

## Levamisole / Oxfendazole Selenised Formulation

Date of last issue: 03.07.2024 Version Revision Date: SDS Number: 7.0 06.07.2024 10822932-00009 Date of first issue: 28.07.2022

**Section 1: Identification** 

Levamisole / Oxfendazole Selenised Formulation Product name

Other means of identification Scanda Selenised (A007368)

Manufacturer or supplier's details

Company MSD

Address 33 Whakatiki Street - Private Bag 908

Upper Hutt - New Zealand

Telephone 0800 800 543

0800 764 766 (0800 POISON) Emergency telephone number: 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 - : Category 2 (Blood, Testis)

repeated exposure (Oral)

Hazardous to the aquatic

environment - acute hazard

Category 1



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Hazardous to the aquatic environment - chronic hazard

Category 2

**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 protec-

tion/ 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 ad-

vice/ attention.

P342 + P311 If experiencing respiratory symptoms: Call a

POISON CENTER/ doctor.

P391 Collect spillage.

#### Storage:



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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

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
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 ad-

vice 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. Flush eyes with water as a precaution.

In case of eye contact Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Harmful if swallowed.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms

and effects, both acute and

delayed

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing difficul-

ties if inhaled.

Suspected of causing cancer.

May damage fertility. May damage the unborn child.



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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).

Treat symptomatically and supportively. Notes to physician

Section 5: Fire-fighting measures

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire-

fighting

Hazardous combustion prod-

ucts

Exposure to combustion products may be a hazard to health.

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec: : tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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

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 absor-

bent.



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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 deter-

mine 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 as-

sessment

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

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	Control parame- ters / Permissible	Basis
		exposure)	concentration	



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levamisole hydrochloride	16595-80-5	TWA	20 μg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	200 μg/100 cm <sup>2</sup>	Internal	
oxfendazole	53716-50-0	TWA	40 μg/m3 (OEB 3)	Internal	
		Wipe limit	400 μg/100 cm <sup>2</sup>	Internal	
Polyethylene glycol stearate	9004-99-3	WES-TWA	10 mg/m3	NZ OEL	
		TWA (Inhal-	10 mg/m3	ACGIH	
		able particu-			
		late matter)			
		TWA (Res-	3 mg/m3	ACGIH	
		pirable par-			
		ticulate mat-			
		ter)			
Sodium selenate	13410-01-0	WES-TWA	0.02 mg/m3	NZ OEL	
			(selenium)		
	Further information: Skin absorption				
		TWA	20 μg/m3 (OEB 3)	Internal	
		Wipe limit	200 μg/100 cm <sup>2</sup>	Internal	
		TWA	0.2 mg/m3	ACGIH	
			(selenium)		
Sodium metabisulphite	7681-57-4	WES-TWA	5 mg/m3	NZ OEL	
	Further information: Skin sensitiser, Respiratory sensitiser				
		TWA	5 mg/m3	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 con-

tainment devices). Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type

Hand protection

: Particulates type

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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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, dis-

posable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

### Section 9: Physical and chemical properties

Appearance : suspension

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 characteristics

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 reac- :

tions

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

Cobalt disodium ethylenediaminetetraacetate:

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



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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

#### 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



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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

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



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#### 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 Result : positive

Remarks : Based on data from similar materials

Assessment : Probability or evidence of low to moderate respiratory sensiti-

sation 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



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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

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

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



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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

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 muta-

genicity 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.



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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

#### 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 - Assess- : Limited evidence of carcinogenicity in animal studies

ment Remarks: Based on data from similar materials

Sodium metabisulphite:

Species : Mouse
Application Route : Ingestion
Exposure time : 24 Months
Result : negative



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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

Application Route: Oral

Result: No significant adverse effects were reported

Effects on foetal develop-

ment

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 - As-

sessment

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



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Effects on foetal develop-

ment

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 - As-

sessment

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 develop-

ment

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

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

Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development

Species: Mouse

Application Route: inhalation (dust/mist/fume)



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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 develop-

ment

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 - As-

sessment

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 develop-

ment

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 develop-

ment

Test Type: Embryo-foetal development

Species: Rabbit

**Application Route: Ingestion** 

Result: negative

STOT - single exposure

Not classified based on available information.



## Levamisole / Oxfendazole Selenised Formulation

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**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 con-

centrations 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 con-

centrations 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 con-

centrations of 10 mg/kg bw or less.

Repeated dose toxicity

**Components:** 

levamisole hydrochloride:

Species : Rat NOAEL : 2.5 mg/kg



# Levamisole / Oxfendazole Selenised Formulation

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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 Exposure time : 1 Months

Remarks : No significant adverse effects were reported

Species : Dog NOAEL : 11 mg/kg Application Route : Oral Exposure time : 2 Weeks



## Levamisole / Oxfendazole Selenised Formulation

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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

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

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



## Levamisole / Oxfendazole Selenised Formulation

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**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

levamisole hydrochloride:

Ingestion : Symptoms: Nausea, Vomiting, Headache, Dizziness, hypo-

tension

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:

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



## Levamisole / Oxfendazole Selenised Formulation

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NOEC (Pseudokirchneriella subcapitata (green algae)): > 4

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

10

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

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 tox-

icity)

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 (Chron-

ic 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



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M-Factor (Chronic aquatic

toxicity)

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

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 tox-

icity)

. '

Toxicity to fish (Chronic tox-

icity)

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 (Chron-

ic 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

Toxicity to algae/aquatic

plants

Exposure time: 48 h

Exposure time. To th

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 tox- : NOEC (Danio rerio (zebra fish)): >= 316 mg/l



## Levamisole / Oxfendazole Selenised Formulation

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icity) Exposure time: 34 d

Method: OECD Test Guideline 210

Remarks: Based on data from similar materials

NOEC (Daphnia magna (Water flea)): >= 10 mg/l

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

Toxicity to microorganisms EC10 (Pseudomonas putida): 30.8 mg/l

Exposure time: 17 h

Exposure time: 21 d

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-

log Pow: 1.95

octanol/water Citric acid:

Partition coefficient: n-

octanol/water

log Pow: -1.72

Cobalt disodium ethylenediaminetetraacetate:

Partition coefficient: nlog Pow: -3.86

octanol/water Remarks: Calculation



## Levamisole / Oxfendazole Selenised Formulation

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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 han-

dling 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)

Packing instruction (passen-

964

964

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)



## Levamisole / Oxfendazole Selenised Formulation

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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**

**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**

HSR100758 Veterinary Medicines Non dispersive Closed System Application Group Standard

Tolerable Exposure Limits (TEL)

Not applicable

Environmental Exposure Limits (EEL)

Not applicable

#### **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



# Levamisole / Oxfendazole Selenised Formulation

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IECSC : not determined

#### Section 16: Other information

Revision Date : 06.07.2024

**Further information** 

Sheet

Sources of key data used to compile the Safety Data

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

cy, 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 Atmospher-

ic 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; 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 Sub-



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stances 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