7</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
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

Material : 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 : suspension

Color : white to off-white

Odor : oily

Odor Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable
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:**

<table>
<thead>
<tr>
<th>Route</th>
<th>Toxicity Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute oral toxicity</strong></td>
<td>&gt; 5,000 mg/kg</td>
<td>Calculation method</td>
</tr>
<tr>
<td><strong>Acute dermal toxicity</strong></td>
<td>&gt; 5,000 mg/kg</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

**Components:**

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Route</th>
<th>Toxicity Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute oral toxicity</strong></td>
<td>&gt; 5,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td><strong>Acute inhalation toxicity</strong></td>
<td>&gt; 5 mg/l</td>
<td></td>
</tr>
<tr>
<td><strong>Acute dermal toxicity</strong></td>
<td>&gt; 2,000 mg/kg</td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
</tbody>
</table>

**Clotrimazole:**

<table>
<thead>
<tr>
<th>Route</th>
<th>Toxicity Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute oral toxicity</strong></td>
<td>708 mg/kg</td>
<td></td>
</tr>
<tr>
<td><strong>LD50 (Mouse)</strong></td>
<td>761 mg/kg</td>
<td></td>
</tr>
<tr>
<td><strong>LD50 (Rabbit)</strong></td>
<td>&gt; 1,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td><strong>Acute inhalation toxicity</strong></td>
<td>&gt; 0.73 mg/l</td>
<td></td>
</tr>
<tr>
<td><strong>Acute dermal toxicity</strong></td>
<td>&gt; 923 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

**Gentamicin:**

<table>
<thead>
<tr>
<th>Route</th>
<th>Toxicity Estimate</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute oral toxicity</strong></td>
<td>8,000 - 10,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td><strong>LD50 (Mouse)</strong></td>
<td>10,000 mg/kg</td>
<td></td>
</tr>
<tr>
<td><strong>Acute inhalation toxicity</strong></td>
<td>&gt; 0.2 mg/l</td>
<td></td>
</tr>
<tr>
<td><strong>Acute dermal toxicity</strong></td>
<td>&gt; 923 mg/kg</td>
<td></td>
</tr>
<tr>
<td><strong>Acute toxicity (other routes of)</strong></td>
<td>&gt; 67 - 96 mg/kg</td>
<td>Remarks: No mortality observed at this dose.</td>
</tr>
</tbody>
</table>
Mometasone:  
Acute oral toxicity:  
LD50 (Rat): > 2,000 mg/kg  
LD50 (Mouse): > 2,000 mg/kg  

Acute inhalation toxicity:  
LC50 (Rat): > 3.3 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Remarks: No mortality observed at this dose.  
LC50 (Mouse): > 3.2 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

Acute toxicity (other routes of administration):  
LD50 (Rat): 300 mg/kg  
Application Route: Subcutaneous  
Symptoms: Breathing difficulties

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

Mometasone:  
Species: Rabbit  
Result: No skin irritation

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

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

clotrimazole:
Species : Rabbit
Result : Mild eye irritation

Gentamicin:
Species : Rabbit
Result : Mild eye irritation

Mometasone:
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

Mometasone:
Test Type : Maximization Test
Routes of exposure : Dermal
Species : Guinea pig
Assessment : Does not cause skin sensitization.
Result : negative
Remarks : The results of a test on guinea pigs showed this substance to be a weak skin 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

Mometasone:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Chinese hamster lung cells
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Chinese hamster ovary cells
  Result: positive
- Test Type: Mouse Lymphoma
  Result: negative

Genotoxicity in vivo:
- Test Type: Micronucleus test
  Species: Mouse
  Application Route: Oral
  Result: negative
- Test Type: Chromosomal aberration
  Species: Rat
  Cell type: Bone marrow
  Result: negative
- Test Type: unscheduled DNA synthesis assay
  Species: Rat
  Cell type: Liver cells
  Result: negative

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
Mometasone:
Species: Rat
Application Route: Inhalation
Exposure time: 2 Years
Dose: 0.067 mg/kg body weight
Result: negative

Species: Mouse
Application Route: Inhalation
Exposure time: 19 Months
Dose: 0.160 mg/kg body weight
Result: negative

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

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

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

Reproductive toxicity - Assessment:
: Some evidence of adverse effects on sexual function and fertility, based on animal experiments. Some evidence of adverse effects on development, based on animal experiments.

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.

Mometasone:
Effects on fertility
: Test Type: Fertility
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 0.015 mg/kg body weight
Symptoms: Reduced embryonic survival, Reduced fetal weight.
**Effects on fetal development**

- **Test Type:** Embryo-fetal development  
  **Species:** Mouse  
  **Application Route:** Subcutaneous  
  **Embryo-fetal toxicity:** LOAEL: 0.06 mg/kg body weight  
  **Result:** Embryotoxic effects, Teratogenicity and developmental toxicity

- **Test Type:** Embryo-fetal development  
  **Species:** Rat  
  **Application Route:** Dermal  
  **Embryo-fetal toxicity:** LOAEL: 0.3 mg/kg body weight  
  **Result:** Embryo-fetal toxicity.

- **Test Type:** Embryo-fetal development  
  **Species:** Rabbit  
  **Application Route:** Dermal  
  **Embryo-fetal toxicity:** LOAEL: 0.15 mg/kg body weight  
  **Result:** Embryo-fetal toxicity, Malformations were observed.

- **Test Type:** Embryo-fetal development  
  **Species:** Rat  
  **Application Route:** Subcutaneous  
  **Embryo-fetal toxicity:** LOAEL: 0.15 mg/kg body weight  
  **Result:** Effects on newborn.

- **Test Type:** Embryo-fetal development  
  **Species:** Rabbit  
  **Application Route:** Oral  
  **Embryo-fetal toxicity:** LOAEL: 0.7 mg/kg body weight  
  **Result:** Embryo-fetal toxicity, Malformations were observed.

**Reproductive toxicity - Assessment**

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

---

**STOT-single exposure**

Not classified based on available information.

**Components:**

**Mometasone:**

**Remarks**

Based on available data, the classification criteria are not met.

---

**STOT-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.

### Mometasone:

**Routes of exposure:** inhalation (dust/mist/fume)  
**Target Organs:** Immune system, Liver, Kidney, Skin  
**Assessment:** May cause damage to organs through prolonged or repeated exposure.

#### Repeated dose toxicity

**Components:**

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
<th>LOAEL</th>
<th>160 mg/kg</th>
<th>Application Route</th>
<th>Ingestion</th>
<th>Exposure time</th>
<th>90 Days</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
<th>LOAEL</th>
<th>&gt;= 1 mg/l</th>
<th>Application Route</th>
<th>inhalation (dust/mist/fume)</th>
<th>Exposure time</th>
<th>4 Weeks</th>
<th>Method</th>
<th>OECD Test Guideline 412</th>
</tr>
</thead>
</table>

**clotrimazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
<th>LOAEL</th>
<th>5 - 40 mg/kg</th>
<th>Application Route</th>
<th>Skin contact</th>
<th>Exposure time</th>
<th>3 Weeks</th>
<th>Target Organs</th>
<th>Skin</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
<th>LOAEL</th>
<th>10 mg/kg</th>
<th>Application Route</th>
<th>Oral</th>
<th>Exposure time</th>
<th>18 Months</th>
<th>Target Organs</th>
<th>Liver, Kidney, Adrenal gland</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>Dog</th>
<th>LOAEL</th>
<th>25 mg/kg</th>
<th>Application Route</th>
<th>Oral</th>
<th>Exposure time</th>
<th>6 - 12 Months</th>
<th>Target Organs</th>
<th>Adrenal gland</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Edema, Fissuring, Necrosis, Redness</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>Rat</td>
</tr>
<tr>
<td>----------</td>
<td>--------------</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>Salivation, Lachrymation, Vomiting</th>
</tr>
</thead>
</table>
### Gentamicin:

<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>3 mg/kg</td>
<td>Intramuscular</td>
<td>12 Months</td>
<td>Kidney</td>
<td>Vomiting, Salivation</td>
</tr>
<tr>
<td>Monkey</td>
<td>50 mg/kg</td>
<td>Subcutaneous</td>
<td>3 Weeks</td>
<td>Kidney, inner ear</td>
<td></td>
</tr>
<tr>
<td>Monkey</td>
<td>6 mg/kg</td>
<td>Intramuscular</td>
<td>3 Weeks</td>
<td>Blood, Kidney, inner ear, Liver</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>5 mg/kg</td>
<td>Intramuscular</td>
<td>52 Weeks</td>
<td>Kidney, Blood</td>
<td></td>
</tr>
<tr>
<td>Rat</td>
<td>12.5 mg/kg</td>
<td>Intramuscular</td>
<td>13 Weeks</td>
<td>Kidney</td>
<td></td>
</tr>
</tbody>
</table>

### Mometasone:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>0.005 mg/kg</td>
<td>0.3 mg/kg</td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Dog</td>
<td>0.5 mg/kg</td>
<td></td>
<td>Oral</td>
<td>30 d</td>
<td>Lymph nodes, Liver, Adrenal gland, Skin, thymus gland</td>
</tr>
<tr>
<td>Rat</td>
<td>0.00013 mg/l</td>
<td></td>
<td>inhalation (dust/mist/fume)</td>
<td>90 d</td>
<td>Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow,</td>
</tr>
</tbody>
</table>
Kidney, Liver, thymus gland

Species: Dog  
NOAEL: 0.0005 mg/l  
Application Route: inhalation (dust/mist/fume)  
Exposure time: 90 d  
Target Organs: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, thymus gland, Liver

Aspiration toxicity
Not classified based on available information.

Components:

Mometasone: Not applicable

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

Mometasone:
Inhalation: Symptoms: allergic rhinitis, Headache, pharyngitis, upper respiratory tract infection, sinusitis, oral candidiasis, Back pain, musculoskeletal pain, immune system effects, indigestion  
Skin contact: Symptoms: Dermatitis, Itching

Further information

Components:

Mometasone:
Remarks: Dermal absorption possible

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
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
Method: OECD Test Guideline 202

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

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

**Mometasone**:
Toxicity to fish:
- **LC50** (Menidia beryllina (Silverside)): 0.11 mg/l
  - Exposure time: 96 h
  - Remarks: No toxicity at the limit of solubility.

- **LC50** (Cyprinodon variegatus (sheepshead minnow)): > 5 mg/l
  - Exposure time: 7 d
  - Remarks: No toxicity at the limit of solubility.

Toxicity to daphnia and other aquatic invertebrates:
- **EC50** (Daphnia magna (Water flea)): > 5 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: No toxicity at the limit of solubility.

- **EC50** (Americamysis): > 5 mg/l
  - Exposure time: 96 h
  - Remarks: No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants:
- **EC50** (Pseudokirchneriella subcapitata (green algae)): > 3.2 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)): 0.00014 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)): 0.34 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility.

Toxicity to microorganisms:

EC50: > 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility.

NOEC: 1,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209
Remarks: No toxicity at the limit of solubility.

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

Mometasone:

Biodegradability: Result: Not readily biodegradable.
Biodegradation: 50 %
Exposure time: 28 d
Method: OECD Test Guideline 314

Stability in water: Hydrolysis: 50% (12 d)
Method: OECD Test Guideline 111

Bioaccumulative potential

Components:

Gentamicin:

Partition coefficient: n-octanol/water: log Pow: < -2
Mometasone: Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 107.1 Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water: log Pow: 4.68

Mobility in soil

Components:

Mometasone:
Distribution among environmental compartments: log Koc: 4.02

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.: UN 3082
Proper shipping name: Environmentally hazardous substance, liquid, n.o.s. (clotrimazole, Gentamicin)
Class: 9
Packing group: III
Labels: Miscellaneous
Packing instruction (cargo aircraft): 964
Packing instruction (passenger aircraft): 964
Environmentally hazardous: yes

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

Class: 9
Packing group: III
Labels: 9
EmS Code: F-A, S-F
Marine pollutant: yes

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

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. Not applicable

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

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.

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