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

Mometasone / Clotrimazole / Gentamicin Formulation

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

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Components</td>
<td></td>
</tr>
<tr>
<td>Chemical name</td>
<td>Common Name/Synonym</td>
</tr>
<tr>
<td>White mineral oil (petroleum)</td>
<td>Paraffinum liquidum</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>No data available</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>No data available</td>
</tr>
<tr>
<td>Mometasone</td>
<td>No data available</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 firefighting: 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>TWAEV (Mist)</td>
<td>5 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>STEV (Mist)</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Inhalable particulate matter)</td>
<td>5 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>clotrimazole</td>
<td>23593-75-1</td>
<td>TWA</td>
<td>0.2 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>TWA</td>
<td>0.1 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</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
Color: white to off-white
Odor: oily
Odor Threshold: No data available
SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

Version 4.10  Revision Date: 04/04/2023  SDS Number: 412812-00021  Date of last issue: 07/22/2022
Date of first issue: 12/14/2015

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

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : 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
LD50 (Rabbit): > 1,000 mg/kg

Acute inhalation toxicity: LC50 (Rat): > 0.73 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity: LD50 (Mouse): 923 mg/kg
**Gentamicin:**

**Acute oral toxicity**
- LD$_{50}$ (Rat): 8,000 - 10,000 mg/kg
- LD$_{50}$ (Mouse): 10,000 mg/kg

**Acute inhalation toxicity**
- LC$_{50}$ (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)**
- LD$_{50}$ (Rat): 67 - 96 mg/kg
  - Application Route: Intravenous
- LD$_{50}$ (Rat): 371 - 384 mg/kg
  - Application Route: Intramuscular
- LD$_{Lo}$ (Monkey): 30 mg/kg
  - Application Route: Intravenous

**Mometasone:**

**Acute oral toxicity**
- LD$_{50}$ (Rat): > 2,000 mg/kg
- LD$_{50}$ (Mouse): > 2,000 mg/kg

**Acute inhalation toxicity**
- LC$_{50}$ (Rat): > 3.3 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Remarks: No mortality observed at this dose.
- LC$_{50}$ (Mouse): > 3.2 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist

**Acute toxicity (other routes of administration)**
- LD$_{50}$ (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:**
**SAFETY DATA SHEET**

**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>
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<tbody>
<tr>
<td>4.10</td>
<td>04/04/2023</td>
<td>412812-00021</td>
<td>07/22/2022</td>
<td>12/14/2015</td>
</tr>
</tbody>
</table>

**Species:**

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

**Mometasone:**

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

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:**

**White mineral oil (petroleum):**

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

**clotrimazole:**

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

**Gentamicin:**

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

**Mometasone:**

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

**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):**

<table>
<thead>
<tr>
<th>Test Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buehler Test</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Routes of exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin contact</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guinea pig</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>negative</td>
</tr>
</tbody>
</table>

**Gentamicin:**

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

**Mometasone:**

<table>
<thead>
<tr>
<th>Test Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximization Test</td>
</tr>
</tbody>
</table>
Germ cell mutagenicity
Not classified based on available information.

Components:

White mineral oil (petroleum):
Genotoxicity in vitro: Test Type: In vitro mammalian cell gene mutation test
Result: negative

Genotoxicity in vivo:
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:
Species: Rat
Application Route: Oral
Result: negative
Test Type: Mammalian spermatogonial chromosome aberration test (in vivo)
Species: Hamster
Result: negative

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

- **Test Type:** Chromosome aberration test in vitro
  - Result: equivocal

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

### Genotoxicity in vivo

#### Mometasone:

- **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

#### White mineral oil (petroleum):

- **Species:** Rat
- **Application Route:** Ingestion
- **Exposure time:** 24 Months
- **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:

<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>Rat</td>
<td>Ingestion</td>
<td>24 Months</td>
<td>negative</td>
</tr>
</tbody>
</table>
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
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: Rat  
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: 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):**
Species: Rat
LOAEL: 160 mg/kg
Application Route: Ingestion
Exposure time: 90 Days

Species: Rat
LOAEL: >= 1 mg/l
Application Route: inhalation (dust/mist/fume)
Exposure time: 4 Weeks
Method: OECD Test Guideline 412

**clotrimazole:**
Species: Rabbit
LOAEL: 5 - 40 mg/kg
Application Route: Skin contact
Exposure time: 3 Weeks
Target Organs: Skin
Symptoms: Edema, Fissuring, Necrosis, Redness

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

<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>25 mg/kg</td>
<td>Oral</td>
<td>6 - 12 Months</td>
<td>Adrenal gland</td>
<td>Salivation, Lachrymation, Vomiting</td>
</tr>
</tbody>
</table>

**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

**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
SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

Version 4.10  Revision Date: 04/04/2023  SDS Number: 412812-00021  Date of last issue: 07/22/2022  Date of first issue: 12/14/2015

**Application Route**
- **Oral**
- **inhalation (dust/mist/fume)**

**Exposure time**
- **30 d**
- **90 d**

**Target Organs**
- Lymph nodes, Liver, Adrenal gland, Skin, thymus gland
- Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

**Species**
- Rat
- Dog

**NOAEL**
- 0.5 mg/kg
- 0.00013 mg/l
- 0.0005 mg/l

**Exposure time**
- **30 d**
- **90 d**

**Target Organs**
- Lymph nodes, Liver, Adrenal gland, Skin, thymus gland
- Adrenal gland, Lungs, Lymph nodes, spleen, Bone marrow, Kidney, Liver, thymus gland

**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:**

<table>
<thead>
<tr>
<th>Component</th>
<th>Test Method</th>
<th>Toxicity Value</th>
<th>Exposure Time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>White mineral oil (petroleum):</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Oncorhynchus mykiss (rainbow trout)): &gt; 100 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>NOEC (Pseudokirchneriella subcapitata (green algae)): 100 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
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<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Oncorhynchus mykiss (rainbow trout)): 1,000 mg/l</td>
<td>28 d</td>
<td>OECD Test Guideline 201</td>
<td></td>
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<tr>
<td></td>
<td>Exposure time: 28 d</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia magna (Water flea)): 1,000 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
<td></td>
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<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clotrimazole:</strong></td>
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<td></td>
</tr>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Brachydanio rerio (zebrafish)): &gt; 0.29 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
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<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): 0.02 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
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<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EC50 (Desmodesmus subspicatus (green algae)): 0.268 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOEC (Desmodesmus subspicatus (green algae)): 0.017 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
<td></td>
</tr>
<tr>
<td>Toxicity to fish (Chronic toxicity)</td>
<td>NOEC (Oncorhynchus mykiss (rainbow trout)): 0.025 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
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<tr>
<td></td>
<td>Exposure time: 32 d</td>
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<tr>
<td>Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)</td>
<td>NOEC (Daphnia magna (Water flea)): 0.01 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
<td></td>
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<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to microorganisms</td>
<td>EC50: &gt; 10,000 mg/l</td>
<td>3 h</td>
<td>OECD Test Guideline 209</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
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</tr>
</tbody>
</table>
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
plants

Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.00014 mg/l
Exposure time: 32 d
Method: OECD Test Guideline 210
Remarks: No toxicity at the limit of solubility.

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 (Blugill sunfish)  
Bioconcentration factor (BCF): 107.1  
Method: OECD Test Guideline 305

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.  
Do not dispose of waste into sewer.  
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
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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
CA QC OEL / STEV : Short-term exposure value

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