SECTION 1. IDENTIFICATION

Product name: Mometasone / Clotrimazole / Gentamicin Formulation
Other means of identification: No data available

Manufacturer or supplier's details
Company name of supplier: Merck & Co., Inc
Address: 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065
Telephone: 908-740-4000
Emergency telephone: 1-908-423-6000
E-mail address: EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use
Recommended use: Veterinary product
Restrictions on use: Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the Hazardous Products Regulations
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 and face protection.
Response:
P308 + P313 IF exposed or concerned: Get medical attention.
SAFETY DATA SHEET
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Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>Paraffinum liquidum</td>
<td>8042-47-5</td>
<td>&gt; 90 - &lt;= 100</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>No data available</td>
<td>23593-75-1</td>
<td>1</td>
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<tr>
<td>Gentamicin</td>
<td>No data available</td>
<td>1403-66-3</td>
<td>0.5</td>
</tr>
<tr>
<td>Mometasone</td>
<td>No data available</td>
<td>83919-23-7</td>
<td>0.1</td>
</tr>
</tbody>
</table>

SECTION 4. FIRST AID MEASURES

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

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

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

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

If swallowed: If swallowed, DO NOT induce vomiting.
Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and delayed: May damage the unborn child. Suspected of damaging fertility.
May cause damage to organs through prolonged or repeated exposure if swallowed.
SAFETY DATA SHEET
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**Mometasone / Clotrimazole / Gentamicin 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>
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<td>4.11</td>
<td>09/30/2023</td>
<td>412812-00022</td>
<td>04/04/2023</td>
<td>12/14/2015</td>
</tr>
</tbody>
</table>

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 (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 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 mist or vapors.
- 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.

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
  - Self-reactive substances and mixtures
  - Organic peroxides
  - Explosives
  - Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>TWA (Mist)</td>
<td>5 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEL (Mist)</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Mist)</td>
<td>1 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWAEV (Mist - Inhalable dust)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</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>
</tbody>
</table>
Further information: OTO

Mometasone | 83919-23-7 | TWA | 1 µg/m³ (OEB 4) | Internal
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 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.

**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.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**

suspension
Mometasone / Clotrimazole / Gentamicin Formulation

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

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor density: No data available

Relative density: No data available

Density: No data available

Solubility(ies)

Water solubility: No data available

Partition coefficient: n-octanol/water: Not applicable

Autoignition temperature: No data available

Decomposition temperature: No data available

Viscosity

Viscosity, kinematic: No data available

Explosive properties: Not explosive

Oxidizing properties: The substance or mixture is not classified as oxidizing.

Particle size: Not applicable
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SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure
Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Acute dermal toxicity: Acute toxicity estimate: > 2,000 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
### Mometasone / Clotrimazole / Gentamicin Formulation

| 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  
Application Route: Intravenous

#### 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.

**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
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
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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

clofiramazole:

- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Ingestion
- Result: negative

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

- Test Type: Embryo-fetal development
- Species: Rat
- Application Route: Oral
- Developmental Toxicity: LOAEL: 100 mg/kg body weight
- Result: Embryo-fetal toxicity. No teratogenic effects.

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

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

Reproductive toxicity - Assessment

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

Gentamicin:

- Test Type: Two-generation reproduction toxicity study
- Species: Rat
- Fertility: NOAEL: 20 mg/kg body weight
- Result: No significant adverse effects were reported

- 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.  
Result: No effects on fertility., Effect on reproduction capacity.

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
**Reproductive toxicity**

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.

**STOT-single exposure**

Not classified based on available information.

**Components:**

**Mometasone:**

<table>
<thead>
<tr>
<th>Remarks</th>
<th>Based on available data, the classification criteria are not met.</th>
</tr>
</thead>
</table>

**STOT-repeated exposure**

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

**Components:**

**Clotrimazole:**

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Liver, Kidney, Adrenal gland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment</td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

**Gentamicin:**

<table>
<thead>
<tr>
<th>Target Organs</th>
<th>Kidney, inner ear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assessment</td>
<td>Causes damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

**Mometasone:**

<table>
<thead>
<tr>
<th>Routes of exposure</th>
<th>inhalation (dust/mist/fume)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target Organs</td>
<td>Immune system, Liver, Kidney, Skin</td>
</tr>
<tr>
<td>Assessment</td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
</tr>
</tbody>
</table>

**Repeated dose toxicity**

**Components:**

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
</table>
### LOAEL:

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Species</th>
<th>LOAEL</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Rat</td>
<td>160 mg/kg</td>
<td>90 Days</td>
<td>Skin</td>
<td>Edema, Fissuring, Necrosis, Redness</td>
</tr>
<tr>
<td>inhalation (dust/mist/fume)</td>
<td>Rabbit</td>
<td>5 - 40 mg/kg</td>
<td>3 Weeks</td>
<td>Skin</td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Rat</td>
<td>10 mg/kg</td>
<td>18 Months</td>
<td>Liver, Kidney, Adrenal gland</td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Dog</td>
<td>25 mg/kg</td>
<td>6 - 12 Months</td>
<td>Adrenal gland</td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td>Monkey</td>
<td>3 mg/kg</td>
<td>12 Months</td>
<td>Kidney</td>
<td></td>
</tr>
<tr>
<td>Subcutaneous</td>
<td>Monkey</td>
<td>50 mg/kg</td>
<td>3 Weeks</td>
<td>Kidney, inner ear</td>
<td></td>
</tr>
<tr>
<td>Intramuscular</td>
<td>Monkey</td>
<td>6 mg/kg</td>
<td>3 Weeks</td>
<td>Blood, Kidney, inner ear, Liver</td>
<td></td>
</tr>
</tbody>
</table>
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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

Mometasone:
Species: Rat
NOAEL: 0.005 mg/kg
LOAEL: 0.3 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species: Dog
NOAEL: 0.5 mg/kg
Application Route: Oral
Exposure time: 30 d
Target Organs: Lymph nodes, Liver, Adrenal gland, Skin, thymus gland

Species: Rat
NOAEL: 0.00013 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 90 d
Target Organs: Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, 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
Method: OECD Test Guideline 203

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

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

Toxicity to fish (Chronic toxicity): NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l
Exposure time: 28 d

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

| Toxicity to fish | LC50 (Brachydanio rerio (zebrafish)): > 0.29 mg/l  
| Exposure time: 96 h  
| Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): 0.02 mg/l  
| Exposure time: 48 h |
| Toxicity to algae/aquatic plants | EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l  
| Exposure time: 72 h  
| NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l  
| Exposure time: 72 h |
| Toxicity to fish (Chronic toxicity) | NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 mg/l  
| Exposure time: 32 d  
| Method: OECD Test Guideline 210 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | NOEC (Daphnia magna (Water flea)): 0.01 mg/l  
| Exposure time: 21 d  
| Method: OECD Test Guideline 211 |
| Toxicity to microorganisms | EC50: > 10,000 mg/l  
| Exposure time: 3 h  
| Test Type: Respiration inhibition  
| Method: OECD Test Guideline 209 |

## Gentamicin:

| Toxicity to daphnia and other aquatic invertebrates | EC50 (Daphnia magna (Water flea)): 86 mg/l  
| Exposure time: 48 h  
| 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
Method: US-EPA OPPTS 850.1035
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 environ-
mental compartments

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Do not dispose of waste into sewer. 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
Environmentally hazardous: yes

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

**TDG**
- **UN number**: UN 3082
- **Proper shipping name**: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (clotrimazole, Gentamicin)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9
- **ERG Code**: 171
- **Marine pollutant**: yes(clotrimazole, Gentamicin)

**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**

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)
- **CA AB OEL**: Canada. Alberta, Occupational Health and Safety Code (table 2: OEL)
- **CA BC OEL**: Canada. British Columbia OEL
- **CA QC OEL**: Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants
- **ACGIH / TWA**: 8-hour, time-weighted average
- **CA AB OEL / TWA**: 8-hour Occupational exposure limit
- **CA AB OEL / STEL**: 15-minute occupational exposure limit
- **CA BC OEL / TWA**: 8-hour time weighted average
- **CA QC OEL / TWAEV**: Time-weighted average exposure value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for
Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50% of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System.

Sources of key data used to compile the Material Safety Data Sheet:
- Revision Date: 09/30/2023
- Date format: mm/dd/yyyy

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.

CA / Z8