

Levamisole / Oxfendazole Selenised Formulation

Version 3.1 Revision Date: 30.09.2023 SDS Number: 10822932-00004 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

Section 1: Identification

Product name : Levamisole / Oxfendazole Selenised Formulation

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

Acute toxicity (Oral) : Category 4

Respiratory sensitisation : Category 1

Skin sensitisation : Category 1

Carcinogenicity : Category 2

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

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GHS label elements

Hazard pictograms



Signal word

: Danger

Hazard statements

: H302 Harmful if swallowed.
H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H351 Suspected of causing cancer.
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.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
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:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
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.

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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

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
Cobalt disodium ethylenediaminetetraacetate	15137-09-4	>= 0.25 -< 1
Sodium selenate	13410-01-0	>= 0.1 -< 0.25
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.
 Never give anything by mouth to an unconscious person.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed.
 May cause an allergic skin reaction.
 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 Suspected of causing cancer.

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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-fighting : Exposure to combustion products may be a hazard to health.

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.

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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.
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.
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.
- 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

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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 selenate	13410-01-0	WES-TWA	0.1 mg/m ³ (selenium)	NZ OEL
		TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal
		TWA	0.2 mg/m ³ (selenium)	ACGIH
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).
 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

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Skin and body protection : potential for direct contact to the face with dusts, mists, or aerosols.
: 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

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

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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.

Section 11: Toxicological information

Exposure routes : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Harmful if swallowed.

Product:

Acute oral toxicity : Acute toxicity estimate: 1,082 mg/kg
Method: Calculation method
Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

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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

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

Cobalt disodium ethylenediaminetetraacetate:

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

Sodium selenate:

Acute oral toxicity : LD50 (Rat): > 5 - 50 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 0.052 - 0.51 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403

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

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Silicon, amorphous:

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

Cobalt disodium ethylenediaminetetraacetate:

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

Sodium selenate:

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 431

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439

Result : Skin irritation

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

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Silicon, amorphous:

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

Cobalt disodium ethylenediaminetetraacetate:

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

Sodium selenate:

Species : Bovine cornea
Method : OECD Test Guideline 437

Result : No eye irritation

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.

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

Cobalt disodium ethylenediaminetetraacetate:

Exposure routes : inhalation (dust/mist/fume)
Species : Humans

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Result : positive
Remarks : Based on data from similar materials

Assessment : Probability or evidence of low to moderate respiratory sensitisation rate in humans

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

Citric acid:

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

Test Type: in vitro micronucleus test
Result: positive

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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

Cobalt disodium ethylenediaminetetraacetate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

Test Type: In vitro mammalian cell gene mutation test
Method: OECD Test Guideline 476
Result: positive
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: positive
Remarks: Based on data from similar materials

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive
Remarks: Based on data from similar materials

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

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Remarks: Based on data from similar materials

Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Germ cell mutagenicity - Assessment : Positive result(s) from in vivo mammalian somatic cell mutagenicity tests.

Remarks: Based on data from similar materials

Sodium selenate:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471

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

Suspected of causing cancer.

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

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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

Cobalt disodium ethylenediaminetetraacetate:

Species : Rat
Application Route : inhalation (dust/mist/fume)
Exposure time : 105 weeks
Result : positive
Remarks : Based on data from similar materials

Species : Mouse
Application Route : inhalation (dust/mist/fume)
Exposure time : 105 weeks
Result : positive
Remarks : Based on data from similar materials

Carcinogenicity - Assessment : Limited evidence of carcinogenicity in animal studies
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

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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
Application Route: Oral
Result: No significant adverse effects were reported

Effects on foetal development : 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

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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.

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

Cobalt disodium ethylenediaminetetraacetate:

Effects on fertility : Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: Ingestion
 Result: positive
 Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development
 Species: Mouse
 Application Route: Ingestion
 Result: positive

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Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development
 Species: Mouse
 Application Route: inhalation (dust/mist/fume)
 Result: positive
 Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development
 Species: Rat
 Application Route: inhalation (dust/mist/fume)
 Result: positive
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Rat
 Application Route: Ingestion
 Method: OECD Test Guideline 414
 Result: negative
 Remarks: Based on data from similar materials

Reproductive toxicity - Assessment : Some evidence of adverse effects on sexual function and fertility, based on animal experiments.
 Remarks: Based on data from similar materials

Sodium selenate:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Ingestion
 Result: negative
 Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development
 Species: Mouse
 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

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STOT - single exposure

Not classified based on available information.

Components:

Citric acid:

Assessment : May cause respiratory irritation.

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.

Cobalt disodium ethylenediaminetetraacetate:

Exposure routes : inhalation (dust/mist/fume)
 Target Organs : Respiratory Tract
 Assessment : Shown to produce significant health effects in animals at concentrations of 0.02 mg/l/6h/d or less.

Remarks : Based on data from similar materials

Exposure routes : Ingestion
 Target Organs : Thyroid, Heart, Blood
 Assessment : Shown to produce significant health effects in animals at concentrations of >10 to 100 mg/kg bw.

Remarks : Based on data from similar materials

Sodium selenate:

Exposure routes : Ingestion
 Assessment : Shown to produce significant health effects in animals at concentrations of 10 mg/kg bw or less.

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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
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

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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

Cobalt disodium ethylenediaminetetraacetate:

Species : Rat
LOAEL : > 10 mg/kg
Application Route : Ingestion
Exposure time : 90 Days
Remarks : Based on data from similar materials

Species : Rat
LOAEL : < 0.01 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks
Method : OECD Test Guideline 413
Remarks : Based on data from similar materials

Species : Mouse
LOAEL : < 0.01 mg/l
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks
Method : OECD Test Guideline 413
Remarks : Based on data from similar materials

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Sodium selenate:

Species : Rat
NOAEL : 0.4 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

Sodium metabisulphite:

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

Cobalt disodium ethylenediaminetetraacetate:

Inhalation : Target Organs: Respiratory system
Remarks: Based on data from similar materials
Ingestion : Target Organs: Blood
Remarks: Based on data from similar materials
Target Organs: Heart
Target Organs: Thyroid

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:

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- 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 (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

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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

Cobalt disodium ethylenediaminetetraacetate:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
 Exposure time: 48 h
 Method: OECD Test Guideline 202
 Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : ErC50 (Raphidocelis subcapitata (freshwater green alga)): > 100 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201
 Remarks: Based on data from similar materials

Toxicity to fish (Chronic toxicity) : EC10 (Danio rerio (zebra fish)): > 1 mg/l
 Exposure time: 34 d
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10 (Hyalella azteca (Amphipod)): > 0.01 - 0.1 mg/l
 Exposure time: 28 d
 Method: OECD Test Guideline 211
 Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1

Sodium selenate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 1 - 10 mg/l
 Exposure time: 96 h
 Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l
 Exposure time: 48 h
 Remarks: Based on data from similar materials

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Toxicity to algae/aquatic plants : ErC50 (Chlamydomonas reinhardtii (green algae)): 245 µg/l
Exposure time: 96 h

NOEC (Chlamydomonas reinhardtii (green algae)): 197 µg/l
Exposure time: 96 h

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC (Lepomis macrochirus (Bluegill sunfish)): > 0.01 - 0.1 mg/l
Exposure time: 258 d
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: > 0.1 - 1 mg/l
Exposure time: 28 d
Remarks: Based on data from similar materials

M-Factor (Chronic aquatic toxicity) : 1

Toxicity to microorganisms : EC10 (activated sludge): 590 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Sodium metabisulphite:

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

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

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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

Cobalt disodium ethylenediaminetetraacetate:

Partition coefficient: n-octanol/water : log Pow: -3.86
Remarks: Calculation

Mobility in soil

Components:

oxfendazole:

Distribution among environmental compartments : log Koc: 3.2

Other adverse effects

No data available

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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, Cobalt disodium ethylenediaminetetraacetate)

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, Cobalt disodium ethylenediaminetetraacetate)

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, Cobalt disodium ethylenediaminetetraacetate)

Class : 9

Packing group : III

Labels : 9

EmS Code : F-A, S-F

Marine pollutant : yes

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

Not applicable for product as supplied.

National Regulations

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NZS 5433

UN number	:	UN 3082
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxfendazole, Cobalt disodium ethylenediaminetetraacetate)
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**

HSR100759 Veterinary Medicines Non dispersive Open 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

Revision Date : 30.09.2023

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/>

Date format : dd.mm.yyyy

Full text of other abbreviations

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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

AIIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally 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; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; 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 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.

NZ / EN