

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Levamisole / Oxfendazole Selenised Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
2.1	30.09.2023	10823277-00004	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

#### 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  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

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)

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)


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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	:	<b>Prevention:</b> 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. <b>Response:</b> 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

### Additional Labelling

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.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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### SECTION 3: Composition/information on ingredients

#### 3.2 Mixtures

##### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
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	$\geq 3 - < 10$
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	$\geq 2.5 - < 10$
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	$\geq 1 - < 10$
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	$\geq 0.25 - < 1$
Sodium selenate	13410-01-0 236-501-8 034-002-00-8	Acute Tox. 2; H300 Acute Tox. 2; H330 Skin Irrit. 2; H315	$\geq 0.1 - < 0.25$

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		STOT RE 1; H372 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 <hr/> M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 <hr/> Acute toxicity esti- mate  Acute oral toxicity: 5.01 mg/kg
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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.

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### 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.

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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : 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.

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## 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).

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### 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.  
Local authorities should be advised if significant spillages cannot be contained.

### 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.

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## 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.

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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/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	OELV - 8 hrs (TWA)	10 mg/m <sup>3</sup>	IE OEL
Silicon, amorphous	112945-52-5	OELV - 8 hrs (TWA) (Respirable dust)	2.4 mg/m <sup>3</sup> (Silica)	IE OEL
		OELV - 8 hrs (TWA) (inhalable dust)	6 mg/m <sup>3</sup> (Silica)	IE OEL
Cobalt disodium ethylenediaminetetraacetate	15137-09-4	OELV - 8 hrs (TWA)	0.02 mg/m <sup>3</sup> (Cobalt)	IE OEL
		Further information: Chemical agents which following exposure may cause sensitisation of the respiratory tract and lead to asthma, rhinitis or extrinsic allergic alveolitis		
Sodium selenate	13410-01-0	OELV - 8 hrs	0.1 mg/m <sup>3</sup>	IE OEL

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		(TWA)	(selenium)	
		TWA	20 µg/m <sup>3</sup> (OEB 3)	Internal
		Wipe limit	200 µg/100 cm <sup>2</sup>	Internal

### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium selenate	Workers	Inhalation	Long-term systemic effects	0.12 mg/m <sup>3</sup>
	Workers	Skin contact	Long-term systemic effects	16.73 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	0.036 mg/m <sup>3</sup>
	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
Workers		Skin contact	Long-term systemic effects	1 mg/kg bw/day
Consumers		Inhalation	Long-term systemic effects	0.087 mg/m <sup>3</sup>
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) according to Regulation (EC) No. 1907/2006:

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
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.)



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	Oral (Secondary Poisoning)	2.39 mg/kg food
Cobalt disodium ethylenedia- minetetraacetate	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 I.S. EN 143

Filter type : Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state : Aqueous solution

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Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	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
Flash point	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
pH	:	No data available
Viscosity		
Viscosity, kinematic	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	Not applicable
Vapour pressure	:	No data available
Relative density	:	No data available
Density	:	No data available
Relative vapour density	:	No data available
Particle characteristics		
Particle size	:	Not applicable

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### 9.2 Other information

Explosives	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Evaporation rate	:	No data available
Molecular weight	:	No data available

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## 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.
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### 10.4 Conditions to avoid

Conditions to avoid	:	None known.
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### 10.5 Incompatible materials

Materials to avoid	:	Oxidizing agents
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### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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## SECTION 11: Toxicological information

### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

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
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Acute inhalation toxicity	:	Acute toxicity estimate: > 5 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

#### **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

#### **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

#### **Citric acid:**

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

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### **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

### **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

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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

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Remarks: Based on data from similar materials

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

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

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

Remarks: Based on data from similar materials

### Sodium selenate:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

### 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



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### **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 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

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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 develop-  
ment : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: positive, Fetal effects

Test Type: Embryo-foetal development  
Species: Rat  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: positive, Embryo-foetal toxicity

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

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

Reproductive toxicity - As-  
sessment : Clear evidence of adverse effects on sexual function and ferti-  
lity, based on animal experiments., Clear evidence of adverse  
effects on development, based on animal experiments.

### Citric acid:

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

### Cobalt disodium ethylenediaminetetraacetate:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat

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

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

### **Sodium selenate:**

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

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

### **STOT - single exposure**

Not classified based on available information.

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### 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

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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

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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.

## 11.2 Information on other hazards

### Endocrine disrupting properties

#### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation

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(EU) 2017/2100 or Commission Regulation (EU) 2018/605 at  
levels of 0.1% or higher.

### Experience with human exposure

#### Components:

##### **levamisole hydrochloride:**

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

##### **Cobalt disodium ethylenediaminetetraacetate:**

Inhalation : Target Organs: Respiratory system  
Remarks: Based on data from similar materials

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

## SECTION 12: Ecological information

### 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 : EC50 (*Daphnia magna* (Water flea)): 64 mg/l  
aquatic invertebrates : 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 : EC50 (*Daphnia magna* (Water flea)): 0.059 mg/l  
aquatic invertebrates : Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (*Pseudokirchneriella subcapitata* (green algae)): > 4  
plants : mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

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

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mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- : 10  
icity)

Toxicity to daphnia and other : NOEC: 0.023 mg/l  
aquatic invertebrates (Chron- Exposure time: 21 d  
ic toxicity) Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic : 1  
toxicity)

### 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: > 1 mg/l  
icity) Exposure time: 34 d  
Species: Danio rerio (zebra fish)  
Remarks: Based on data from similar materials

Toxicity to daphnia and other : EC10: > 0.01 - 0.1 mg/l  
aquatic invertebrates (Chron- Exposure time: 28 d  
ic toxicity) Species: Hyalella azteca (Amphipod)  
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



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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

### 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

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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

## 12.4 Mobility in soil

### Components:

#### **oxfendazole:**

Distribution among environ-  
mental 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 Endocrine disrupting properties

### Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

## 12.7 Other adverse effects

No data available

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## 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.

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### SECTION 14: Transport information

#### 14.1 UN number or ID 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
<b>ADN</b>	: 9	
<b>ADR</b>	: 9	
<b>RID</b>	: 9	
<b>IMDG</b>	: 9	
<b>IATA</b>	: 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

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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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

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### SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Number on list 75, 3

If you intend to use this product as tattoo ink, please contact your vendor.

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.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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#### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

AICS : not determined

DSL : not determined

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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  
IE OEL : List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2

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## Levamisole / Oxfendazole Selenised Formulation

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2.1	30.09.2023	10823277-00004	Date of first issue: 28.07.2022

IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour 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; AIIIC - 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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:

Acute Tox. 4	H302
Repr. 1B	H360FD
Aquatic Acute 1	H400
Aquatic Chronic 2	H411

### Classification procedure:

Calculation method
Calculation method
Calculation method
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

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



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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.

IE / EN