

**Levamisole / Oxfendazole Selenised Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
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**SECTION 1. IDENTIFICATION**

Product name : Levamisole / Oxfendazole Selenised Formulation

Other means of identification : Scanda Selenised (A007368)

**Manufacturer or supplier's details**

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma  
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

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. HAZARDS IDENTIFICATION****GHS Classification**

Acute toxicity (Oral) : Category 4

Reproductive toxicity : Category 1B

Short-term (acute) aquatic hazard : Category 1

Long-term (chronic) aquatic hazard : Category 2

**GHS label elements**

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.  
H360FD May damage fertility. May damage the unborn child.  
H400 Very toxic to aquatic life.  
H411 Toxic to aquatic life with long lasting effects.

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**Precautionary Statements****Prevention:**

P201 Obtain special instructions before use.  
P202 Do not handle until all safety precautions have been read and understood.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.  
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**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Levamisole hydrochloride	16595-80-5	$\geq 5$ -< 10
oxfendazole	53716-50-0	$\geq 2,5$ -< 5
Polyethylene glycol stearate	9004-99-3	$\geq 1$ -< 5
Citric acid	77-92-9	$\geq 1$ -< 5
Cobalt disodium ethylenediaminetetraacetate	15137-09-4	$\geq 0,25$ -< 1
Sodium selenate	13410-01-0	$\geq 0,1$ -< 0,25

**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.

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In case of eye contact	: Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.
If swallowed	: Get medical attention if irritation develops and persists. 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 damage fertility. May damage the unborn child.
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 (CO <sub>2</sub> ) 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 fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers).

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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 diking or other appropriate containment to keep material from spreading. If diked 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 vapors.  
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.

Conditions for safe storage : Keep in properly labeled containers.  
Store locked up.  
Keep tightly closed.  
Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:  
Strong oxidizing agents  
Self-reactive substances and mixtures  
Organic peroxides  
Explosives  
Gases

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

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Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Levamisole hydrochloride	16595-80-5	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal
oxfendazole	53716-50-0	TWA	40 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	400 µg/100 cm <sup>2</sup>	Internal
Polyethylene glycol stearate	9004-99-3	CMP	10 mg/m <sup>3</sup>	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		TWA (Inhalable particulate matter)	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable particulate matter)	3 mg/m <sup>3</sup>	ACGIH
Sodium selenate	13410-01-0	TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal
		CMP	0,2 mg/m <sup>3</sup> (selenium)	AR OEL
		TWA	0,2 mg/m <sup>3</sup> (selenium)	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 potential for direct contact to the face with dusts, mists, or

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

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance	: suspension
Color	: No data available
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
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
Vapor pressure	: No data available
Relative vapor density	: No data available
Relative density	: No data available

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Density	:	No data available
Solubility(ies)	:	
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, kinematic	:	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

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**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**

Information on likely routes of exposure	:	Inhalation Skin contact Ingestion Eye contact
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**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: > 10 mg/l Exposure time: 4 h

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Test atmosphere: dust/mist  
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
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**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

**Skin corrosion/irritation**

Not classified based on available information.



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**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

**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

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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
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**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Components:****Levamisole hydrochloride:**

Remarks	: No data available
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**Polyethylene glycol stearate:**

Test Type	: Open epicutaneous test
Routes of exposure	: Skin contact
Species	: Guinea pig
Result	: negative

**Cobalt disodium ethylenediaminetetraacetate:**

Routes of exposure	: inhalation (dust/mist/fume)
Species	: Humans
Result	: positive
Remarks	: Based on data from similar materials

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

**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

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	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
	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

## Carcinogenicity

Not classified based on available information.

## 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

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|| 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 - Assessment : Limited evidence of carcinogenicity in animal studies  
|| 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 fetal development : Test Type: Embryo-fetal development  
|| Species: Rat  
|| Application Route: Oral  
|| Developmental Toxicity: NOAEL: 20 mg/kg body weight  
|| Result: Fetotoxicity.

|| Test Type: Embryo-fetal development  
|| Species: Rabbit  
|| Application Route: Oral  
|| Developmental Toxicity: LOAEL: 40 mg/kg body weight

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	Result: Fetotoxicity.
Reproductive toxicity - Assessment	: Some evidence of adverse effects on development, based on animal experiments.
<b>oxfendazole:</b>	
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 fetal development	: Test Type: Embryo-fetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: positive, Fetal effects.  Test Type: Embryo-fetal development Species: Rat Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: positive, Embryo-fetal toxicity.  Test Type: Embryo-fetal development Species: Mouse Application Route: Oral Developmental Toxicity: NOAEL: 108 mg/kg body weight Result: positive, Embryo-fetal toxicity., Fetal abnormalities.  Test Type: Embryo-fetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 0,625 mg/kg body weight
Reproductive toxicity - Assessment	: Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal

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experiments.

**Citric acid:**

Effects on fetal development : 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)  
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 fetal development : Test Type: Embryo-fetal 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

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

**STOT-single exposure**

Not classified based on available information.

**Components:****Citric acid:**

Assessment : May cause respiratory irritation.

**STOT-repeated exposure**

Not classified based on available information.

**Components:****Levamisole hydrochloride:**

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

**oxfendazole:**

Routes of exposure : Oral  
Target Organs : Liver, Testis  
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Cobalt disodium ethylenediaminetetraacetate:**

Routes of exposure : 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

Routes of exposure : 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:**

Routes of exposure : 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
Exposure time	: 1 Months
Remarks	: No significant adverse effects were reported

**Levamisole / Oxfendazole Selenised Formula-  
tion**

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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

**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

**Aspiration toxicity**

Not classified based on available information.

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## Experience with human exposure

### Components:

#### **Levamisole hydrochloride:**

Ingestion	:	Symptoms: Nausea, Vomiting, Headache, Dizziness, hypotension
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#### **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  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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icity)  
 Toxicity to daphnia and other : NOEC (Daphnia magna (Water flea)): 0,023 mg/l  
 aquatic invertebrates (Chronic toxicity)  
 Exposure time: 21 d  
 Method: OECD Test Guideline 211

M-Factor (Chronic aquatic : 1  
 toxicity)

## 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 : EC50 (Daphnia magna (Water flea)): 1.535 mg/l  
 aquatic invertebrates  
 Exposure time: 24 h

## Cobalt disodium ethylenediaminetetraacetate:

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

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

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

Toxicity to daphnia and other : EC10 (Hyalomma azteca (Amphipod)): > 0,01 - 0,1 mg/l  
 aquatic invertebrates (Chronic toxicity)  
 Exposure time: 28 d  
 Method: OECD Test Guideline 211  
 Remarks: Based on data from similar materials

M-Factor (Chronic aquatic : 1  
 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 : EC50 (Daphnia magna (Water flea)): > 1 - 10 mg/l

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aquatic invertebrates		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 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

## Persistence and degradability

### Components:

#### oxfendazole:

Stability in water	:	Hydrolysis: < 5 %(4 d)
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#### Polyethylene glycol stearate:

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

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

### Components:

#### oxfendazole:

Partition coefficient: n-octanol/water	:	log Pow: 1,95
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**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 environ-  
mental 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, 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 (passen-  
ger aircraft) : 964

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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.

**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**Argentina. Carcinogenic Substances and Agents : Not applicable  
Registry.Control of precursors and essential chemicals for the : Not applicable  
preparation of drugs.**The ingredients of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

**SECTION 16. OTHER INFORMATION**

Revision Date	: 14.04.2025
Date format	: dd.mm.yyyy

**Further information**

Sources of key data used to compile the Material Safety Data Sheet	: Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <a href="http://echa.europa.eu/">http://echa.europa.eu/</a>
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Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)  
AR OEL : Argentina. Occupational Exposure Limits

ACGIH / TWA : 8-hour, time-weighted average  
AR OEL / CMP : TLV (Threshold Limit Value)

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; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; 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.

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