

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## Oxfendazole / Oxytoclozanide Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04/04/2023
3.1	09/30/2023	7942487-00007	Date of first issue: 03/19/2021

### SECTION 1. IDENTIFICATION

Product name : Oxfendazole / Oxytoclozanide Formulation

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc  
Address : 126 E. Lincoln Avenue  
Rahway, New Jersey U.S.A. 07065  
Telephone : 908-740-4000  
Emergency telephone : 1-908-423-6000  
E-mail address : EHSDATASTEWART@merck.com

#### Recommended use of the chemical and restrictions on use

Recommended use : Veterinary medicine  
Restrictions on use : Not applicable

### 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 : Category 2 (Central nervous system)  
- single exposure (Oral)

Specific target organ toxicity : Category 2 (Liver, Testis, Brain)  
- repeated exposure

#### 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

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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

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Oxytoclozanide	2277-92-1	48
oxfendazole	53716-50-0	24
Starch, oxidized	65996-62-5	16.7216
Magnesium stearate	557-04-0	1.392

## 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.

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Most important symptoms and effects, both acute and delayed	: Never give anything by mouth to an unconscious person. 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.
Protection of first-aiders	: Dust contact with the eyes can lead to mechanical irritation. 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 (CO <sub>2</sub> ) 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 (NO <sub>x</sub> ) 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	: Sweep up or vacuum up spillage and collect in suitable

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containment and cleaning up 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 Self-reactive substances and mixtures Organic peroxides Explosives Gases

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

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inert or nuisance dust      50 Million particles per cubic foot  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

15 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (total dust)  
Basis: OSHA Z-3

5 mg/m<sup>3</sup>  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

15 Million particles per cubic foot  
Value type (Form of exposure): TWA (respirable fraction)  
Basis: OSHA Z-3

Dust, nuisance dust and particulates      10 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (Total dust)  
Basis: CAL PEL

5 mg/m<sup>3</sup>  
Value type (Form of exposure): PEL (respirable dust fraction)  
Basis: CAL PEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Oxytoclozanide	2277-92-1	TWA	0.4 mg/m <sup>3</sup> (OEB 2)	Internal
oxfendazole	53716-50-0	TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal
Starch, oxidized	65996-62-5	TWA (Inhalable dust)	0.5 mg/m <sup>3</sup>	ACGIH
Magnesium stearate	557-04-0	TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH

**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

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

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

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

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : 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

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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/cm <sup>3</sup>
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	Not applicable
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available

### 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.

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Incompatible materials	:	Avoid dust formation.
Hazardous decomposition products	:	Oxidizing agents
	:	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:

##### **Oxytoclozanide:**

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

#### **Skin corrosion/irritation**

Not classified based on available information.

#### Components:

##### **Oxytoclozanide:**



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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

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Oxytetracycline:

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

### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

### Components:

#### Oxytetracycline:

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

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### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### **Oxytetracycline:**

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

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### Carcinogenicity

Not classified based on available information.

### Components:

#### Oxytoclozanide:

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

**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:

#### Oxytoclozanide:

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.

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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  
Result: Fetotoxicity., Skeletal malformations.

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

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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

### STOT-single exposure

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

### Components:

#### Oxytetracycline:

Routes of exposure : Oral

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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:

##### **Oxclozanide:**

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:

##### **Oxclozanide:**

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

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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

### Starch, oxidized:

Species : Rat  
NOAEL : 22,500 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days

### Magnesium stearate:

Species : Rat  
NOAEL : > 100 mg/kg  
Application Route : Ingestion  
Exposure time : 90 Days  
Remarks : Based on data from similar materials

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Oxyclozanide:

Not applicable

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### Experience with human exposure

#### Components:

##### **Oxytoclozanide:**

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

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

##### **Oxytoclozanide:**

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

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

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

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

##### **Magnesium stearate:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l  
Exposure time: 48 h  
Method: DIN 38412  
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EL50 (Daphnia magna (Water flea)): > 1 mg/l  
Exposure time: 47 h



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## Oxfendazole / Oxytetracycline Formulation

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Test substance: Water Accommodated Fraction  
Method: Directive 67/548/EEC, Annex V, C.2.  
Remarks: Based on data from similar materials  
No toxicity at the limit of solubility.

Toxicity to algae/aquatic plants : EL50 (Pseudokirchneriella subcapitata (green algae)): > 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.

NOELR (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l  
Exposure time: 72 h  
Test substance: Water Accommodated Fraction  
Method: OECD Test Guideline 201  
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (Pseudomonas putida): > 100 mg/l  
Exposure time: 16 h  
Test substance: Water Accommodated Fraction  
Remarks: Based on data from similar materials

### Persistence and degradability

#### Components:

##### **Oxytetracycline:**

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:

##### **Oxytetracycline:**

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

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## Oxfendazole / Oxytoclozanide Formulation

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octanol/water

### Magnesium stearate:

Partition coefficient: n- : log Pow: > 4  
octanol/water

### Mobility in soil

### Components:

### Oxytoclozanide:

Distribution among environ- : log Koc: 4.83  
mental compartments Method: OECD Test Guideline 106

### oxfendazole:

Distribution among environ- : log Koc: 3.2  
mental compartments

### Other adverse effects

No data available

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

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

## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

UN number : UN 3077  
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,  
N.O.S.  
(oxfendazole, oxytoclozanide)  
Class : 9  
Packing group : III  
Labels : 9  
Environmentally hazardous : yes

#### IATA-DGR

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

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## Oxfendazole / Oxyclozanide Formulation

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ger aircraft)

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)

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**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 List of Hazardous Substances

Polyvinyl pyrrolidone	9003-39-8
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#### California Permissible Exposure Limits for Chemical Contaminants

Starch, oxidized	65996-62-5
Magnesium stearate	557-04-0

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

AICS : not determined

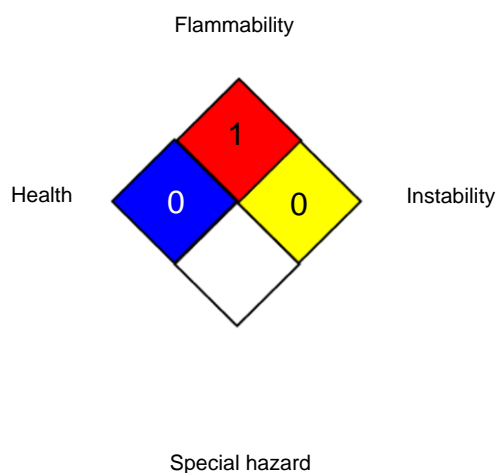
DSL : not determined

IECSC : not determined

## SECTION 16. OTHER INFORMATION

### Further information

#### NFPA 704:



#### HMIS® IV:

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

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ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)
CAL PEL	:	California permissible exposure limits for chemical contaminants (Title 8, Article 107)
OSHA Z-3	:	USA. Occupational Exposure Limits (OSHA) - Table Z-3 Mineral Dusts
ACGIH / TWA	:	8-hour, time-weighted average
CAL PEL / PEL	:	Permissible exposure limit
OSHA Z-3 / TWA	:	8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; 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; IECS - 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (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; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - 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 : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Revision Date : 09/30/2023

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

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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