

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Levamisole / Oxfendazole Selenised Formulation

Manufacturer or supplier's details

Company : MSD

Address : Rua Coronel Bento Soares, 530
Cruzeiro - Sao Paulo - Brazil CEP 12730-340

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 in accordance with ABNT NBR 14725 Standard

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 in accordance with ABNT NBR 14725 Standard

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.

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
 Date of first issue: 28.07.2022

Precautionary Statements : **Prevention:**
 P201 Obtain special instructions before use.
 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:
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P391 Collect spillage.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Levamisole hydrochloride	16595-80-5	Acute toxicity (Oral), Category 3 Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Oral) (Blood, Testis), Category 2 Short-term (acute) aquatic hazard, Category 3 Long-term (chronic) aquatic hazard, Category 3	≥ 5 -< 10
oxfendazole	53716-50-0	Reproductive toxicity, Category 1B Specific target organ toxicity - repeated exposure (Liver, Testis), Category 2 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	$\geq 2,5$ -< 5
Polyethylene glycol stearate	9004-99-3		≥ 1 -< 5
Citric acid	77-92-9	Eye irritation,	≥ 1 -< 5

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
 Date of first issue: 28.07.2022

		Category 2A Specific target organ toxicity - single exposure, Category 3	
Cobalt disodium ethylenediaminetetraacetate	15137-09-4	Respiratory sensitization, Sub-category 1B Germ cell mutagenicity, Category 2 Carcinogenicity, Category 2 Reproductive toxicity, Category 2 Specific target organ toxicity - repeated exposure (Respiratory Tract, Thyroid, Heart, Blood), Category 1 Long-term (chronic) aquatic hazard, Category 1	$\geq 0,25$ - < 1
Sodium selenate	13410-01-0	Acute toxicity (Oral), Category 2 Acute toxicity (Inhalation), Category 2 Skin irritation, Category 2 Specific target organ toxicity - repeated exposure, Category 1 Short-term (acute) aquatic hazard, Category 1 Long-term (chronic) aquatic hazard, Category 1	$\geq 0,1$ - $< 0,25$

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.
Get medical attention.
Wash clothing before reuse.

Levamisole / Oxfendazole Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10822938-00003	Date of first issue: 28.07.2022

In case of eye contact	:	Thoroughly clean shoes before reuse. 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 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 ₂) 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). 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

Levamisole / Oxfendazole Selenised Formula- tion

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10822938-00003	Date of first issue: 28.07.2022

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. |
| 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 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 |

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
 Date of first issue: 28.07.2022

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Levamisole hydrochloride	16595-80-5	TWA	20 µg/m ³ (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 µg/100 cm ²	Internal
oxfendazole	53716-50-0	TWA	40 µg/m ³ (OEB 3)	Internal
		Wipe limit	400 µg/100 cm ²	Internal
Polyethylene glycol stearate	9004-99-3	TWA (Inhalable particulate matter)	10 mg/m ³	ACGIH
		TWA (Respirable particulate matter)	3 mg/m ³	ACGIH
Sodium selenate	13410-01-0	TWA	20 µg/m ³ (OEB 3)	Internal
		Wipe limit	200 µg/100 cm ²	Internal
		TWA	0,2 mg/m ³ (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 aerosols.

Levamisole / Oxfendazole Selenised Formulation

Version 1.2	Revision Date: 30.09.2023	SDS Number: 10822938-00003	Date of last issue: 04.04.2023 Date of first issue: 28.07.2022
----------------	------------------------------	-------------------------------	---

Skin and body protection : Work uniform or laboratory coat.
Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces.
Use appropriate degowning techniques to remove potentially contaminated clothing.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Aqueous solution
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
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

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

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

Information on likely routes of exposure : 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: > 10 mg/l
Exposure time: 4 h
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

**Levamisole / Oxfendazole Selenised Formula-
tion**

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

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

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:

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

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
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

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

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

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

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

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:

**Levamisole / Oxfendazole Selenised Formula-
tion**

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

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
Species: Mouse
Application Route: Intraperitoneal injection
Result: positive
Remarks: Based on data from similar materials

Levamisole / Oxfendazole Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10822938-00003	Date of first issue: 28.07.2022

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
 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

Levamisole / Oxfendazole Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10822938-00003	Date of first issue: 28.07.2022

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
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.

Levamisole / Oxfendazole Selenised Formula- tion

Version 1.2	Revision Date: 30.09.2023	SDS Number: 10822938-00003	Date of last issue: 04.04.2023 Date of first issue: 28.07.2022
----------------	------------------------------	-------------------------------	---

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 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

Levamisole / Oxfendazole Selenised Formulation

Version 1.2	Revision Date: 30.09.2023	SDS Number: 10822938-00003	Date of last issue: 04.04.2023 Date of first issue: 28.07.2022
----------------	------------------------------	-------------------------------	---

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

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.

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

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.

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

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
 Date of first issue: 28.07.2022

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
 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

Levamisole / Oxfendazole Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10822938-00003	Date of first issue: 28.07.2022

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.

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

Levamisole / Oxfendazole Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10822938-00003	Date of first issue: 28.07.2022

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 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

Levamisole / Oxfendazole Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10822938-00003	Date of first issue: 28.07.2022

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 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

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

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

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)

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

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

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 (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.

Domestic regulation

Levamisole / Oxfendazole Selenised Formulation

Version 1.2 Revision Date: 30.09.2023 SDS Number: 10822938-00003 Date of last issue: 04.04.2023
Date of first issue: 28.07.2022

ANTT

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
Hazard Identification Number : 90

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**

National List of Carcinogenic Agents for Humans - (LINACH)

Group 2B: Possibly carcinogenic to humans
Cobalt disodium ethylenediaminetetraacetate 15137-09-4

Brazil. List of chemicals controlled by the Federal Police : Not applicable

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 : 30.09.2023
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, <http://echa.europa.eu/>

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH / TWA : 8-hour, time-weighted average

Levamisole / Oxfendazole Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
1.2	30.09.2023	10822938-00003	Date of first issue: 28.07.2022

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECl - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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.

BR / Z8