SECTION 1. IDENTIFICATION

Product name : Oxfendazole / Oxyclozanide Formulation

Manufacturer or supplier’s details
Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
           Kenilworth - New Jersey - U.S.A. 07033
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 medicine

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Combustible dust
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)

GHS label elements
Hazard pictograms : 
Signal Word : Danger
Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
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.

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.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

Response:
P308 + P311 IF exposed or concerned: Call a doctor.
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
Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Mixture</th>
</tr>
</thead>
</table>

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxyclozanide</td>
<td>2277-92-1</td>
<td>48</td>
</tr>
<tr>
<td>oxfendazole</td>
<td>53716-50-0</td>
<td>24</td>
</tr>
<tr>
<td>Starch, oxidized</td>
<td>65996-62-5</td>
<td>16.7216</td>
</tr>
<tr>
<td>Magnesium stearate</td>
<td>557-04-0</td>
<td>1.392</td>
</tr>
<tr>
<td>Silicon, amorphous</td>
<td>112945-52-5</td>
<td>0.7955</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: 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.

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:
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 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. 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.

SECTION 7. HANDLING AND STORAGE

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.

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 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>Oxyclozanide</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 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>
</tbody>
</table>
Wipe limit | 400 µg/100 cm² | Internal
---|---|---
Magnesium stearate | TWA (Inhalable particulate matter) 10 mg/m³ | ACGIH
| TWA (Respirable particulate matter) 3 mg/m³ | ACGIH
Silicon, amorphous | TWA (Dust) 20 Million particles per cubic foot (Silica) | OSHA Z-3
| TWA (Dust) 80 mg/m³ / %SiO₂ (Silica) | OSHA Z-3
| TWA 6 mg/m³ (Silica) | NIOSH REL

**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**: 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**: 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,
6 / 22

Hygiene measures:
- Use appropriate degowning techniques to remove potentially contaminated clothing.
- 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: powder
Color: white to off-white, light cream, cream
Odor: No data available
Odor Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling range: No data available
Flash point: Not applicable
Evaporation rate: Not applicable
Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids): Not applicable
Upper explosion limit / Upper flammability limit: No data available
Lower explosion limit / Lower flammability limit: No data available
Vapor pressure: Not applicable
Relative vapor density: Not applicable
Relative density: No data available
Density: 0.88 g/cm³
Solubility(ies):
SAFETY DATA SHEET

Oxfendazole / Oxyclozanide Formulation

Version 1.1
Revision Date: 08/27/2021
SDS Number: 7942487-00002
Date of last issue: 03/19/2021
Date of first issue: 03/19/2021

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<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>Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
</tbody>
</table>

SECTION 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.

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: > 5,000 mg/kg
  - Method: Calculation method

Components:

Oxyclozanide:
- Acute oral toxicity: LD50 (Rat): 3.519 mg/kg
  - Target Organs: Central nervous system
  - Acute toxicity (other routes of): LDLo (sheep): 10 mg/kg
SAFETY DATA SHEET

Oxfendazole / Oxyclozanide Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date</th>
<th>SDS Number</th>
<th>Date of last issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>08/27/2021</td>
<td>7942487-00002</td>
<td>03/19/2021</td>
</tr>
</tbody>
</table>

administration)  

**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:
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:

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

Oxfendazole:
Species : Rabbit
Result : No eye irritation

Magnesium stearate:
Species : Rabbit
Result : No eye irritation
Remarks : Based on data from similar materials

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:

Oxyclozanide:
Routes of exposure : Dermal
Remarks : Not classified due to lack of data.

Magnesium stearate:
Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials
SAFETY DATA SHEET
Oxfendazole / Oxyclozanide Formulation

Germ cell mutagenicity
Not classified based on available information.

Components:

Oxyclozanide:
Genotoxicity in vitro:
- Test Type: Bacterial reverse mutation assay (AMES)
  Result: negative
- Test Type: Chromosomal aberration
  Test system: Human lymphocytes
  Result: positive
- Test Type: Mouse Lymphoma
  Result: positive

Genotoxicity in vivo:
- Test Type: Micronucleus test
  Species: Mouse
  Application Route: Oral
  Result: negative
- Test Type: unscheduled DNA synthesis assay
  Species: Rat
  Cell type: Liver cells
  Application Route: Oral
  Result: negative

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

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

Magnesium stearate:
Genotoxicity in vitro:
- Test Type: In vitro mammalian cell gene mutation test
  Result: negative
  Remarks: Based on data from similar materials
- Test Type: Chromosome aberration test in vitro
  Method: OECD Test Guideline 473
  Result: negative
  Remarks: Based on data from similar materials
- Test Type: Bacterial reverse mutation assay (AMES)
  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:**

**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

<table>
<thead>
<tr>
<th>Species</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Symptoms</th>
<th>Target Organs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>Oral</td>
<td>2 Years</td>
<td>No adverse effects.</td>
<td>Liver</td>
</tr>
</tbody>
</table>

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

**IARC**
- Group 1: Carcinogenic to humans
- Silicon, amorphous 112945-52-5

**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**
- Known to be human carcinogen
- Silicon, amorphous 112945-52-5

**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 embryofetal 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 embryofetal 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.

Effects on fetal 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

Reproductive toxicity - Assessment:
- Suspected of damaging the unborn child.

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.

Magnesium stearate:
- Effects on fertility:
  - Test Type: Combined repeated dose toxicity study with the reproduction/developmental toxicity screening test
  - Species: Rat
  - Application Route: Ingestion
Method: OECD Test Guideline 422
Result: negative
Remarks: Based on data from similar materials

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

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
May cause damage to organs (Central nervous system) if swallowed.

Components:

Oxyclozanide:
Routes of exposure: 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:

Oxyclozanide:
Target Organs: Brain, Liver
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:

Oxyclozanide:
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
LOAEL: 25 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Brain, Liver
Symptoms: blood effects, alteration in liver enzymes

**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
Magnesium stearate:
Species : Rat
NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
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

SECTION 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

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
### Magnesium stearate:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Leuciscus idus (Golden orfe)): &gt; 100 mg/l Exposure time: 48 h Method: DIN 38412 Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicity to algae/aquatic plants</td>
<td>EL50 (Pseudokirchneriella subcapitata (green algae)): &gt; 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials No toxicity at the limit of solubility.</td>
</tr>
<tr>
<td>NOELR (Pseudokirchneriella subcapitata (green algae))</td>
<td>&gt; 1 mg/l Exposure time: 72 h Test substance: Water Accommodated Fraction Method: OECD Test Guideline 201 Remarks: Based on data from similar materials</td>
</tr>
</tbody>
</table>

### Silicon, amorphous:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Toxicity to fish</td>
<td>LC50 (Danio rerio (zebra fish)): &gt; 10,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials</td>
</tr>
<tr>
<td>Toxicity to daphnia and other aquatic invertebrates</td>
<td>EC50 (Daphnia magna (Water flea)): &gt; 1,000 mg/l</td>
</tr>
</tbody>
</table>
aquatic invertebrates
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:
SECTON 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.

SECTON 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, 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.

Domestic regulation

49 CFR
UN/ID/NA number : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(oxfendazole, Oxyclozanide)
Class : 9
Packing group : III
Labels : CLASS 9
ERG Code : 171
Marine pollutant : yes (oxfendazole, Oxyclozanide)
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 : Combustible dust
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
Oxyclozanide 2277-92-1
oxfendazole 53716-50-0
Starch, oxidized 65996-62-5
Polyvinyl pyrrolidone 9003-39-8
California Prop. 65
WARNING: This product can expose you to chemicals including Silicon, amorphous, which is/are known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

California List of Hazardous Substances
Polyvinyl pyrrolidone 9003-39-8

California Permissible Exposure Limits for Chemical Contaminants
Starch, oxidized 65996-62-5
Magnesium stearate 557-04-0

California Regulated Carcinogens
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:
HMIS® IV:

Flammability
Health
0 1 0
Instability

HEALTH
* 3
FLAMMABILITY
3
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 Dists
ACGIH / TWA: 8-hour, time-weighted average
NIOSH REL / TWA: Time-weighted average concentration for up to a 10-hour
Handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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.

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