SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

Version 5.4  Revision Date: 10.10.2020  SDS Number: 412823-00015  Date of last issue: 23.03.2020  Date of first issue: 14.12.2015

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: EHSDATASETWARD@msd.com

Recommended use of the chemical and restrictions on use
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.
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Disposal:
P501 Dispose of contents/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>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White mineral oil (petroleum)</td>
<td>8042-47-5</td>
<td>&gt; 90 - &lt;= 100</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>23593-75-1</td>
<td>1</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>1403-66-3</td>
<td>0.5</td>
</tr>
<tr>
<td>Mometasone</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.

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 local exhaust ventilation.

Advice on safe handling:
Do not get on skin or clothing.
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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.

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/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>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>
<tr>
<td>Further information: Skin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>10 µg/100 cm²</td>
<td>Internal</td>
</tr>
</tbody>
</table>

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**
  - **Hand protection**

- **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
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<thead>
<tr>
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<td>23.03.2020</td>
<td>14.12.2015</td>
</tr>
</tbody>
</table>

- **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 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></th>
<th>Acute toxicity estimate: &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Method: Calculation method</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): &gt; 5,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute inhalation toxicity</td>
<td>LC50 (Rat): &gt; 5 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 4 h</td>
</tr>
<tr>
<td></td>
<td>Test atmosphere: dust/mist</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute inhalation toxicity</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>LD50 (Rabbit): &gt; 2,000 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Assessment: The substance or mixture has no acute dermal toxicity</td>
</tr>
</tbody>
</table>

**Clotrimazole:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 708 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Mouse): 761 mg/kg</td>
<td></td>
</tr>
<tr>
<td>LD50 (Rabbit): &gt; 1,000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

| 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:**

<table>
<thead>
<tr>
<th>Acute oral toxicity</th>
<th>LD50 (Rat): 8,000 - 10,000 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD50 (Mouse): 10,000 mg/kg</td>
<td></td>
</tr>
</tbody>
</table>

| Acute inhalation toxicity | LC50 (Rat): > 0.2 mg/l |
|                          | Exposure time: 4 h     |
|                          | Test atmosphere: dust/mist|

Remarks: No mortality observed at this dose.
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<table>
<thead>
<tr>
<th>Application Route</th>
<th>LD50 (Rat)</th>
<th>LD50 (Mouse)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intravenous</td>
<td>371 - 384 mg/kg</td>
<td>&gt; 2,000 mg/kg</td>
</tr>
<tr>
<td>Intramuscular</td>
<td></td>
<td>&gt; 2,000 mg/kg</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: 200 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.
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
- **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):**
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

Species : Dog
LOAEL : 25 mg/kg
Application Route : Oral
Exposure time : 6 - 12 Months
Target Organs : Adrenal gland
Symptoms : Salivation, Lachrymation, Vomiting
Gentamicin:
Species: Dog
LOAEL: 3 mg/kg
Application Route: Intramuscular
Exposure time: 12 Months
Target Organs: Kidney, Salivation
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: 3 Weeks
Target Organs: Kidney, Blood

Species: Rat
NOAEL: 12.5 mg/kg
LOAEL: 50 mg/kg
Application Route: Intramuscular
Exposure time: 3 Weeks
Target Organs: Kidney

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,

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
LOAEL: 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
### Toxicity to daphnia and other aquatic invertebrates

<table>
<thead>
<tr>
<th>Compound</th>
<th>Method</th>
<th>EC50</th>
<th>Exposure time</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>OECD Test Guideline 202</td>
<td>&gt; 100 mg/l</td>
<td>48 h</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>OECD Test Guideline 202</td>
<td>0.02 mg/l</td>
<td>48 h</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>OECD Test Guideline 202</td>
<td>86 mg/l</td>
<td>48 h</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

### Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Compound</th>
<th>Method</th>
<th>EC50</th>
<th>Exposure time</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>OECD Test Guideline 202</td>
<td>100 mg/l</td>
<td>72 h</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>-</td>
<td>0.268 mg/l</td>
<td>72 h</td>
<td>0.017 mg/l</td>
<td>72 h</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>OECD Test Guideline 202</td>
<td>86 mg/l</td>
<td>48 h</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

### Toxicity to fish (Chronic toxicity)

<table>
<thead>
<tr>
<th>Compound</th>
<th>Method</th>
<th>LC50</th>
<th>Exposure time</th>
<th>NOEC</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>OECD Test Guideline 203</td>
<td>&gt; 0.29 mg/l</td>
<td>96 h</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>OECD Test Guideline 203</td>
<td>0.02 mg/l</td>
<td>48 h</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>US-EPA OPPTS 850.1035</td>
<td>30 mg/l</td>
<td>96 h</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

### Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Compound</th>
<th>Method</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Test Type</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mometasone</td>
<td>OECD Test Guideline 202</td>
<td>&gt; 10,000 mg/l</td>
<td>3 h</td>
<td>Respiration inhibition</td>
<td>OECD Test Guideline 209</td>
</tr>
<tr>
<td>Clotrimazole</td>
<td>OECD Test Guideline 202</td>
<td>86 mg/l</td>
<td>48 h</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>US-EPA OPPTS 850.1035</td>
<td>30 mg/l</td>
<td>96 h</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>
### 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

Clothrimazole:

- 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
SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

Version 5.4  Revision Date: 10.10.2020  SDS Number: 412823-00015  Date of last issue: 23.03.2020  Date of first issue: 14.12.2015

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
SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

Version: 5.4
Revision Date: 10.10.2020
SDS Number: 412823-00015
Date of last issue: 23.03.2020
Date of first issue: 14.12.2015

ACGIH / TWA : 8-hour, time-weighted average
NOM-010-STPS-2014 / VLE-PPT : Time weighted average limit value


Revision Date: 10.10.2020

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.

MX / Z8