

Levamisole / Oxfendazole Formulation

Version 4.0 Revision Date: 05.12.2023 SDS Number: 10808158-00005 Date of last issue: 30.09.2023
Date of first issue: 05.07.2022

Section 1: Identification

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

Manufacturer or supplier's details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone : 0800 800 543
Emergency telephone number : 0800 764 766 (0800 POISON) 0800 243 622 (0800 CHEMCALL)
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

Section 2: Hazard identification



GHS Classification

Respiratory sensitisation : Category 1
Skin sensitisation : Category 1
Reproductive toxicity : Category 1
Specific target organ toxicity - repeated exposure : Category 2 (Liver, Testis)
Specific target organ toxicity - repeated exposure (Oral) : Category 2 (Blood, Testis)
Hazardous to the aquatic environment - acute hazard : Category 1
Hazardous to the aquatic environment - chronic hazard : Category 2

GHS label elements

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- Hazard pictograms :  
- Signal word : Danger
- Hazard statements : H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H360FD May damage fertility. May damage the unborn child.
H373 May cause damage to organs (Liver, Testis) through prolonged or repeated exposure.
H373 May cause damage to organs (Blood, Testis) through prolonged or repeated exposure if swallowed.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.
- Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P260 Do not breathe mist or vapours.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
P284 Wear respiratory protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of water.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P391 Collect spillage.
Storage:
P405 Store locked up.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

Section 3: Composition/information on ingredients

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Substance / Mixture : Mixture

Components

| Chemical name | CAS-No. | Concentration (% w/w) |
|------------------------------|-------------|-----------------------|
| levamisole hydrochloride | 16595-80-5 | >= 2.5 -< 10 |
| oxfendazole | 53716-50-0 | >= 2.5 -< 10 |
| Polyethylene glycol stearate | 9004-99-3 | >= 1 -< 10 |
| Citric acid | 77-92-9 | >= 1 -< 10 |
| Silicon, amorphous | 112945-52-5 | >= 1 -< 10 |
| Sodium metabisulphite | 7681-57-4 | >= 0.1 -< 1 |

Section 4: First-aid measures

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
When symptoms persist or in all cases of doubt seek medical advice.
- If inhaled : If inhaled, remove to fresh air.
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.
- In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage fertility. May damage the unborn child.
May cause damage to organs through prolonged or repeated exposure.
- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment 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- : Exposure to combustion products may be a hazard to health.

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fighting
Hazardous combustion products : Carbon oxides

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

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

Hazchem Code : 3Z

Section 6: Accidental release measures

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

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

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

Section 7: Handling and storage

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

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling : Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Avoid contact with eyes.
Handle in accordance with good industrial hygiene and safety

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- practice, based on the results of the workplace exposure assessment
- Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment.
- 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.
- Conditions for safe storage : Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:
Strong oxidizing agents

Section 8: Exposure controls/personal protection

Components with workplace control parameters

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|------------------------------|-------------|--|--|----------|
| levamisole hydrochloride | 16595-80-5 | TWA | 20 µg/m ³ (OEB 3) | Internal |
| | | Further information: Skin | | |
| | | Wipe limit | 200 µg/100 cm ² | Internal |
| oxfendazole | 53716-50-0 | TWA | 40 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 400 µg/100 cm ² | Internal |
| Polyethylene glycol stearate | 9004-99-3 | WES-TWA | 10 mg/m ³ | NZ OEL |
| | | TWA (Inhalable particulate matter) | 10 mg/m ³ | ACGIH |
| | | TWA (Respirable particulate matter) | 3 mg/m ³ | ACGIH |
| Silicon, amorphous | 112945-52-5 | WES-TWA | 10 mg/m ³ | NZ OEL |
| Sodium metabisulphite | 7681-57-4 | WES-TWA | 5 mg/m ³ | NZ OEL |
| | | Further information: Skin sensitiser, Respiratory sensitiser | | |
| | | TWA | 5 mg/m ³ | ACGIH |

- Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

Personal protective equipment

| | | |
|--------------------------|---|--|
| Respiratory protection | : | If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type | : | Particulates type |
| 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. |

Section 9: Physical and chemical properties

| | | |
|---|---|-------------------|
| Appearance | : | Aqueous solution |
| Colour | : | No data available |
| Odour | : | No data available |
| Odour 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 | : | No data available |
| Evaporation rate | : | No data available |

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|--|---|--|
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | No data available |
| Density | : | No data available |
| Solubility(ies) | : | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | : | |
| Viscosity, kinematic | : | No data available |
| Explosive properties | : | Not explosive |
| Oxidizing properties | : | The substance or mixture is not classified as oxidizing. |
| Molecular weight | : | No data available |
| Particle size | : | Not applicable |

Section 10: Stability and reactivity

| | | |
|------------------------------------|---|--|
| Reactivity | : | Not classified as a reactivity hazard. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | Can react with strong oxidizing agents. |
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

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Section 11: Toxicological information

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:**levamisole hydrochloride:**

Acute oral toxicity : LD50 (Rat): 180 mg/kg
LD50 (Mouse): 223 mg/kg
LD50 (Rabbit): 458 mg/kg
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available

oxfendazole:

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

Polyethylene glycol stearate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Citric acid:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg
Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Silicon, amorphous:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401
Remarks: Based on data from similar materials

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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

Sodium metabisulphite:

Acute oral toxicity : LD50 (Rat): 1,540 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 5.5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 402
Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:**levamisole hydrochloride:**

Remarks : No data available

oxfendazole:

Species : Rabbit
Result : No skin irritation

Polyethylene glycol stearate:

Species : Rabbit
Method : Draize Test
Result : No skin irritation

Citric acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Silicon, amorphous:

Species : Rabbit

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Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

Sodium metabisulphite:

Result : Skin irritation
Remarks : Based on national or regional regulation.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**levamisole hydrochloride:**

Remarks : No data available

oxfendazole:

Species : Rabbit
Result : No eye irritation

Polyethylene glycol stearate:

Species : Rabbit
Result : No eye irritation
Method : Draize Test

Citric acid:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Silicon, amorphous:

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405
Remarks : Based on data from similar materials

Sodium metabisulphite:

Species : Rabbit
Result : Irreversible effects on the eye
Method : OECD Test Guideline 405

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

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Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:

levamisole hydrochloride:

||Remarks : No data available

Polyethylene glycol stearate:

||Test Type : Open epicutaneous test
 ||Exposure routes : Skin contact
 ||Species : Guinea pig
 ||Result : negative

Sodium metabisulphite:

||Assessment : Probability or evidence of skin sensitisation in humans
 ||Remarks : Based on national or regional regulation.

||Assessment : May cause sensitisation by inhalation.
 ||Remarks : Based on national or regional regulation.

Chronic toxicity

Germ cell mutagenicity

Not classified based on available information.

Components:

levamisole hydrochloride:

||Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
 ||Result: negative
 ||Test Type: Chromosome aberration test in vitro
 ||Result: negative

oxfendazole:

||Genotoxicity in vitro : 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

Polyethylene glycol stearate:

||Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
 ||Result: negative

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Citric acid:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
- Test Type: in vitro micronucleus test
Result: positive
- 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: Rat
Application Route: Ingestion
Result: negative

Silicon, amorphous:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials
- Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow
cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

Sodium metabisulphite:

- Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
- Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: negative
- Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo
cytogenetic assay)
Species: Mouse
Application Route: Subcutaneous
Method: OECD Test Guideline 474
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

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Components:**levamisole hydrochloride:**

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
NOAEL : 80 mg/kg body weight
Remarks : No significant adverse effects were reported

Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : 40 mg/kg body weight
Remarks : No significant adverse effects were reported

oxfendazole:

Species : Rat
Application Route : Oral
Exposure time : 1 Years
Symptoms : No adverse effects
Target Organs : Liver

Species : Rat
Application Route : Oral
Exposure time : 2 Years
Symptoms : No adverse effects
Target Organs : Liver

Silicon, amorphous:

Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative
Remarks : Based on data from similar materials

Sodium metabisulphite:

Species : Mouse
Application Route : Ingestion
Exposure time : 24 Months
Result : negative
Remarks : Based on data from similar materials

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:**levamisole hydrochloride:**

Effects on fertility : Test Type: Three-generation reproduction toxicity study
Species: Rat

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| | |
|------------------------------------|--|
| Effects on foetal development | : Application Route: Oral Result: No significant adverse effects were reported : Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 20 mg/kg body weight Result: Fetotoxicity Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 40 mg/kg body weight Result: Fetotoxicity |
| Reproductive toxicity - Assessment | : Some evidence of adverse effects on development, based on animal experiments. |

oxfendazole:

| | |
|-------------------------------|---|
| Effects on fertility | : Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Oral Fertility: NOAEL: 17 mg/kg body weight Target Organs: Testes Result: Effects on fertility Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: NOAEL: 0.9 mg/kg body weight Target Organs: Liver Result: No effects on fertility Test Type: Fertility Species: Mouse Application Route: Oral Duration of Single Treatment: 1 Months Fertility: NOAEL: 750 mg/kg body weight Target Organs: Testes Result: Effects on fertility |
| Effects on 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 |

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| | | 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. |

Citric acid:

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

Silicon, amorphous:

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

Sodium metabisulphite:

| | | |
|-------------------------------|---|---|
| Effects on fertility | : | Test Type: Three-generation study Species: Rat Application Route: Ingestion Result: negative |
| Effects on foetal development | : | Test Type: Embryo-foetal development Species: Rabbit Application Route: Ingestion Result: negative |

STOT - single exposure

Not classified based on available information.

Components:**Citric acid:**

| | | |
|------------|---|-----------------------------------|
| Assessment | : | May cause respiratory irritation. |
|------------|---|-----------------------------------|

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STOT - repeated exposure

May cause damage to organs (Liver, Testis) through prolonged or repeated exposure.
 May cause damage to organs (Blood, Testis) through prolonged or repeated exposure if swallowed.

Components:**levamisole hydrochloride:**

| | | |
|---------------|---|--|
| Target Organs | : | Blood, Testis |
| Assessment | : | May cause damage to organs through prolonged or repeated exposure. |

oxfendazole:

| | | |
|-----------------|---|--|
| Exposure routes | : | Oral |
| Target Organs | : | Liver, Testis |
| Assessment | : | May cause damage to organs through prolonged or repeated exposure. |

Repeated dose toxicity**Components:****levamisole hydrochloride:**

| | | |
|-------------------|---|-----------|
| Species | : | Rat |
| NOAEL | : | 2.5 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 18 Months |
| Target Organs | : | Testis |

| | | |
|-------------------|---|-----------|
| Species | : | Dog |
| LOAEL | : | 20 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 18 Months |
| Target Organs | : | Blood |

| | | |
|-------------------|---|----------|
| Species | : | Dog |
| LOAEL | : | 40 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 3 Months |

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 |

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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

Citric acid:

Species : Rat
 NOAEL : 4,000 mg/kg
 LOAEL : 8,000 mg/kg
 Application Route : Ingestion
 Exposure time : 10 Days

Silicon, amorphous:

Species : Rat
 NOAEL : 1.3 mg/l
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 13 Weeks
 Remarks : Based on data from similar materials

Sodium metabisulphite:

Species : Rat
 NOAEL : 110 mg/kg
 LOAEL : 220 mg/kg

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Application Route : Ingestion
 Exposure time : 104 Weeks

Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****levamisole hydrochloride:**

Ingestion : Symptoms: Nausea, Vomiting, Headache, Dizziness, hypotension

Section 12: Ecological information**Ecotoxicity****Components:****levamisole hydrochloride:**

Toxicity to fish : LC50 (*Oryzias latipes* (Japanese medaka)): 37.3 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 64 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

M-Factor (Acute aquatic tox- : 10

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Toxicity (Acute)

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

M-Factor (Chronic aquatic toxicity) : 1

Polyethylene glycol stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
 Exposure time: 96 h
 Method: DIN 38412

Toxicity to microorganisms : EC10 (Bacteria): > 10,000 mg/l
 Exposure time: 16 h

Citric acid:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1,535 mg/l
 Exposure time: 24 h

Silicon, amorphous:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 10,000 mg/l
 Exposure time: 96 h
 Method: OECD Test Guideline 203
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1,000 mg/l
 Exposure time: 24 h
 Method: OECD Test Guideline 202
 Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials

NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials

Sodium metabisulphite:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 178 mg/l
 Exposure time: 96 h

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| | | |
|--|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 89 mg/l Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Desmodesmus subspicatus (green algae)): 43.8 mg/l Exposure time: 72 h EC10 (Desmodesmus subspicatus (green algae)): 33.3 mg/l Exposure time: 72 h |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Danio rerio (zebra fish)): >= 316 mg/l Exposure time: 34 d Method: OECD Test Guideline 210 Remarks: Based on data from similar materials |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): >= 10 mg/l Exposure time: 21 d |
| Toxicity to microorganisms | : | EC10 (Pseudomonas putida): 30.8 mg/l Exposure time: 17 h |

Persistence and degradability**Components:****oxfendazole:**

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

Polyethylene glycol stearate:

Biodegradability : Result: Readily biodegradable.
Biodegradation: > 70 %
Exposure time: 10 d
Method: OECD Test Guideline 302B

Citric acid:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 97 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Bioaccumulative potential**Components:****oxfendazole:**

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

Citric acid:

Partition coefficient: n-octanol/water : log Pow: -1.72

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Mobility in soil**Components:****oxfendazole:**

|| Distribution among environmental compartments : log Koc: 3.2

Other adverse effects

No data available

Section 13: Disposal considerations**Disposal methods**

|| Waste from residues : Do not dispose of waste into sewer.
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.

Section 14: Transport information**International Regulations****UNRTDG**

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(oxfendazole)

Class : 9

Packing group : III

Labels : 9

Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.
(oxfendazole)

Class : 9

Packing group : III

Labels : Miscellaneous

Packing instruction (cargo aircraft) : 964

Packing instruction (passenger aircraft) : 964

Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(oxfendazole)

Class : 9

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Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations**NZS 5433**

UN number : UN 3082
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,
N.O.S.
(oxfendazole)
Class : 9
Packing group : III
Labels : 9
Hazchem Code : 3Z
Marine pollutant : no

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**Safety, health and environmental regulations/legislation specific for the substance or mixture****HSNO Approval Number**

HSR100758 Veterinary Medicines Non dispersive Closed System Application Group Standard

HSW Controls

Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

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

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

Section 16: Other information

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Further information

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NZ OEL : New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

ACGIH / TWA : 8-hour, time-weighted average
NZ OEL / WES-TWA : Workplace Exposure Standard - Time Weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; 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; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be

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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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