SAFETY DATA SHEET

Levamisole / Oxfendazole Formulation

SECTION 1. IDENTIFICATION

Product name : Levamisole / Oxfendazole Formulation

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 OSHA Hazard Communication Standard (29 CFR 1910.1200)
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.

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>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levamisole hydrochloride</td>
<td>16595-80-5</td>
<td>8</td>
</tr>
<tr>
<td>Oxfendazole</td>
<td>53716-50-0</td>
<td>4.53</td>
</tr>
<tr>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>2.44</td>
</tr>
<tr>
<td>Polyethylene glycol stearate</td>
<td>9004-99-3</td>
<td>1.8</td>
</tr>
<tr>
<td>Citric acid</td>
<td>77-92-9</td>
<td>1.76</td>
</tr>
<tr>
<td>Silicon, amorphous</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.
Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during fire fighting:
Exposure to combustion products may be a hazard to health.

Hazardous combustion products:
Carbon oxides

Specific extinguishing methods:
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

Special protective equipment for fire-fighters:
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

Environmental precautions:
Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g., by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

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

SECTION 7. HANDLING AND STORAGE

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

Local/Total ventilation:
If sufficient ventilation is unavailable, use with local exhaust ventilation.
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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</td>
<td>25322-68-3</td>
<td>TWA (aerosol)</td>
<td>10 mg/m³</td>
<td>US WEEL</td>
</tr>
<tr>
<td>Polyethylene glycol stearate</td>
<td>9004-99-3</td>
<td>TWA (Inhalable particulate matter)</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable particulate matter)</td>
<td>3 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
<td>TWA (Dust)</td>
<td>20 Million particles per cubic foot (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Dust)</td>
<td>80 mg/m³ / %SiO₂ (Silica)</td>
<td>OSHA Z-3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA</td>
<td>6 mg/m³ (Silica)</td>
<td>NIOSH REL</td>
</tr>
</tbody>
</table>

Engineering 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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate 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.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution
<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>No data available</td>
</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>
<td>No data available</td>
</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>
<td>No data available</td>
</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>
<td>No data available</td>
</tr>
<tr>
<td>Solubility/ies</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
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<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
</tbody>
</table>
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SECTION 10. STABILITY AND REACTIVITY

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

SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Product:
Acute oral toxicity: Acute toxicity estimate: 2,250 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:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Remarks: Based on data from similar materials
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

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

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
Remarks  :  Based on data from similar materials

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

**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:
Test Type: Maximization Test
Routes of exposure: Skin contact
Species: Guinea pig
Result: negative
Remarks: Based on data from similar materials

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 cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Oral
Result: positive

Polyethylene glycol:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Remarks: Based on data from similar materials
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 cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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 cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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
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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

IARC No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.
NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 0.625 mg/kg body weight

Reproductive toxicity - Assessment: Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

Citric acid:
Effects on fetal development: Test Type: One-generation reproduction toxicity study
Species: Rat
Silicon, amorphous:
Effects on fetal development
Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT-single exposure
Not classified based on available information.

Components:
Citric acid:
Assessment: May cause respiratory irritation.

STOT-repeated exposure
May cause damage to organs (Liver, Testis) through prolonged or repeated exposure. May cause damage to organs (Blood, Testis) through prolonged or repeated exposure if swallowed.

Components:
Levamisole hydrochloride:
Target Organs: Blood, Testis
Assessment: May cause damage to organs through prolonged or repeated exposure.

oxfendazole:
Routes of exposure: Oral
Target Organs: Liver, Testis
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
Levamisole hydrochloride:
Species: Rat
NOAEL: 2.5 mg/kg
Application Route: Oral
Exposure time: 18 Months
Target Organs: Testis

Species: Dog
LOAEL: 20 mg/kg
Application Route: Oral
Exposure time: 18 Months
Target Organs: Blood
Species: Dog
LOAEL: 40 mg/kg
Application Route: Oral
Exposure time: 3 Months

oxfendazole:
Species: Rat
NOAEL: 11 mg/kg
Application Route: Oral
Exposure time: 2 Weeks
Target Organs: Blood, Liver, Testis
Species: Rat
NOAEL: 3.8 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Liver, Testis
Species: Mouse
NOAEL: 750 mg/kg
Application Route: Oral
Exposure time: 1 Months
Target Organs: Liver
Species: Mouse
NOAEL: 37.5 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Liver
Species: Dog
NOAEL: 6 mg/kg
Application Route: Oral
Exposure time: 1 Months
Remarks: No significant adverse effects were reported

Species: Dog
NOAEL: 11 mg/kg
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:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rat</th>
</tr>
</thead>
<tbody>
<tr>
<td>NOAEL</td>
<td>1.3 mg/l</td>
</tr>
<tr>
<td>Application Route</td>
<td>inhalation (dust/mist/fume)</td>
</tr>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**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
<table>
<thead>
<tr>
<th>Substance</th>
<th>Toxicity to daphnia and other aquatic invertebrates</th>
<th>Toxicity to fish</th>
<th>Toxicity to microorganisms</th>
<th>Toxicity to algae/aquatic plants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polyethylene glycol</td>
<td>NOEC (Daphnia magna (Water flea)): 0.023 mg/l</td>
<td>LC50 (Poecilia reticulata (guppy)): &gt; 100 mg/l</td>
<td>EC10 (Bacteria): &gt; 10,000 mg/l</td>
<td>EC50 (Desmodesmus subspicatus (green algae)): &gt; 10,000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 21 d</td>
<td>Exposure time: 96 h</td>
<td>Exposure time: 16 h</td>
<td>Exposure time: 24 h</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td>Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>NOEC (Desmodesmus subspicatus (green algae)): &gt; 1,000 mg/l</td>
<td>NOEC (Daphnia magna (Water flea)): &gt; 1,000 mg/l</td>
<td>NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l</td>
<td>NOEC (Desmodesmus subspicatus (green algae)): &gt; 10,000 mg/l</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 24 h</td>
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</tr>
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<td></td>
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<td></td>
</tr>
</tbody>
</table>

Method: OECD Test Guideline 201

Toxicity to fish

- LC50 (Poecilia reticulata (guppy)): > 100 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

- NOEC (Daphnia magna (Water flea)): 0.023 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211
Persistence and degradability

**Components:**

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

**Polyethylene glycol:**
Biodegradability: Result: rapidly degradable
Remarks: Based on data from similar materials

**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

**Polyethylene glycol:**
Partition coefficient: n-octanol/water: log Pow: < 3

**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

49 CFR
UN/ID/NA number : UN 3082
Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(oxfendazole)
Class : 9
**SAFETY DATA SHEET**

**Levamisole / Oxfendazole Formulation**

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.2</td>
<td>04/04/2023</td>
<td>10808156-00003</td>
<td>10/01/2022</td>
<td>07/05/2022</td>
</tr>
</tbody>
</table>

- **Packing group**: III
- **Labels**: CLASS 9
- **ERG Code**: 171
- **Marine pollutant**: yes (oxfendazole)
- **Remarks**: Above applies only to containers over 119 gallons or 450 liters. Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

**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

**CERCLA Reportable Quantity**
This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**
This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**
This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards**
- Reproductive toxicity
- Specific target organ toxicity (single or repeated exposure)

**SARA 313**
- This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations**

**Pennsylvania Right To Know**
- Water: 7732-18-5
- Levamisole hydrochloride: 16595-80-5
- oxfendazole: 53716-50-0
- Silicon, amorphous: 112945-52-5

**California Permissible Exposure Limits for Chemical Contaminants**
- Silicon, amorphous: 112945-52-5

**The ingredients of this product are reported in the following inventories:**

- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined
SAFETY DATA SHEET
Levamisole / Oxfendazole Formulation

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:

Health: 0
Flammability: 1
Instability: 0
Special hazard: 0

HMIS® IV:

HEALTH: * 2
FLAMMABILITY: 1
PHYSICAL HAZARD: 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL: USA. NIOSH Recommended Exposure Limits
OSHA Z-3: USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
US WEEL: USA. Workplace Environmental Exposure Levels (WEEL)
ACGIH / TWA: 8-hour, time-weighted average
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
OSHA Z-3 / TWA: 8-hour time weighted average
US WEEL / TWA: 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; BC - 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; KECl - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Oth-
SAFETY DATA SHEET

Levamisole / Oxfendazole Formulation

Version 1.2  Revision Date: 04/04/2023  SDS Number: 10808156-00003  Date of last issue: 10/01/2022  Date of first issue: 07/05/2022

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

Revision Date: 04/04/2023

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.

US / Z8