SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758

Levamisole / Oxfendazole Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024
6.1	28.09.2024	10823275-00010	Date of first issue: 28.07.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Levamisole / Oxfendazole Selenised Formulation

Other means of identification : Scanda Selenised (A007368)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Substance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Acute toxicity, Category 4	H302: Harmful if swallowed.
Reproductive toxicity, Category 1B	H360FD: May damage fertility. May damage the unborn child.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 2	H411: Toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms :

Signal word : Danger

Hazard statements :

H302	Harmful if swallowed.
H360FD	May damage fertility. May damage the unborn child.
H410	Very toxic to aquatic life with long lasting effects.

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.

Hazardous components which must be listed on the label:
levamisole hydrochloride
oxfendazole
Sodium selenate

EUH208	Contains Cobalt disodium ethylenediaminetetraacetate. May produce an allergic reaction.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No.	Classification	Concentration (% w/w)

	Index-No. Registration number		
levamisole hydrochloride	16595-80-5 240-654-6	Acute Tox. 3; H301 Repr. 2; H361d STOT RE 2; H373 (Blood, Testis) Aquatic Chronic 3; H412	>= 3 - < 10
oxfendazole	53716-50-0 258-714-5	Repr. 1B; H360FD STOT RE 2; H373 (Liver, Testis) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——————— M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 1	>= 2.5 - < 10
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	>= 1 - < 10
Cobalt disodium ethylenediaminetetraacetate	15137-09-4 239-198-0	Resp. Sens. 1B; H334 Muta. 2; H341 Carc. 2; H351 Repr. 2; H361f STOT RE 1; H372 (Respiratory Tract, Thyroid, Heart, Blood) Aquatic Chronic 1; H410 ——————— M-Factor (Chronic aquatic toxicity): 1	>= 0.25 - < 1
Sodium selenate	13410-01-0 236-501-8 034-002-00-8	Acute Tox. 2; H300 Acute Tox. 2; H330 Skin Irrit. 2; H315 STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ——————— M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 0.1 - < 0.25

Substances with a workplace exposure limit :			
Silicon, amorphous	112945-52-5		>= 1 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of 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.

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).

If inhaled : If inhaled, remove to fresh air.
Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact : Flush eyes with water as a precaution.
Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.
Get medical attention.
Rinse mouth thoroughly with water.
Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Harmful if swallowed.
May damage fertility. May damage the unborn child.

May produce an allergic reaction.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides

5.3 Advice for firefighters

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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

6.2 Environmental precautions

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. If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

6.3 Methods and material for containment and cleaning up

Methods for cleaning up	:	Soak up with inert absorbent material.

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

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures	:	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Local/Total ventilation	:	If sufficient ventilation is unavailable, use with local exhaust ventilation.
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment.
Hygiene measures	:	If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers	:	Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.
Advice on common storage	:	Do not store with the following product types:

Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
levamisole hydrochloride	16595-80-5	TWA	20 µg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 µg/100 cm²	Internal
oxfendazole	53716-50-0	TWA	40 µg/m3 (OEB 3)	Internal
		Wipe limit	400 µg/100 cm²	Internal
Silicon, amorphous	112945-52-5	TWA (inhalable dust)	6 mg/m3 (Silica)	GB EH40
		TWA (Respirable dust)	2.4 mg/m3 (Silica)	GB EH40
Cobalt disodium ethylenediaminetetraacetate	15137-09-4	TWA	0.1 mg/m3 (Cobalt)	GB EH40
	Further information: Capable of causing occupational asthma., Capable of causing cancer and/or heritable genetic damage.			
Sodium selenate	13410-01-0	TWA	0.1 mg/m3 (selenium)	GB EH40
		TWA	20 µg/m3 (OEB 3)	Internal
		Wipe limit	200 µg/100 cm²	Internal

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium selenate	Workers	Inhalation	Long-term systemic effects	0.12 mg/m3
	Workers	Skin contact	Long-term systemic effects	16.73 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0.036 mg/m3
	Consumers	Skin contact	Long-term systemic effects	10.28 mg/kg bw/day

	Consumers	Ingestion	Long-term systemic effects	0.01028 mg/kg bw/day
Cobalt disodium ethylenediaminetetraacetate	Workers	Inhalation	Long-term systemic effects	0.349 mg/m3
	Workers	Skin contact	Long-term systemic effects	1 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0.087 mg/m3
	Consumers	Skin contact	Long-term systemic effects	0.5 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	0.025 mg/kg bw/day

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Citric acid	Fresh water	0.44 mg/l
	Marine water	0.044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34.6 mg/kg dry weight (d.w.)
	Marine sediment	3.46 mg/kg dry weight (d.w.)
	Soil	33.1 mg/kg dry weight (d.w.)
Sodium selenate	Fresh water	6.38 µg/l
	Freshwater - intermittent	6.38 µg/l
	Marine water	4.09 µg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	19.7 mg/kg dry weight (d.w.)
	Marine sediment	12.6 mg/kg dry weight (d.w.)
	Soil	0.47 mg/kg dry weight (d.w.)
	Oral (Secondary Poisoning)	2.39 mg/kg food
Cobalt disodium ethylenediaminetetraacetate	Fresh water	0.1 mg/l
	Marine water	0.01 mg/l
	Fresh water sediment	0.758 mg/kg dry weight (d.w.)
	Marine sediment	0.0758 mg/kg dry weight (d.w.)
	Soil	0.5636 mg/kg dry weight (d.w.)

8.2 Exposure controls

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

Eye/face 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.
Hand protection		
Material	:	Chemical-resistant gloves
Remarks	:	Consider double gloving.
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.
Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	:	Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic 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

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

9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Particle size	:	Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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: > 5 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

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

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

Silicon, amorphous:

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

Acute inhalation toxicity : LC50 (Rat): > 2.08 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg
Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:

levamisole hydrochloride:

Remarks : No data available

oxfendazole:

Species : Rabbit
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

Silicon, amorphous:

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

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

Citric acid:

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

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

Silicon, amorphous:

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

levamisole hydrochloride:

Remarks : No data available

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 sensitisation 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:

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

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

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

Silicon, amorphous:

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

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative
Remarks: Based on data from similar materials

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
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

Silicon, amorphous:

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

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:

levamisole hydrochloride:

Effects on fertility	:	Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral Result: No significant adverse effects were reported

Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 20 mg/kg body weight Result: Fetotoxicity Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 40 mg/kg body weight Result: Fetotoxicity
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.

oxfendazole:

Effects on fertility	:	Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Oral Fertility: NOAEL: 17 mg/kg body weight Target Organs: Testes Result: Effects on fertility Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: NOAEL: 0.9 mg/kg body weight Target Organs: Liver Result: No effects on fertility Test Type: Fertility Species: Mouse Application Route: Oral Duration of Single Treatment: 1 Months Fertility: NOAEL: 750 mg/kg body weight Target Organs: Testes Result: Effects on fertility
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: positive, Fetal effects Test Type: Embryo-foetal development Species: Rat Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: positive, Embryo-foetal toxicity Test Type: Embryo-foetal development

Species: Mouse
Application Route: Oral
Developmental Toxicity: NOAEL: 108 mg/kg body weight
Result: positive, Embryo-foetal toxicity, foetal abnormalities

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 0.625 mg/kg body weight

Reproductive toxicity - Assessment : Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Clear evidence of adverse effects on development, based on animal experiments.

Citric acid:

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

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 foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

Remarks: Based on data from similar materials

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

Sodium selenate:

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

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

Silicon, amorphous:

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

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:

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

Cobalt disodium ethylenediaminetetraacetate:

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

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

Sodium selenate:

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

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

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

Silicon, amorphous:

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

levamisole hydrochloride:

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

Cobalt disodium ethylenediaminetetraacetate:

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

SECTION 12: Ecological information

12.1 Toxicity

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: 0.023 mg/l Exposure time: 21 d Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1

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: > 1 mg/l Exposure time: 34 d Species: Danio rerio (zebra fish) Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	EC10: > 0.01 - 0.1 mg/l Exposure time: 28 d Species: Hyalella azteca (Amphipod) 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 microorganisms	:	EC10 (activated sludge): 590 mg/l Exposure time: 3 h Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity)	:	NOEC: > 0.01 - 0.1 mg/l Exposure time: 258 d Species: Lepomis macrochirus (Bluegill sunfish) 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

Silicon, amorphous:

Toxicity to fish	:	LC50 (Danio rerio (zebra fish)): > 10,000 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): > 1,000 mg/l Exposure time: 24 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials
Toxicity to algae/aquatic plants	:	EC50 (Desmodesmus subspicatus (green algae)): > 10,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

oxfendazole:

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

Citric acid:

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

12.3 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

12.4 Mobility in soil

Components:

oxfendazole:

Distribution among environmental compartments	:	log Koc: 3.2

12.5 Results of PBT and vPvB assessment

Product:

Assessment	:	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

Product:

Endocrine disrupting potential	:	This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product	:	Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer.
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

14.1 UN number

ADN : UN 3082

ADR : UN 3082

RID : UN 3082

IMDG : UN 3082

IATA : UN 3082

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S.
(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

IATA : Environmentally hazardous substance, liquid, n.o.s.
(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

14.3 Transport hazard class(es)

	Class	Subsidiary risks
ADN	9	
ADR	9	
RID	9	
IMDG	9	
IATA	9	

14.4 Packing group

ADN

Packing group : III
Classification Code : M6
Hazard Identification Number : 90
Labels : 9

ADR

Packing group	:	III
Classification Code	:	M6
Hazard Identification Number	:	90
Labels	:	9
Tunnel restriction code	:	(-)

RID

Packing group	:	III
Classification Code	:	M6
Hazard Identification Number	:	90
Labels	:	9

IMDG

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

IATA (Cargo)

Packing instruction (cargo aircraft)	:	964
Packing instruction (LQ)	:	Y964
Packing group	:	III
Labels	:	Miscellaneous

IATA (Passenger)

Packing instruction (passenger aircraft)	:	964
Packing instruction (LQ)	:	Y964
Packing group	:	III
Labels	:	Miscellaneous

14.5 Environmental hazards

ADN
Environmentally hazardous : yes

ADR
Environmentally hazardous : yes

RID
Environmentally hazardous : yes

IMDG
Marine pollutant : yes

IATA (Passenger)
Environmentally hazardous : yes

IATA (Cargo)
Environmentally hazardous : yes

14.6 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.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Conditions of restriction for the following entries should be considered: Number on list 3 Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EC) on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH)

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.
Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

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

Full text of H-Statements

H300	:	Fatal if swallowed.
H301	:	Toxic if swallowed.
H315	:	Causes skin irritation.
H319	:	Causes serious eye irritation.
H330	:	Fatal if inhaled.
H334	:	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	:	May cause respiratory irritation.
H341	:	Suspected of causing genetic defects.
H351	:	Suspected of causing cancer.
H360FD	:	May damage fertility. May damage the unborn child.
H361d	:	Suspected of damaging the unborn child.
H361f	:	Suspected of damaging fertility.
H372	:	Causes damage to organs through prolonged or repeated exposure.
H373	:	May cause damage to organs through prolonged or repeated exposure.
H373	:	May cause damage to organs through prolonged or repeated exposure if swallowed.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
H412	:	Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox.	:	Acute toxicity
Aquatic Acute	:	Short-term (acute) aquatic hazard
Aquatic Chronic	:	Long-term (chronic) aquatic hazard
Carc.	:	Carcinogenicity
Eye Irrit.	:	Eye irritation
Muta.	:	Germ cell mutagenicity
Repr.	:	Reproductive toxicity
Resp. Sens.	:	Respiratory sensitisation
Skin Irrit.	:	Skin irritation
STOT RE	:	Specific target organ toxicity - repeated exposure
STOT SE	:	Specific target organ toxicity - single exposure
GB EH40	:	UK. EH40 WEL - Workplace Exposure Limits
GB EH40 / TWA	:	Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:		**Classification procedure:**
Acute Tox. 4	H302	Calculation method
Repr. 1B	H360FD	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 2	H411	Calculation method

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.

GB / EN