1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Mometasone / Clotrimazole / Gentamicin Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
          Wagholi - Pune - India  412 207
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

GHS Classification
Reproductive toxicity : Category 1A
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 2

GHS label elements
Hazard pictograms :  
Signal word : Danger
Hazard statements : H360D May damage the unborn child.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.

**Response:**
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- P391 Collect spillage.

**Storage:**
- P405 Store locked up.

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

Other hazards which do not result in classification
None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

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

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.

**If swallowed:**
- Get medical attention if irritation develops and persists.
- If swallowed, DO NOT induce vomiting.
### 5. FIREFIGHTING 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 firefighters**
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal precautions, protective equipment and emergency procedures**
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

**Environmental precautions**
- Discharge into the environment must be avoided.
- Prevent further leakage or spillage if safe to do so.
- Prevent spreading over a wide area (e.g. by containment or oil barriers).
- Retain and dispose of contaminated wash water.
- Local authorities should be advised if significant spills cannot be contained.

**Methods and materials for containment and cleaning up**
- Soak up with inert absorbent material.
- For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
- Clean up remaining materials from spill with suitable absorbent.
- Local or national regulations may apply to releases and disposal of this material, as well as those materials and items.
employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling: Do not get on skin or clothing. Do not breathe vapours or spray mist. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Keep container tightly closed. Take care to prevent spills, waste and minimize release to the environment.

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

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

| Components                     | CAS-No.    | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis  
|-------------------------------|------------|-------------------------------|-----------------------------------------------|--------
| White mineral oil (petroleum) | 8042-47-5  | TWA (Mist)                    | 5 mg/m3 (OEL)                                | IN OEL |
|                               |            | STEL (Mist)                   | 10 mg/m3 (OEL)                               |        |
| clotrimazole                  | 23593-75-1 | TWA (Inhalable particulate matter) | 5 mg/m3 (ACGIH) |        |
| Gentamicin                    | 1403-66-3  | TWA                           | 0.2 mg/m3 (OEB 2)                            | Internal |
| Mometasone                    | 83919-23-7 | TWA                           | 0.1 mg/m3 (OEB 2)                            | 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 vapour 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.**

### 9. PHYSICAL AND CHEMICAL PROPERTIES

- **Appearance:** suspension
- **Colour:** white to off-white
- **Odour:** oily
- **Odour Threshold:** No data available
- **pH:** No data available
- **Melting point/freezing point:** No data available
### Initial boiling point and boiling range
- No data available

### Flash point
- No data available

### Evaporation rate
- No data available

### Flammability (solid, gas)
- Not applicable

### Flammability (liquids)
- No data available

### Upper explosion limit / Upper flammability limit
- No data available

### Lower explosion limit / Lower flammability limit
- No data available

### Vapour pressure
- No data available

### Relative vapour density
- No data available

### Relative density
- No data available

### Density
- No data available

### Solubility(ies)
- Water solubility
  - No data available

### Partition coefficient: n-octanol/water
- Not applicable

### Auto-ignition temperature
- No data available

### Decomposition temperature
- No data available

### Viscosity
- Viscosity, kinematic
  - No data available

### Explosive properties
- Not explosive

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

### Particle size
- Not applicable

### 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
- No hazardous decomposition products are known.
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: > 5,000 mg/kg
  Method: Calculation method
- **Acute dermal toxicity**: Acute toxicity estimate: > 5,000 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**: LD50 (Rat): 8,000 - 10,000 mg/kg
  LD50 (Mouse): 10,000 mg/kg
SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

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.

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 sensitisation**

**Skin sensitisation**
Not classified based on available information.

**Respiratory sensitisation**
Not classified based on available information.

**Components:**

**White mineral oil (petroleum):**
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

**Gentamicin:**
Remarks: No data available

**Mometasone:**
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Assessment: Does not cause skin sensitisation.
Result: negative
Remarks: The results of a test on guinea pigs showed this substance to
be a weak skin sensitiser.

**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)
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
**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>
</thead>
</table>

<table>
<thead>
<tr>
<th>Gentamicin:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Carcinogenicity - Assessment</td>
<td>: No data available</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Mometasone:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>: Rat</td>
<td></td>
</tr>
<tr>
<td>Application Route</td>
<td>: Inhalation</td>
<td></td>
</tr>
<tr>
<td>Exposure time</td>
<td>: 2 Years</td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td>: 0.067 mg/kg body weight</td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td>: negative</td>
<td></td>
</tr>
</tbody>
</table>

| 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.

**Components:**

**White mineral oil (petroleum):**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>: Test Type: One-generation reproduction toxicity study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>: Rat</td>
</tr>
<tr>
<td>Application Route: Skin contact</td>
<td>Result: negative</td>
</tr>
</tbody>
</table>

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

**clotrimazole:**

<table>
<thead>
<tr>
<th>Effects on fertility</th>
<th>: Test Type: Fertility/early embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species</td>
<td>: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td>Fertility: LOAEL: 50 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Effects on fertility</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Effects on foetal development</th>
<th>: Test Type: Embryo-foetal development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
<td>Application Route: Oral</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 100 mg/kg body weight</td>
<td>Result: Embryo-foetal toxicity, No teratogenic effects</td>
</tr>
<tr>
<td>Test Type: Embryo-foetal development</td>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Oral</td>
<td>Developmental Toxicity: NOAEL: 50 mg/kg body weight</td>
</tr>
</tbody>
</table>
Reproductive toxicity - Assessment: Some evidence of adverse effects on sexual function and fertility, based on animal experiments. Some evidence of adverse effects on development, based on animal experiments.

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 foetal development: Test Type: Embryo-foetal development
Species: Rabbit
Developmental Toxicity: NOAEL: 3.6 mg/kg body weight
Result: No embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 75 mg/kg body weight
Result: Embryo-foetal toxicity

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 10 mg/kg body weight
Result: foetal mortality, No malformations were observed.

Test Type: Embryo-foetal development
Species: Rat
Application Route: Intraperitoneal
Developmental Toxicity: LOAEL: 50 mg/kg body weight
Result: foetal mortality, No malformations were observed.

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 foetal weight
- Result: No effects on fertility, Effect on reproduction capacity

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

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

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

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

- Test Type: Embryo-foetal development
  - Species: Rabbit
  - Application Route: Oral
  - Embryo-foetal toxicity: LOAEL: 0.7 mg/kg body weight
  - Result: Embryo-foetal 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
Not classified based on available information.
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**:  
Exposure routes: 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: Oedema, 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
Gentamicin:

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

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

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
LOAEL : 0.5 mg/kg
Application Route : Oral
Exposure time : 30 d
Target Organs : Lymph nodes, Liver, Adrenal gland, Skin, thymus gland
SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

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, Oedema, Redness
Ingestion: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea

Gentamicin:
Ingestion: Target Organs: Kidney
Target Organs: inner ear
Symptoms: Dizziness, Vertigo, hearing loss, tinnitus, fetal deafness

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
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: 1,000 mg/l
Exposure time: 28 d
Species: Oncorhynchus mykiss (rainbow trout)

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

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

M-Factor (Acute aquatic toxicity) : 10

Toxicity to microorganisms : EC50: > 10,000 mg/l
Exposure time: 3 h
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 0.025 mg/l
### 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>
</thead>
</table>

#### Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

- **Species**: Oncorhynchus mykiss (rainbow trout)
- **Method**: OECD Test Guideline 210
- **Exposure time**: 32 d
- **NOEC**: 0.01 mg/l
- **Species**: Daphnia magna (Water flea)
- **Method**: OECD Test Guideline 211
- **Exposure time**: 21 d

#### M-Factor (Chronic aquatic toxicity)

- **NOEC**: 10

#### 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

- **M-Factor (Acute aquatic toxicity)**
  - **EC50**: 288.7 mg/l
  - **Exposure time**: 3 h
  - **Test Type**: Respiration inhibition
  - **Method**: OECD Test Guideline 209

- **M-Factor (Chronic aquatic toxicity)**
  - **NOEC**: 1

#### 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 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

Toxicity to fish (Chronic toxicity)

NOEC: 0.00014 mg/l
Exposure time: 32 d
Species: Pimephales promelas (fathead minnow)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

NOEC: 0.34 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211
Remarks: No toxicity at the limit of solubility

M-Factor (Chronic aquatic toxicity): 100

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:

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

Bioaccumulative potential

Components:

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

Mometasone:
Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish) Bioconcentration factor (BCF): 107.1 Method: OECD Test Guideline 305

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

Mobility in soil

Components:

Mometasone:
Distribution among environmental compartments: log Koc: 4.02

Other adverse effects
No data available
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.

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 IMO instruments*
Not applicable for product as supplied.

**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.
SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

15. REGULATORY INFORMATION

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

The components of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Further information


Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

IN OEL : India. Permissible levels of certain chemical substances in work environment.

ACGIH / TWA : 8-hour, time-weighted average

IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)

IN OEL / STEL : Short-term exposure Limit STEL (15 min)

AICS - Australian Inventory of Chemical Substances; 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 Develop-
SAFETY DATA SHEET

Mometasone / Clotrimazole / Gentamicin Formulation

Version 4.3  Revision Date: 23.03.2020  SDS Number: 415341-00014  Date of last issue: 13.09.2019

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.

IN / EN