SECTION 1. IDENTIFICATION

Product name: Levamisole / Oxfendazole 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 1B
Specific target organ toxicity - repeated exposure: Category 2 (Liver, Testis)
Specific target organ toxicity - repeated exposure (Oral): Category 2 (Blood, Testis)

GHS label elements
Hazard pictograms: ⚠️

Signal Word: Danger

Hazard Statements: H360FD May damage fertility. May damage the unborn child.
                H373 May cause damage to organs (Liver, Testis) through prolonged or repeated exposure.
                H373 May cause damage to organs (Blood, Testis) 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.
SAFETY DATA SHEET

Levamisole / Oxfendazole Formulation

Version 1.1  Revision Date: 04/04/2023  SDS Number: 10808165-00002  Date of last issue: 07/05/2022  Date of first issue: 07/05/2022

Response:
P308 + P313 IF exposed or concerned: Get medical attention.

Storage:
P405 Store locked up.

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

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Common Name/Synonym</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levamisole hydrochloride</td>
<td>No data available</td>
<td>16595-80-5</td>
<td>8</td>
</tr>
<tr>
<td>oxfendazole</td>
<td>No data available</td>
<td>53716-50-0</td>
<td>4.53</td>
</tr>
<tr>
<td>Polyethylene glycol stearate</td>
<td>Ethoxylated stearic acid</td>
<td>9004-99-3</td>
<td>1.8</td>
</tr>
<tr>
<td>Citric acid</td>
<td>2-hydroxypropane-1,2,3-tricarboxylic acid</td>
<td>77-92-9</td>
<td>1.76</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>Silicon dioxide</td>
<td>112945-52-5</td>
<td>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 fertility. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure.

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.
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>Levamisole hydrochloride</td>
<td>16595-80-5</td>
<td>TWA</td>
<td>20 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 200 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>oxfendazole</td>
<td>53716-50-0</td>
<td>TWA</td>
<td>40 µg/m³ (OEB 3)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Wipe limit 400 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Polyethylene glycol stearate</td>
<td>9004-99-3</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>CA AB OEL</td>
</tr>
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<td></td>
<td></td>
<td>TWAEV</td>
<td>10 mg/m³</td>
<td>CA QC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA  (Inhalable)</td>
<td>10 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA  (Respirable)</td>
<td>3 mg/m³</td>
<td>CA BC OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA  (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Levamisole / Oxfendazole Formulation

Engineer measures:
Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless quick connections).
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

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: Particulates 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., sleevelists, 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Aqueous solution</td>
</tr>
<tr>
<td>Color</td>
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</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
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</tr>
<tr>
<td>Flash point</td>
<td>No data available</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>No data available</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
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</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
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</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
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</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
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<tr>
<td>Viscosity</td>
<td>Viscosity, kinematic</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Levamisole / Oxfendazole Formulation

Molecular weight: No data available
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:
Acute oral toxicity: Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:
Levamisole hydrochloride:
Acute oral toxicity: LD50 (Rat): 180 mg/kg
LD50 (Mouse): 223 mg/kg
LD50 (Rabbit): 458 mg/kg

Acute inhalation toxicity: Remarks: No data available
Acute dermal toxicity: Remarks: No data available

Oxfendazole:
Acute oral toxicity: LD50 (Rat): > 6,000 mg/kg
LD50 (Dog): 1,600 mg/kg
LD50 (sheep): 250 mg/kg

Polyethylene glycol stearate:
## Acute oral toxicity

**LD50 (Rat):** > 5,000 mg/kg

### Citric acid:

- **Acute oral toxicity:** LD50 (Mouse): 5,400 mg/kg
- **Acute dermal toxicity:** LD50 (Rat): > 2,000 mg/kg
  - Method: OECD Test Guideline 402
  - Assessment: The substance or mixture has no acute dermal toxicity

### Silicon, amorphous:

- **Acute oral toxicity:** LD50 (Rat): > 5,000 mg/kg
  - Method: OECD Test Guideline 401
  - Remarks: Based on data from similar materials
- **Acute inhalation toxicity:** LC50 (Rat): > 2.08 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Assessment: The substance or mixture has no acute inhalation toxicity
  - Remarks: Based on data from similar materials
- **Acute dermal toxicity:** LD50 (Rabbit): > 5,000 mg/kg
  - Remarks: Based on data from similar materials

## Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Levamisole hydrochloride:

- Remarks: No data available

#### oxfendazole:

- Species: Rabbit
- Result: No skin irritation

#### Polyethylene glycol stearate:

- Species: Rabbit
- Method: Draize Test
- Result: No skin irritation

#### Citric acid:

- Species: Rabbit
- Method: OECD Test Guideline 404
- Result: No skin irritation

#### Silicon, amorphous:

- Species: Rabbit
- Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

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

**Components:**

**Levamisole hydrochloride:**
Remarks: No data available

**oxfendazole:**
Species: Rabbit
Result: No eye irritation

**Polyethylene glycol stearate:**
Species: Rabbit
Result: No eye irritation
Method: Draize Test

**Citric acid:**
Species: Rabbit
Result: Irritation to eyes, reversing within 21 days
Method: OECD Test Guideline 405

**Silicon, amorphous:**
Species: Rabbit
Result: No eye irritation
Method: OECD Test Guideline 405
Remarks: Based on data from similar materials

**Respiratory or skin sensitization**

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

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

**Components:**

**Levamisole hydrochloride:**
Remarks: No data available

**Polyethylene glycol stearate:**
Test Type: Open epicutaneous test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Germ cell mutagenicity
Not classified based on available information.

Components:

Levamisole hydrochloride:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosome aberration test in vitro
Result: negative

Oxfendazole:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogentic test, chromosomal analysis)
Species: Mouse
Application Route: Oral
Result: positive

Polyethylene glycol stearate:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Citric acid:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: in vitro micronucleus test
Result: positive

Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Silicon, amorphous:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Genotoxicity in vivo: Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
SAFETY DATA SHEET

Levamisole / Oxfendazole Formulation

Carcinogenicity
Not classified based on available information.

Components:

Levamisole hydrochloride:
Species : Mouse
Application Route : Oral
Exposure time : 2 Years
NOAEL : 80 mg/kg body weight
Remarks : No significant adverse effects were reported

Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : 40 mg/kg body weight
Remarks : No significant adverse effects were reported

Oxfendazole:
Species : Rat
Application Route : Oral
Exposure time : 1 Years
Symptoms : No adverse effects.
Target Organs : Liver

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Symptoms : No adverse effects.
Target Organs : Liver

Silicon, amorphous:
Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative
Remarks : Based on data from similar materials

Reproductive toxicity
May damage fertility. May damage the unborn child.

Components:

Levamisole hydrochloride:
Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Rat
Application Route: Oral
Result: No significant adverse effects were reported

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 20 mg/kg body weight  
Result: Fetotoxicity.

Test Type: Embryo-fetal development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 40 mg/kg body weight  
Result: Fetotoxicity.

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

**oxfendazole:**

Effects on fertility:  
Test Type: Fertility/early embryonic development  
Species: Rat, male  
Application Route: Oral  
Fertility: NOAEL: 17 mg/kg body weight  
Target Organs: Testes  
Result: Effects on fertility.

Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 0.9 mg/kg body weight  
Target Organs: Liver  
Result: No effects on fertility.

Test Type: Fertility  
Species: Mouse  
Application Route: Oral  
Duration of Single Treatment: 1 Months  
Fertility: NOAEL: 750 mg/kg body weight  
Target Organs: Testes  
Result: Effects on fertility.

Effects on fetal development:  
Test Type: Embryo-fetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: positive, Fetal effects.

Test Type: Embryo-fetal development  
Species: Rat  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: positive, Embryo-fetal toxicity.

Test Type: Embryo-fetal development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: NOAEL: 108 mg/kg body weight  
Result: positive, Embryo-fetal toxicity., Fetal abnormalities.
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive toxicity - Assessment</td>
<td>Rabbit</td>
<td>Oral</td>
<td>NOAEL: 0.625 mg/kg body weight</td>
<td>Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.</td>
</tr>
<tr>
<td>Citric acid:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effects on fetal development</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type</td>
<td>Species</td>
<td>Application Route</td>
<td>Result</td>
<td>Remarks</td>
</tr>
<tr>
<td>One-generation reproduction toxicity study</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>Silicon, amorphous:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Effects on fetal development</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test Type</td>
<td>Species</td>
<td>Application Route</td>
<td>Result</td>
<td>Remarks</td>
</tr>
<tr>
<td>Embryo-fetal development</td>
<td>Rat</td>
<td>Ingestion</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Not classified based on available information.</td>
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<tr>
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</tr>
<tr>
<td>Citric acid:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessment</td>
<td></td>
<td></td>
<td></td>
<td>May cause respiratory irritation.</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>May cause damage to organs (Liver, Testis) through prolonged or repeated exposure.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>May cause damage to organs (Blood, Testis) through prolonged or repeated exposure if swallowed.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Components:</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Levamisole hydrochloride:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
<td></td>
<td></td>
<td>Blood, Testis</td>
<td></td>
</tr>
<tr>
<td>Assessment</td>
<td></td>
<td></td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
<td></td>
</tr>
<tr>
<td>oxfendazole:</td>
<td></td>
<td></td>
<td>Oral</td>
<td></td>
</tr>
<tr>
<td>Routes of exposure</td>
<td></td>
<td></td>
<td>Liver, Testis</td>
<td></td>
</tr>
<tr>
<td>Target Organs</td>
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<tr>
<td>Assessment</td>
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<td></td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
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</table>
Repeated dose toxicity

**Components:**

**Levamisole hydrochloride:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>2.5 mg/kg</td>
<td>Oral</td>
<td>18 Months</td>
<td>Testis</td>
</tr>
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<table>
<thead>
<tr>
<th>Species</th>
<th>LOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
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<td>Dog</td>
<td>20 mg/kg</td>
<td>Oral</td>
<td>18 Months</td>
<td>Blood</td>
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</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>40 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td></td>
</tr>
</tbody>
</table>

**oxfendazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>11 mg/kg</td>
<td>Oral</td>
<td>2 Weeks</td>
<td>Blood, Liver, Testis</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>3.8 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Liver, Testis</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>750 mg/kg</td>
<td>Oral</td>
<td>1 Months</td>
<td>Liver</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Species</th>
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<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>37.5 mg/kg</td>
<td>Oral</td>
<td>3 Months</td>
<td>Liver</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>6 mg/kg</td>
<td>Oral</td>
<td>1 Months</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dog</td>
<td>11 mg/kg</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

Levamisole / Oxfendazole Formulation

Application Route: Oral
Exposure time: 2 Weeks
Target Organs: Lymph nodes, thymus gland

Species: Dog
NOAEL: 13.5 mg/kg
Application Route: Oral
Exposure time: 12 Months
Target Organs: Liver

Citric acid:
Species: Rat
NOAEL: 4,000 mg/kg
LOAEL: 8,000 mg/kg
Application Route: Ingestion
Exposure time: 10 Days

Silicon, amorphous:
Species: Rat
NOAEL: 1.3 mg/l
Application Route: Inhalation (dust/mist/fume)
Exposure time: 13 Weeks
Remarks: Based on data from similar materials

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Levamisole hydrochloride:
Ingestion: Symptoms: Nausea, Vomiting, Headache, Dizziness, hypotension

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Levamisole hydrochloride:
Toxicity to fish: LC50 (Oryzias latipes (Japanese medaka)): 37.3 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 64 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

oxfendazole:
Toxicity to fish: LC50 (Lepomis macrochirus (Bluegill sunfish)): > 2.7 mg/l
Exposure time: 96 h

LC50 (Oncorhynchus mykiss (rainbow trout)): > 2.5 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 0.059 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants:
EC50 (Pseudokirchneriella subcapitata (green algae)): > 4 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): > 4 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 0.023 mg/l
Exposure time: 21 d
Method: OECD Test Guideline 211

Polyethylene glycol stearate:

Toxicity to fish:
LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 96 h
Method: DIN 38412

Toxicity to microorganisms:
EC10 (Bacteria): > 10,000 mg/l
Exposure time: 16 h

Citric acid:

Toxicity to fish:
LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): 1,535 mg/l
Exposure time: 24 h

Silicon, amorphous:

Toxicity to fish:
LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants:
EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

Persistence and degradability

Components:

oxfendazole:
Stability in water: Hydrolysis: < 5 %(4 d)

Polyethylene glycol stearate:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 70 %
Exposure time: 10 d
Method: OECD Test Guideline 302B

Citric acid:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

oxfendazole:
Partition coefficient: n-octanol/water: log Pow: 1.95

Citric acid:
Partition coefficient: n-octanol/water: log Pow: -1.72

Mobility in soil

Components:

oxfendazole:
Distribution among environmental compartments: log Koc: 3.2

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. (oxfendazole)
- **Class**: 9
- **Packing group**: III
- **Labels**: 9

**IATA-DGR**

- **UN/ID No.**: UN 3082
- **Proper shipping name**: Environmentally hazardous substance, liquid, n.o.s. (oxfendazole)
- **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. (oxfendazole)
- **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. (oxfendazole)
<table>
<thead>
<tr>
<th>Class</th>
<th>9</th>
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</thead>
<tbody>
<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>9</td>
</tr>
<tr>
<td>ERG Code</td>
<td>171</td>
</tr>
<tr>
<td>Marine pollutant</td>
<td>yes (oxfendazole)</td>
</tr>
</tbody>
</table>

**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 BC OEL / TWA**: 8-hour time weighted average
- **CA QC OEL / TWAEV**: Time-weighted average exposure value

**Abbreviations**

- AICL - Australian Inventory of Industrial Chemicals
- ANTT - National Agency for Transport by Land of Brazil
- ASTM - American Society for the Testing of Materials
- bw - Body weight
- CMR - Carcinogen, Mutagen or Reproductive Toxicant
- DIN - Standard of the German Institute for Standardisation
- DSL - Domestic Substances List (Canada)
- ECx - Concentration associated with x% response
- ELx - Loading rate associated with x% response
- EmS - Emergency Schedule
- ENCS - Existing and New Chemical Substances (Japan)
- ErCx - Concentration associated with x% growth rate response
- ERG - Emergency Response Guide
- GHS - Globally Harmonized System
- GLP - Good Laboratory Practice
- IARC - International Agency for Research on Cancer
- IATA - International Air Transport Association
- IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
- IC50 - Half maximal inhibitory concentration
- ICAO - International Civil Aviation Organization
- IECSC - Inventory of Existing Chemical Substances in China
- IMDG - International Maritime Dangerous Goods
- IMO - International Maritime Organization
- ISHL - Industrial Safety and Health Law (Japan)
- ISO - International Organisation for Standardization
- KECI - Korea Existing Chemicals Inventory
- LC50 - Lethal Concentration to 50% of a test population
- LD50 - Lethal Dose to 50% of a test population
- MARPOL - International Convention for the Prevention of Pollution from Ships
SAFETY DATA SHEET

Levamisole / Oxfendazole Formulation

Version 1.1  Revision Date: 04/04/2023  SDS Number: 10808165-00002  Date of last issue: 07/05/2022
Date of first issue: 07/05/2022

Sources of key data used to compile the Material Safety Data Sheet:

Revision Date: 04/04/2023
Date format: mm/dd/yyyy

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

CA / Z8