SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

Levamisole / Oxfendazole Formulation

SECTION 1. IDENTIFICATION

Product name: Levamisole / Oxfendazole Formulation
Other means of identification: Scanda (A007130)

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
Levamisole / Oxfendazole Formulation

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
<td>Levamisole hydrochloride</td>
<td>16595-80-5</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>oxfendazole</td>
<td>53716-50-0</td>
<td>4.53</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Polyethylene glycol</td>
<td>25322-68-3</td>
<td>2.44</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Polyethylene glycol stearate</td>
<td>9004-99-3</td>
<td>1.8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Citric acid</td>
<td>77-92-9</td>
<td>1.76</td>
</tr>
<tr>
<td></td>
<td></td>
<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.
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Version 1.4  Revision Date: 12/05/2023  SDS Number: 10808156-00005  Date of last issue: 09/30/2023  Date of first issue: 07/05/2022

Notes to physician: Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Water spray
                                          Alcohol-resistant foam
                                          Carbon dioxide (CO2)
                                          Dry chemical

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: Carbon oxides

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

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

SECTION 6. ACCIDENTAL RELEASE MEASURES

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

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

Methods and materials for containment and cleaning up: Soak up with inert absorbent material.
                                                        For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
                                                        Clean up remaining materials from spill with suitable absorbent.
                                                        Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
                                                        Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.
SECTION 7. HANDLING AND STORAGE

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

Local/Total ventilation: If sufficient ventilation is unavailable, use 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</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>
</tbody>
</table>
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Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less 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

<table>
<thead>
<tr>
<th>TWA (Dust)</th>
<th>80 mg/m³ / %SiO2 (Silica)</th>
<th>OSHA Z-3</th>
</tr>
</thead>
<tbody>
<tr>
<td>TWA</td>
<td>6 mg/m³ (Silica)</td>
<td>NIOSH REL</td>
</tr>
</tbody>
</table>
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>
<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>No data available</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>
</tbody>
</table>
Viscosity, kinematic: No data available
Explosive properties: Not explosive
Oxidizing properties: The substance or mixture is not classified as oxidizing.
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: 2,250 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:
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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
Remarks: Based on data from similar materials

**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:**
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

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<table>
<thead>
<tr>
<th>Substance</th>
<th>Test Type</th>
<th>Result</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotoxicity in vitro</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotoxicity in vivo</td>
<td>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</td>
<td>positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Species: Mouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Application Route: Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyethylene glycol:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Polyethylene glycol stearate:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Citric acid:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: in vitro micronucleus test</td>
<td>positive</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Silicon, amorphous:</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>negative</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 471</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified based on available information.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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 Year
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
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

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouse</td>
<td>Oral</td>
<td>NOAEL: 108 mg/kg body weight</td>
<td>positive, Embryo-fetal toxicity, Fetal abnormalities.</td>
</tr>
<tr>
<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, Clear evidence of adverse effects on development, based on animal experiments.</td>
</tr>
</tbody>
</table>

**Citric acid:**

Effects on fetal development: Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

**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

oxfendazole:
Species: Rat
NOAEL: 11 mg/kg
Application Route: Oral
Exposure time: 2 Weeks
Target Organs: Blood, 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
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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:
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: EC50 (Daphnia magna (Water flea)): 64 mg/l
aquatic invertebrates

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

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:

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

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:
Levamisole / Oxfendazole Formulation

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:
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-
log Pow: 1.95
octanol/water

**Polyethylene glycol:**
Partition coefficient: n-octanol/water  \[ \text{log Pow: } < 3 \]

**Citric acid:**
Partition coefficient: n-octanol/water  \[ \text{log Pow: } -1.72 \]

**Mobility in soil**

**Components:**

**oxfendazole:**
Distribution among environmental compartments  \[ \text{log Koc: } 3.2 \]

**Other adverse effects**
No data available

### SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**
Waste from residues  \[ \text{Dispose of in accordance with local regulations.} \]
\[ \text{Do not dispose of waste into sewer.} \]
Contaminated packaging  \[ \text{Empty containers should be taken to an approved waste handling site for recycling or disposal.} \]
\[ \text{If not otherwise specified: Dispose of as unused product.} \]

### SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
UN number  \[ \text{UN 3082} \]
Proper shipping name  \[ \text{ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxfendazole)} \]
Class  \[ 9 \]
Packing group  \[ III \]
Labels  \[ 9 \]
Environmentally hazardous  \[ yes \]

**IATA-DGR**
UN/ID No.  \[ \text{UN 3082} \]
Proper shipping name  \[ \text{Environmentally hazardous substance, liquid, n.o.s. (oxfendazole)} \]
Class  \[ 9 \]
Packing group  \[ III \]
Labels  \[ Miscellaneous \]
Packing instruction (cargo aircraft)  \[ 964 \]
Packing instruction (passenger aircraft)  \[ 964 \]
Levamisole / Oxfendazole Formulation

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
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)
Levamisole / Oxfendazole Formulation

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

SECTION 16. OTHER INFORMATION

Further information
NFPA 704:
- Health: 0
- Flammability: 1
- Instability: 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
## SAFETY DATA SHEET
according to the OSHA Hazard Communication Standard

### Levamisole / Oxfendazole Formulation

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<th>Revision Date</th>
<th>SDS Number:</th>
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- **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

### AIIA - 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; 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; IECSG - 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 Standardisation; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observes (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RO - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TCSI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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


### Revision Date

12/05/2023

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