SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name: Oxfendazole / Oxyclozanide Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture: Veterinary medicine

1.3 Details of the supplier of the safety data sheet
Company: MSD
Kilsheelan
Clonmel Tipperary, IE

Telephone: 353-51-601000
E-mail address of person responsible for the SDS: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Reproductive toxicity, Category 1B: H360FD: May damage fertility. May damage the unborn child.
Specific target organ toxicity - single exposure, Category 2: H371: May cause damage to organs.
Specific target organ toxicity - repeated exposure, Category 2: H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1: H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1: H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Hazard pictograms: 
Signal word: Danger
Hazard statements: H360FD: May damage fertility. May damage the unborn child.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Oxfendazole / Oxyclozanide Formulation

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Date of first issue: 19.03.2021

H371 May cause damage to organs.
H373 May cause damage to organs through prolonged or repeated exposure.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements:
Prevention:
P201 Obtain special instructions before use.
P260 Do not breathe dust.
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.

Hazardous components which must be listed on the label:
oxyclozanide
oxfendazole

2.3 Other hazards
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxyclozanide</td>
<td>2277-92-1</td>
<td>218-904-0</td>
<td></td>
<td>Repr. 2; H361d STOT SE 2; H371 (Central nervous system) STOT RE 2; H373 (Brain, Liver)</td>
<td>&gt;= 30 - &lt; 50</td>
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</table>
SAFETY DATA SHEET
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
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<tr>
<td>1.1</td>
<td>27.08.2021</td>
<td>7978723-00002</td>
<td>19.03.2021</td>
<td>19.03.2021</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS Number</th>
<th>Repr. 1B; H360FD STOT RE 2; H373 (Liver, Testis)</th>
<th>Aquatic Acute 1; H400 Aquatic Chronic 1; H410</th>
</tr>
</thead>
<tbody>
<tr>
<td>oxfendazole</td>
<td>53716-50-0 258-714-5</td>
<td>&gt;= 20 - &lt; 25</td>
<td>M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 1</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

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.

4.2 Most important symptoms and effects, both acute and delayed

Risks: May damage fertility. May damage the unborn child. May cause damage to organs. 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.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance or mixture

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

5.3 Advice for firefighters

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

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.
SECTION 6: Accidental release measures

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

6.2 Environmental precautions
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 spills cannot be contained.

6.3 Methods and material for containment and cleaning up
Methods for 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.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.
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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.

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.

7.2 Conditions for safe storage, including any incompatibilities
Requirements for storage areas and containers: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage: Do not store with the following product types:
- Strong oxidizing agents
- Organic peroxides
- Explosives
- Gases

7.3 Specific end use(s)
Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</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>
<tr>
<td></td>
<td></td>
<td>Wipe limit</td>
<td>400 µg/100 cm²</td>
<td>Internal</td>
</tr>
<tr>
<td>Starch, oxidized</td>
<td>65996-62-5</td>
<td>OELV - 8 hrs (TWA) (Dust)</td>
<td>1 mg/m³</td>
<td>IE OEL</td>
</tr>
</tbody>
</table>

Further information: Chemical agents which following exposure may cause sensitisation of the respiratory tract and lead to asthma, rhinitis or extrinsic allergic alveolitis.

Magnesium stearate 557-04-0 OELV - 8 hrs (TWA) 10 mg/m³ IE OEL
8.2 Exposure controls

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

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.

Hand protection

Material: Chemical-resistant gloves
Remarks: Consider double gloving.

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.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to I.S. EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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
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
Upper explosion limit / Upper flammability limit: No data available
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<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
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<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</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>Solubility(ies)</td>
<td></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>0.88 g/cm³</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>9.2 Other information</td>
<td></td>
</tr>
<tr>
<td>Explosives</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>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Molecular weight</td>
<td>No data available</td>
</tr>
</tbody>
</table>

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

10.3 Possibility of hazardous reactions
Hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid: Heat, flames and sparks. Avoid dust formation.
10.5 Incompatible materials

Materials to avoid: Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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

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

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

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

oxyclozanide:
Exposure routes: Dermal
Remarks: Not classified due to lack of data.

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:
Species: Mouse
Application Route: Oral
Result: positive

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

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

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

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

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

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

Test Type: Embryo-foetal 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.

STOT - single exposure
May cause damage to organs.

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

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Components:
oxyclozanide:
Target Organs: Brain, Liver
Assessment: May cause damage to organs through prolonged or repeated exposure.
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**oxfendazole:**
- **Exposure routes**: 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 Month
- **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

Aspiration toxicity
Not classified based on available information.

Components:
oxyclozanide:
Not applicable

11.2 Information on other hazards
Endocrine disrupting properties
Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Experience with human exposure
Components:
oxyclozanide:
Ingestion: Symptoms: May cause, Gastrointestinal disturbance, Central nervous system depression

SECTION 12: Ecological information

12.1 Toxicity
Components:
oxyclozanide:
Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): 0.69 mg/l
Exposure time: 48 h
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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 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

M-Factor (Acute aquatic toxicity): 10

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

M-Factor (Chronic aquatic toxicity): 1

12.2 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)
12.3 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

12.4 Mobility in soil

**Components:**

**oxyclozanide:**
Distribution among environmental compartments : log Koc: 4.83  
  Method: OECD Test Guideline 106

**oxfendazole:**
Distribution among environmental compartments : log Koc: 3.2

12.5 Results of PBT and vPvB assessment

**Product:**
Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

**Product:**
Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

**Product:**
Dispose of in accordance with local regulations.  
According to the European Waste Catalogue, Waste Codes are not product specific, but application specific.  
Waste codes should be assigned by the user, preferably in
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

14.1 UN number or ID number

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
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14.2 UN proper shipping name

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<tbody>
<tr>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (oxfendazole, oxyclozanide)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (oxfendazole, oxyclozanide)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (oxfendazole, oxyclozanide)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (oxfendazole, oxyclozanide)</td>
<td>Environmentally hazardous substance, solid, n.o.s. (oxfendazole, oxyclozanide)</td>
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14.3 Transport hazard class(es)

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<th>IMDG</th>
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<tbody>
<tr>
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14.4 Packing group

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<tr>
<td>Packing group: III</td>
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<tr>
<td>Labels: 9</td>
<td>Labels: 9</td>
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</table>
14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Oxfendazole / Oxyclozanide Formulation

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII): Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59): Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast): Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable

<table>
<thead>
<tr>
<th>Quantity 1</th>
<th>Quantity 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 t</td>
<td>200 t</td>
</tr>
</tbody>
</table>

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

The components of this product are reported in the following inventories:

AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H360FD: May damage fertility. May damage the unborn child.
H361d: Suspected of damaging the unborn child.
H371: May cause damage to organs if swallowed.
H373: May cause damage to organs through prolonged or repeated exposure.
Oxfendazole / Oxyclozanide Formulation

<table>
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<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
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<td>7978723-00002</td>
<td>19.03.2021</td>
<td>19.03.2021</td>
</tr>
</tbody>
</table>

H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Repr. : Reproductive toxicity
STOT RE : Specific target organ toxicity - repeated exposure
STOT SE : Specific target organ toxicity - single exposure
IE OEL : Ireland. List of Chemical Agents and Occupational Exposure Limit Values - Schedule 1
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; GHS - Globally Harmonized System; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observeable Effect Loading Rate; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

**Further information**


Classification of the mixture: H360FD

Classification procedure: Calculation method
# Oxfendazole / Oxyclozanide Formulation

<table>
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</tr>
<tr>
<td>STOT RE 2</td>
<td>H373</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
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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.

IE / EN