1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Oxfendazole / Oxyclozanide Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000

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

2. HAZARDS IDENTIFICATION

GHS classification of chemical product
Reproductive toxicity : Category 1B
Specific target organ toxicity - single exposure (Oral) : Category 2 (Central nervous system)
Specific target organ toxicity - repeated exposure : Category 2 (Liver, Testis, Brain)
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms :

Signal word : Danger
Hazard statements : H360FD May damage fertility. May damage the unborn child.
H371 May cause damage to organs (Central nervous system) if swallowed.
H373 May cause damage to organs (Liver, Testis, Brain) through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.
Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe dust.
- P264 Wash skin thoroughly after handling.
- P270 Do not eat, drink or smoke when using this product.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**
- P308 + P311 IF exposed or concerned: Call a POISON CENTER/ doctor.
- P391 Collect spillage.

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

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

Other hazards which do not result in classification:

**Important symptoms and outlines of the emergency assumed:**
- Dust contact with the eyes can lead to mechanical irritation.
- Contact with dust can cause mechanical irritation or drying of the skin.
- May form explosive dust-air mixture during processing, handling or other means.

### 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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxyclozanide</td>
<td>2277-92-1</td>
<td>&gt;= 40 - &lt; 50</td>
<td>9-1297</td>
</tr>
<tr>
<td>oxfendazole</td>
<td>53716-50-0</td>
<td>&gt;= 20 - &lt; 25</td>
<td></td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>&gt;= 1 - &lt; 10</td>
<td>2-611</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
<td>&gt;= 0.1 - &lt; 1</td>
<td>1-548</td>
</tr>
</tbody>
</table>

### 4. FIRST AID MEASURES

**General advice:** In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

**If inhaled:** If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact: In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: If in eyes, rinse well with water. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: May damage fertility. May damage the unborn child. May cause damage to organs if swallowed. May cause damage to organs through prolonged or repeated exposure. Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.

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.

5. FIREFIGHTING MEASURES

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Chlorine compounds
Nitrogen oxides (NOx)
Metal oxides
Oxides of phosphorus

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

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

6. ACCIDENTAL RELEASE MEASURES
SAFETY DATA SHEET

Oxfendazole / Oxyclozanide Formulation

Version: 2.0  
Revision Date: 2021/08/27  
SDS Number: 7942510-00002  
Date of last issue: 2021/03/19  
Date of first issue: 2021/03/19

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. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

7. HANDLING AND STORAGE

Handling

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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 dust. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

Keep container tightly closed. Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.

Avoidance of contact

Hygiene measures: Oxidizing agents

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.

**Storage**

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

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

**Packaging material**
- Unsuitable material: None known.

---

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Threshold limit value and permissible exposure limits for each component in the work environment**

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxclozanide</td>
<td>2277-92-1</td>
<td>TWA</td>
<td>0.4 mg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 mg/100 cm³</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>Wipe limit</td>
<td>400 µg/100 cm³</td>
<td>Internal</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</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>
</tbody>
</table>

**Engineering measures**
- All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
- 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
  - Hand protection: Particulates type
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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state: powder

Colour: white to off-white, light cream, cream

Odour: No data available

Odour Threshold: No data available

Melting point/freezing point: No data available

Boiling point, initial boiling point and boiling range: No data available

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): Not applicable

Lower explosion limit and upper explosion limit / flammability limit:
- Upper explosion limit / Upper flammability limit: No data available
- Lower explosion limit / Lower flammability limit: No data available

Flash point: Not applicable

Decomposition temperature: No data available

pH: No data available

Evaporation rate: Not applicable

Auto-ignition temperature: No data available

Viscosity
Viscosity, kinematic : Not applicable

Solubility(ies)
   Water solubility : No data available

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Density and / or relative density
   Relative density : No data available

Density : 0.88 g/cm³

Relative vapour density : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
   May form explosive dust-air mixture during processing, handling or other means.
   Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.
   Avoid dust formation.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity
Not classified based on available information.

Components:

oxyclozanide:
   Acute oral toxicity : LD50 (Rat): 3,519 mg/kg
   Target Organs: Central nervous system
Acute toxicity (other routes of administration): LDLo (sheep): 10 mg/kg

Application Route: Intravenous

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

Magnesium stearate:
Acute oral toxicity: LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Assessment: The substance or mixture has no acute oral toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity: LD50 (Rabbit): > 2,000 mg/kg
Remarks: Based on data from similar materials

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:

oxyclozanide:
Remarks: Not classified due to lack of data.

oxfendazole:
Species: Rabbit
Result: No skin irritation

Magnesium stearate:
Species: Rabbit
Result: No skin irritation
Remarks: Based on data from similar materials
Silicon, amorphous:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Method</td>
<td>OECD Test Guideline 404</td>
</tr>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

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

**Components:**

**oxyclozanide:**

| Remarks | Not classified due to lack of data. |

**oxfendazole:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Silicon, amorphous:**

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No eye irritation</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 405</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>

**Respiratory or skin sensitisation**

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

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

**Components:**

**oxyclozanide:**

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Dermal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Not classified due to lack of data.</td>
</tr>
</tbody>
</table>

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Maximisation Test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure routes</td>
<td>Skin contact</td>
</tr>
<tr>
<td>Species</td>
<td>Guinea pig</td>
</tr>
<tr>
<td>Method</td>
<td>OECD Test Guideline 406</td>
</tr>
<tr>
<td>Result</td>
<td>negative</td>
</tr>
<tr>
<td>Remarks</td>
<td>Based on data from similar materials</td>
</tr>
</tbody>
</table>
Germ cell mutagenicity
Not classified based on available information.

Components:

**oxyclozanide:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosomal aberration Test system: Human lymphocytes Result: positive</td>
</tr>
<tr>
<td></td>
<td>Test Type: Mouse Lymphoma Result: positive</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Genotoxicity in vivo</th>
<th>Test Type: Micronucleus test Species: Mouse Application Route: Oral Result: negative</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: unscheduled DNA synthesis assay Species: Rat Cell type: Liver cells Application Route: Oral Result: negative</td>
</tr>
</tbody>
</table>

Germ cell mutagenicity - Assessment: Weight of evidence does not support classification as a germ cell mutagen.

**oxfendazole:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: Bacterial reverse mutation assay (AMES) Result: negative</th>
</tr>
</thead>
</table>

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

**Magnesium stearate:**

<table>
<thead>
<tr>
<th>Genotoxicity in vitro</th>
<th>Test Type: In vitro mammalian cell gene mutation test Result: negative Remarks: Based on data from similar materials</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

| Test Type: Bacterial reverse mutation assay (AMES) 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 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:
oxyclozanide:
Remarks: Not classified due to lack of data.
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:
oxyclozanide:
Effects on fertility: Test Type: Two-generation reproduction toxicity study
Species: Rat, male and female
Application Route: Oral
### General Toxicity - Parent

**NOAEL:** 25 - 35 mg/kg body weight  
**Symptoms:** Reduced body weight, No effects on embryofoetal and postnatal development  
**Result:** No effects on fertility

**Test Type:** Two-generation reproduction toxicity study  
**Species:** Rat  
**Application Route:** Oral

**General Toxicity - Parent:** LOAEL: 75 - 100 mg/kg body weight  
**Symptoms:** Reduced body weight, No effects on embryofoetal and postnatal development  
**Result:** No effects on fertility

**Test Type:** Two-generation reproduction toxicity study  
**Species:** Rat  
**Application Route:** Oral

**Early Embryonic Development:** LOAEL: 75 - 100 mg/kg body weight  
**Result:** No fetotoxicity, No teratogenic effects

**Test Type:** One-generation reproduction toxicity study  
**Species:** Rat  
**Application Route:** Oral

**General Toxicity - Parent:** LOAEL: 80 - 160 mg/kg body weight  
**Result:** No fetotoxicity, No teratogenic effects, No effects on fertility

**Test Type:** Development  
**Species:** Rat  
**Application Route:** Oral

**Developmental Toxicity:** NOAEL: 200 mg/kg body weight  
**Result:** No fetotoxicity, No teratogenic effects

**Test Type:** Development  
**Species:** Rat  
**Application Route:** Oral

**General Toxicity Maternal:** LOAEL: 100 mg/kg body weight  
**Result:** No fetotoxicity, No teratogenic effects

**Test Type:** Development  
**Species:** Rabbit  
**Application Route:** Oral

**Developmental Toxicity:** NOAEL: 32 mg/kg body weight  
**Result:** Fetotoxicity, Skeletal malformations

### Effects on foetal development

**Test Type:** Development  
**Species:** Rat  
**Application Route:** Oral

**Developmental Toxicity:** NOAEL: 200 mg/kg body weight  
**Result:** No fetotoxicity, No teratogenic effects

**Test Type:** Development  
**Species:** Rat  
**Application Route:** Oral

**General Toxicity Maternal:** LOAEL: 100 mg/kg body weight  
**Result:** No fetotoxicity, No teratogenic effects

**Test Type:** Development  
**Species:** Rabbit  
**Application Route:** Oral

**Developmental Toxicity:** NOAEL: 32 mg/kg body weight  
**Result:** Fetotoxicity, Skeletal malformations

### Reproductive toxicity - Assessment

**oxfendazole:**  
**Suspected of damaging the unborn child.**

### 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 foetal development:
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: positive, Fetal effects

Species: Rat
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: positive, Embryo-foetal toxicity

Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 108 mg/kg body weight
Result: positive, Embryo-foetal toxicity, foetal abnormalities

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.

Magnesium stearate:
Effects on fertility:
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

Effects on foetal development:
Test Type: Embryo-foetal development
SAFETY DATA SHEET

Oxfendazole / Oxyclozanide Formulation

Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Silicon, amorphous:

Effects on foetal development:
Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

STOT - single exposure
May cause damage to organs (Central nervous system) if swallowed.

Components:
oxyclonanide:
Exposure routes: Oral
Target Organs: Central nervous system
Assessment: May cause damage to organs.

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

Components:
oxyclonanide:
Target Organs: Brain, Liver
Assessment: May cause damage to organs through prolonged or repeated exposure.
oxindazole:
Exposure routes: Oral
Target Organs: Liver, Testis
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:
oxyclonanide:
Species: Rat
NOAEL: 9 mg/kg
LOAEL: 44.5 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Brain, Liver, spleen, Adrenal gland
Symptoms: Liver effects

Species: Dog
NOAEL: 5 mg/kg
SAFETY DATA SHEET

Oxfendazole / Oxyclozanide Formulation

Version 2.0  Revision Date: 2021/08/27  SDS Number: 7942510-00002  Date of last issue: 2021/03/19  Date of first issue: 2021/03/19

<table>
<thead>
<tr>
<th>LOAEL</th>
<th>25 mg/kg</th>
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<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>3 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Brain, Liver</td>
</tr>
<tr>
<td>Symptoms</td>
<td>blood effects, alteration in liver enzymes</td>
</tr>
</tbody>
</table>

oxfendazole:

Species: Rat

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

Species: Rat

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

Species: Mouse

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

Species: Mouse

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

Species: Dog

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

Species: Dog

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>11 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>2 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Lymph nodes, thymus gland</td>
</tr>
</tbody>
</table>

Species: Dog

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>13.5 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Oral</td>
</tr>
<tr>
<td>Exposure time</td>
<td>12 Months</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
</tbody>
</table>

Magnesium stearate:

Species: Rat

<table>
<thead>
<tr>
<th>NOAEL</th>
<th>&gt; 100 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application Route</td>
<td>Ingestion</td>
</tr>
<tr>
<td>Exposure time</td>
<td>90 Days</td>
</tr>
</tbody>
</table>
Oxfendazole / Oxyclozanide Formulation

| Remarks | : | Based on data from similar materials |
| 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.

Components:
oxyclozanide:
Not applicable

Experience with human exposure

Components:
oxyclozanide:

Ingestion: Symptoms: May cause, Gastrointestinal disturbance, Central nervous system depression

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:
oxyclozanide:

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.69 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

M-Factor (Acute aquatic toxicity): 1
M-Factor (Chronic aquatic toxicity): 1

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: EC50 (Pseudokirchneriella subcapitata (green algae)): > 4
## Magnesium stearate:

<table>
<thead>
<tr>
<th>Test Category</th>
<th>Description</th>
<th>Result</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l</td>
<td></td>
<td>Method: DIN 38412</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 48 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to daphnia and other</td>
<td>EL50 (Daphnia magna (Water flea)): &gt; 1 mg/l</td>
<td></td>
<td>Method: Directive 67/548/EEC, Annex V, C.2.</td>
<td>No toxicity at the limit of solubility</td>
</tr>
<tr>
<td>aquatic invertebrates</td>
<td>Exposure time: 47 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No toxicity at the limit of solubility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</td>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No toxicity at the limit of solubility</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOELR (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l</td>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td>Based on data from similar materials</td>
</tr>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Test substance: Water Accommodated Fraction</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Remarks: Based on data from similar materials</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## Silicon, amorphous:

<table>
<thead>
<tr>
<th>Test Category</th>
<th>Description</th>
<th>Result</th>
<th>Method</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Danio rerio (zebra fish)): &gt; 10,000 mg/l</td>
<td></td>
<td>Method: OECD Test Guideline 203</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Exposure time: 96 h</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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:

oxyclozanide:
- Stability in water: Hydrolysis: 50 % (156 d)
- Method: OECD Test Guideline 111

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

Magnesium stearate:
- Biodegradability: Result: Not biodegradable
- Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

oxyclozanide:
- Partition coefficient: n-octanol/water: log Pow: 3.99
- pH: 7
- Method: OECD Test Guideline 107

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

Magnesium stearate:
- Partition coefficient: n-octanol/water: log Pow: > 4
Mobility in soil

Components:

oxyclozanide:
- Distribution among environmental compartments: \( \log K_{oc} = 4.83 \)
- Method: OECD Test Guideline 106

oxfendazole:
- Distribution among environmental compartments: \( \log K_{oc} = 3.2 \)

Hazardous to the ozone layer
- Not applicable

Other adverse effects
- No data available

13. DISPOSAL CONSIDERATIONS

Disposal methods
- Waste from residues: Dispose of in accordance with local regulations.
- Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

International Regulations

UNRTDG
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (oxfendazole, oxyclozanide)
- Class: 9
- Packing group: III
- Labels: 9

IATA-DGR
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (oxfendazole, oxyclozanide)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes

IMDG-Code
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
SAFETY DATA SHEET

Oxfendazole / Oxyclozanide Formulation

N.O.S. (oxfendazole, oxyclozanide)

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.

National Regulations
Refer to section 15 for specific national regulation.

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.

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law
Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law
Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture
Not applicable

Harmful Substances Required Permission for Manufacture
Not applicable

Substances Prevented From Impairment of Health
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity
Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity
Not applicable

Substances Subject to be Notified Names

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
<th>Concentration (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
<td>&gt;=1 - &lt;10</td>
</tr>
<tr>
<td>Crystalline silica</td>
<td>165</td>
<td>&gt;=0.1 - &lt;1</td>
</tr>
</tbody>
</table>
Substances Subject to be Indicated Names

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Magnesium stearate</td>
<td>327</td>
</tr>
<tr>
<td>Crystalline silica</td>
<td>165 (2)</td>
</tr>
</tbody>
</table>

Ordinance on Prevention of Hazards Due to Specified Chemical Substances
Not applicable

Ordinance on Prevention of Lead Poisoning
Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning
Not applicable

Ordinance on Prevention of Organic Solvent Poisoning
Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)
Not applicable

Poisonous and Deleterious Substances Control Law
Not applicable

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof
Not applicable

High Pressure Gas Safety Act
Not applicable

Explosive Control Law
Not applicable

Vessel Safety Law
Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law
Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law
Bulk transportation : Not classified as noxious liquid substance
Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act
Narcotic or Psychotropic Raw Material (Export / Import Permission)
Not applicable
Specific Narcotic or Psychotropic Raw Material (Export / Import permission)
Not applicable

Waste Disposal and Public Cleansing Law
Industrial waste

The components of this product are reported in the following inventories:
### 16. OTHER INFORMATION

**Further information**


Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format: yyyy/mm/dd

**Full text of other abbreviations**

- **ACGIH**: USA. ACGIH Threshold Limit Values (TLV)
- **ACGIH / TWA**: 8-hour, time-weighted average

**Abbreviations**:
- **AICS**: not determined
- **DSL**: not determined
- **IECSC**: not determined

**Additional abbreviations**:
- **AIIIC**: 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 Harmonised System
- **GLP**: Good Laboratory Practice
- **IARC**: International Agency for Research on Cancer
- **IATA**: International Air Transport Association
- **IC50**: Half maximal inhibitory concentration
- **ICAO**: International Civil Aviation Organization
- **IECSC**: Inventory of Existing Chemical Substances in China
- **IMDG**: International Maritime Dangerous Goods
- **IMO**: International Maritime Organization
- **ISHL**: Industrial Safety and Health Law (Japan)
- **ISO**: International Organisation for Standardization
- **KECI**: Korea Existing Chemicals Inventory
- **LC50**: Lethal Concentration to 50 % of a test population
- **LD50**: Lethal Dose to 50% of a test population (Median Lethal Dose)
- **MARPOL**: International Convention for the Prevention of Pollution from Ships
- **n.o.s.**: Not Otherwise Specified
- **Nch**: Chilean Norm
- **NO(A)EC**: No Observed (Adverse) Effect Concentration
- **NO(A)EL**: No Observed (Adverse) Effect Level
- **NOM**: Official Mexican Norm
- **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
- **PHCC**: Philippines Inventory of Chemicals and Chemical Substances
- **(Q)SAR**: (Quantitative) Structure Activity Relationship
- **SADT**: Self-Accelerating Decomposition Temperature
- **SDS**: Safety Data Sheet
- **TCSI**: Taiwan Chemical Substance Inventory
- **TDG**: Transport of Dangerous Goods
- **TECI**: 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
- **WHMIS**: Workplace Hazardous Materials Information System
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.

JP / EN