according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

Version Revision Date: SDS Number: Date of last issue: 07/03/2024 4.0 07/06/2024 10822840-00009 Date of first issue: 07/28/2022

#### **SECTION 1. IDENTIFICATION**

Product name : Levamisole / Oxfendazole Selenised Formulation

Other means of identification : Scanda Selenised (A007368)

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc

Address : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product Restrictions on use : Not applicable

#### **SECTION 2. HAZARDS IDENTIFICATION**

# GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity (Oral) : Category 4

Carcinogenicity : Category 2

Reproductive toxicity : Category 1B

Specific target organ toxicity

- repeated exposure

Category 2 (Liver, Testis)

Specific target organ toxicity

- repeated exposure (Oral)

Category 2 (Blood, Testis)

#### **GHS** label elements

Hazard pictograms





Signal Word : Danger

Hazard Statements : H302 Harmful if swallowed.

H351 Suspected of causing cancer.

H360FD May damage fertility. May damage the unborn child. H373 May cause damage to organs (Liver, Testis) through pro-

longed or repeated exposure.

H373 May cause damage to organs (Blood, Testis) through

prolonged or repeated exposure if swallowed.

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**Precautionary Statements** 

#### Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapors.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P280 Wear protective gloves, protective clothing, eye protection

and face protection.

#### Response:

P301 + P312 + P330 IF SWALLOWED: Call a doctor if you feel

unwell. Rinse mouth.

P308 + P313 IF exposed or concerned: Get medical attention.

### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

#### Other hazards

None known.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

### Components

Chemical name	CAS-No.	Concentration (% w/w)
Levamisole hydrochloride	16595-80-5	8
oxfendazole	53716-50-0	4.53
Polyethylene glycol	25322-68-3	2.44
Polyethylene glycol stearate	9004-99-3	1.8
Citric acid	77-92-9	1.76
Silicon, amorphous	112945-52-5	1
Cobalt disodium ethylenediaminetet-	15137-09-4	0.36
raacetate		
Sodium selenate	13410-01-0	0.24

#### **SECTION 4. FIRST AID MEASURES**

General advice : In the case of accident or if you feel unwell, seek medical

advice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

according to the OSHA Hazard Communication Standard



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of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

Most important symptoms

In case of eye contact

and effects, both acute and

delayed

Harmful if swallowed. Suspected of causing cancer.

May damage fertility. May damage the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

Protection of first-aiders First Aid responders should pay attention to self-protection,

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

#### **SECTION 5. FIRE-FIGHTING MEASURES**

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment :

for fire-fighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

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

**Environmental precautions** Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g., by containment or

oil barriers).

according to the OSHA Hazard Communication Standard



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Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Soak up with inert absorbent material.

For large spills, provide diking or other appropriate

containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate

container.

Clean up remaining materials from spill with suitable

absorbent.

Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### **SECTION 7. HANDLING AND STORAGE**

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

Advice on safe handling : Do not get on skin or clothing.

Do not breathe mist or vapors.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure

assessment

Keep container tightly closed.

Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

according to the OSHA Hazard Communication Standard



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

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis	
Levamisole hydrochloride	16595-80-5	TWA	20 μg/m3 (OEB 3)	Internal	
	Further information: Skin				
		Wipe limit	200 μg/100 cm <sup>2</sup>	Internal	
oxfendazole	53716-50-0	TWA	40 μg/m3 (OEB 3)	Internal	
		Wipe limit	400 μg/100 cm <sup>2</sup>	Internal	
Polyethylene glycol	25322-68-3	TWA (aero- sol)	10 mg/m³	US WEEL	
Polyethylene glycol stearate	9004-99-3	TWA (Inhal- able particu- late matter)	10 mg/m³	ACGIH	
		TWA (Respirable particulate matter)	3 mg/m³	ACGIH	
Silicon, amorphous	112945-52-5	TWA (Dust)	20 Million particles per cubic foot (Silica)	OSHA Z-3	
		TWA (Dust)	80 mg/m3 / %SiO2 (Silica)	OSHA Z-3	
		TWA	6 mg/m³ (Silica)	NIOSH REL	
Sodium selenate	13410-01-0	TWA	20 μg/m3 (OEB 3)	Internal	
		Wipe limit	200 μg/100 cm <sup>2</sup>	Internal	
		TWA	0.2 mg/m³ (selenium)	OSHA Z-1	
		TWA	0.2 mg/m³ (selenium)	ACGIH	
		TWA	0.2 mg/m <sup>3</sup> (selenium)	NIOSH REL	

**Engineering measures** 

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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.

according to the OSHA Hazard Communication Standard



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### Personal protective equipment

Respiratory protection : General and local exhaust ventilation is recommended to

maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided

by air purifying respirators against exposure to any

hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other

circumstance where air purifying respirators may not provide

adequate protection.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Eye protection : Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

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 suite) to evoid expected skip surfaces.

disposable suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : suspension

Color : No data available

Odor : No data available

Odor Threshold : No data available

pH : No data available

according to the OSHA Hazard Communication Standard



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Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : Not applicable

#### **SECTION 10. STABILITY AND REACTIVITY**

according to the OSHA Hazard Communication Standard



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Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials : Oxidizing agents

Hazardous decomposition : No hazardous decomposition products are known.

products

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

#### **Acute toxicity**

Harmful if swallowed.

**Product:** 

Acute oral toxicity : Acute toxicity estimate: 1,082 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate: 20.88 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

#### Polyethylene glycol:

according to the OSHA Hazard Communication Standard



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Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 423

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Remarks: Based on data from similar materials

Polyethylene glycol stearate:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Citric acid:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg

Method: OECD Test Guideline 402

Assessment: The substance or mixture has no acute dermal

toxicity

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 inhala-

tion toxicity

Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Remarks: Based on data from similar materials

Cobalt disodium ethylenediaminetetraacetate:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

Remarks: Based on data from similar materials

Sodium selenate:

Acute oral toxicity : LD50 (Rat): > 5 - 50 mg/kg

Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 0.052 - 0.51 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

Method: OECD Test Guideline 403

Skin corrosion/irritation

Not classified based on available information.

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**Components:** 

Levamisole hydrochloride:

Remarks : No data available

oxfendazole:

Species : Rabbit

Result : No skin irritation

Polyethylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Polyethylene glycol stearate:

Species : Rabbit
Method : Draize Test
Result : No skin irritation

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Silicon, amorphous:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

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

according to the OSHA Hazard Communication Standard



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### Serious eye damage/eye irritation

Not classified based on available information.

### **Components:**

#### Levamisole hydrochloride:

Remarks : No data available

oxfendazole:

Species : Rabbit

Result : No eye irritation

Polyethylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

Polyethylene glycol stearate:

Species : Rabbit

Result : No eye irritation Method : Draize Test

Citric acid:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Method : OECD Test Guideline 405

Silicon, amorphous:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Remarks : Based on data from similar materials

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

according to the OSHA Hazard Communication Standard



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#### Respiratory or skin sensitization

#### Skin sensitization

Not classified based on available information.

#### Respiratory sensitization

Not classified based on available information.

#### **Components:**

#### Levamisole hydrochloride:

Remarks : No data available

### Polyethylene glycol:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Remarks : Based on data from similar materials

#### Polyethylene glycol stearate:

Test Type : Open epicutaneous test

Routes of exposure : Skin contact Species : Guinea pig Result : negative

### Cobalt disodium ethylenediaminetetraacetate:

Routes of exposure : inhalation (dust/mist/fume)

Species : Humans Result : positive

Remarks : Based on data from similar materials

Assessment : Probability or evidence of low to moderate respiratory

sensitization rate in humans

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

### Levamisole hydrochloride:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

oxfendazole:

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

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Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Mouse Application Route: Oral

Result: positive

Polyethylene glycol:

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

Result: negative

Remarks: Based on data from similar materials

Polyethylene glycol stearate:

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

Result: negative

Citric acid:

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

Result: negative

Test Type: in vitro micronucleus test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Ingestion

Result: negative

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

Cobalt disodium ethylenediaminetetraacetate:

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

Method: OECD Test Guideline 471

according to the OSHA Hazard Communication Standard



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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 muta-

genicity tests.

Remarks: Based on data from similar materials

Sodium selenate:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: Based on data from similar materials

Carcinogenicity

Suspected of causing cancer.

**Components:** 

Levamisole hydrochloride:

Species : Mouse Application Route : Oral

according to the OSHA Hazard Communication Standard



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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

Silicon, amorphous:

Species : Rat
Application Route : Ingestion
Exposure time : 103 weeks
Result : negative

Remarks : Based on data from similar materials

Cobalt disodium ethylenediaminetetraacetate:

Species : Rat

Application Route : inhalation (dust/mist/fume)

Exposure time : 105 weeks Result : positive

Remarks : Based on data from similar materials

Species : Mouse

Application Route : inhalation (dust/mist/fume)

Exposure time : 105 weeks Result : positive

Remarks : Based on data from similar materials

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

ment Remarks: Based on data from similar materials

IARC No ingredient of this product present at levels greater than or equal to 0.1% is

identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**No component of this product present at levels greater than or equal to 0.1% is

according to the OSHA Hazard Communication Standard



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on OSHA's list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is

identified as a known or anticipated carcinogen by NTP.

#### Reproductive toxicity

May damage fertility. May damage the unborn child.

### **Components:**

### Levamisole hydrochloride:

Effects on fertility : Test Type: Three-generation reproduction toxicity study

Species: Rat

Application Route: Oral

Result: No significant adverse effects were reported

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

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 20 mg/kg body weight

Result: Fetotoxicity.

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: LOAEL: 40 mg/kg body weight

Result: Fetotoxicity.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

#### oxfendazole:

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

Species: Rat, male Application Route: Oral

Fertility: NOAEL: 17 mg/kg body weight

Target Organs: Testes Result: Effects on fertility.

Test Type: Two-generation reproduction toxicity study

Species: Rat

Application Route: Oral

Fertility: NOAEL: 0.9 mg/kg body weight

Target Organs: Liver

Result: No effects on fertility.

Test Type: Fertility Species: Mouse Application Route: Oral

Duration of Single Treatment: 1 Months Fertility: NOAEL: 750 mg/kg body weight

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Target Organs: Testes Result: Effects on fertility.

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

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 10 mg/kg body weight

Result: positive, Fetal effects.

Test Type: Embryo-fetal development

Species: Rat

Developmental Toxicity: NOAEL: 10 mg/kg body weight

Result: positive, Embryo-fetal toxicity.

Test Type: Embryo-fetal development

Species: Mouse Application Route: Oral

Developmental Toxicity: NOAEL: 108 mg/kg body weight Result: positive, Embryo-fetal toxicity., Fetal abnormalities.

Test Type: Embryo-fetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 0.625 mg/kg body weight

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on sexual function and fertility, based on animal experiments.. Clear evidence of

adverse effects on development, based on animal

experiments.

Citric acid:

Effects on fetal development : Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Result: negative

Silicon, amorphous:

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

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

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

according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

Version Revision Date: SDS Number: Date of last issue: 07/03/2024 4.0 07/06/2024 10822840-00009 Date of first issue: 07/28/2022

Test Type: Fertility/early embryonic development

Species: Mouse

Application Route: Ingestion

Result: positive

Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development

Species: Mouse

Application Route: inhalation (dust/mist/fume)

Result: positive

Remarks: Based on data from similar materials

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: inhalation (dust/mist/fume)

Result: positive

Remarks: Based on data from similar materials

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

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 414

Result: negative

Remarks: Based on data from similar materials

Reproductive toxicity - 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 fetal development : Test Type: Embryo-fetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

#### STOT-single exposure

Not classified based on available information.

#### **Components:**

#### Citric acid:

Assessment : May cause respiratory irritation.

according to the OSHA Hazard Communication Standard



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#### STOT-repeated exposure

May cause damage to organs (Liver, Testis) through prolonged or repeated exposure. May cause damage to organs (Blood, Testis) through prolonged or repeated exposure if swallowed.

#### **Components:**

### Levamisole hydrochloride:

Target Organs : Blood, Testis

Assessment : May cause damage to organs through prolonged or repeated

exposure.

oxfendazole:

Routes of exposure : Oral

Target Organs : Liver, Testis

Assessment : May cause damage to organs through prolonged or repeated

exposure.

#### Cobalt disodium ethylenediaminetetraacetate:

Routes of exposure : inhalation (dust/mist/fume)

Target Organs : Respiratory Tract

Assessment : Shown to produce significant health effects in animals at con-

centrations of 0.02 mg/l/6h/d or less.

Remarks : Based on data from similar materials

Routes of exposure : Ingestion

Target Organs : Thyroid, Heart, Blood

Assessment : Shown to produce significant health effects in animals at con-

centrations of >10 to 100 mg/kg bw.

Remarks : Based on data from similar materials

Sodium selenate:

Routes of exposure : Ingestion

Assessment : Shown to produce significant health effects in animals at con-

centrations 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

according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

Version Revision Date: SDS Number: Date of last issue: 07/03/2024 4.0 07/06/2024 10822840-00009 Date of first issue: 07/28/2022

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

according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

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Citric acid:

Species : Rat

NOAEL : 4,000 mg/kg
LOAEL : 8,000 mg/kg
Application Route : Ingestion
Exposure time : 10 Days

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

Cobalt disodium ethylenediaminetetraacetate:

Species : Rat

LOAEL : > 10 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Remarks : Based on data from similar materials

Species : Rat

LOAEL : < 0.01 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

Method : OECD Test Guideline 413

Remarks : Based on data from similar materials

Species : Mouse LOAEL : < 0.01 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

Method : OECD Test Guideline 413

Remarks : Based on data from similar materials

Sodium selenate:

Species : Rat
NOAEL : 0.4 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

Components:

Levamisole hydrochloride:

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

according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

Version Revision Date: SDS Number: Date of last issue: 07/03/2024 4.0 07/06/2024 10822840-00009 Date of first issue: 07/28/2022

tension

Cobalt disodium ethylenediaminetetraacetate:

Inhalation : Target Organs: Respiratory system

Remarks: Based on data from similar materials

Ingestion : Target Organs: Blood

Remarks: Based on data from similar materials

Target Organs: Heart Target Organs: Thyroid

#### **SECTION 12. ECOLOGICAL INFORMATION**

#### **Ecotoxicity**

#### **Components:**

Levamisole hydrochloride:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): 37.3 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 64 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

oxfendazole:

Toxicity to fish : LC50 (Lepomis macrochirus (Bluegill sunfish)): > 2.7 mg/l

Exposure time: 96 h

LC50 (Oncorhynchus mykiss (rainbow trout)): > 2.5 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.059 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

: EC50 (Pseudokirchneriella subcapitata (green algae)): > 4

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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

NOEC (Daphnia magna (Water flea)): 0.023 mg/l

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

Exposure time: 21 d

ic toxicity)

Method: OECD Test Guideline 211

#### Polyethylene glycol:

according to the OSHA Hazard Communication Standard



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Toxicity to fish : LC50 (Poecilia reticulata (guppy)): > 100 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: Based on data from similar materials

Polyethylene glycol stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l

Exposure time: 96 h Method: DIN 38412

Toxicity to microorganisms : EC10 (Bacteria): > 10,000 mg/l

Exposure time: 16 h

Citric acid:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 100 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,535 mg/l

Exposure time: 24 h

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

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

according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

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Toxicity to algae/aquatic

plants

ErC50 (Raphidocelis subcapitata (freshwater green alga)): >

100 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

Toxicity to fish (Chronic tox-

icity)

EC10 (Danio rerio (zebra fish)): > 1 mg/l

Exposure time: 34 d

Remarks: Based on data from similar materials

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

EC10 (Hyalella azteca (Amphipod)): > 0.01 - 0.1 mg/l

Exposure time: 28 d

Method: OECD Test Guideline 211

Remarks: Based on data from similar materials

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

Toxicity to fish (Chronic tox-

icity)

NOEC (Lepomis macrochirus (Bluegill sunfish)): > 0.01 - 0.1

mg/i

Exposure time: 258 d

Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates (Chron-

ic toxicity)

NOEC: > 0.1 - 1 mg/l Exposure time: 28 d

Remarks: Based on data from similar materials

Toxicity to microorganisms : EC10 (activated sludge): 590 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Persistence and degradability

Components:

oxfendazole:

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

Polyethylene glycol:

according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

Version Revision Date: SDS Number: Date of last issue: 07/03/2024 4.0 07/06/2024 10822840-00009 Date of first issue: 07/28/2022

Biodegradability : Result: rapidly degradable

Remarks: Based on data from similar materials

Polyethylene glycol stearate:

Biodegradability : Result: Readily biodegradable.

Biodegradation: > 70 % Exposure time: 10 d

Method: OECD Test Guideline 302B

Citric acid:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 97 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Bioaccumulative potential

**Components:** 

oxfendazole:

Partition coefficient: n-

octanol/water

log Pow: 1.95

Polyethylene glycol:

Partition coefficient: n-

octanol/water

log Pow: < 3

Citric acid:

Partition coefficient: n-

octanol/water

log Pow: -1.72

Cobalt disodium ethylenediaminetetraacetate:

Partition coefficient: n- : log Pow: -3.86

octanol/water Remarks: Calculation

Mobility in soil

**Components:** 

oxfendazole:

Distribution among environ-

mental compartments

: log Koc: 3.2

Other adverse effects

No data available

**SECTION 13. DISPOSAL CONSIDERATIONS** 

**Disposal methods** 

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

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Contaminated packaging : Empty containers should be taken to an approved waste

handling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

#### **SECTION 14. TRANSPORT INFORMATION**

#### **International Regulations**

**UNRTDG** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

Class : 9
Packing group : III
Labels : 9
Environmentally hazardous : yes

**IATA-DGR** 

UN/ID No. : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 964

aircraft)

Packing instruction (passen-

964

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3082

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

Class : 9
Packing group : III
Labels : 9
EmS Code : F-A, S-F
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

**Domestic regulation** 

**49 CFR** 

UN/ID/NA number : UN 3082

Proper shipping name : Environmentally hazardous substance, liquid, n.o.s.

(oxfendazole, Cobalt disodium ethylenediaminetetraacetate)

Class : 9 Packing group : III

Labels : CLASS 9

according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

Version Revision Date: SDS Number: Date of last issue: 07/03/2024 10822840-00009 4.0 07/06/2024 Date of first issue: 07/28/2022

**ERG Code** 171

Marine pollutant yes(oxfendazole, Cobalt disodium ethylenediaminetetraace-

tate)

Remarks Above applies only to containers over 119 gallons or 450

liters.

Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

#### Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### **SECTION 15. REGULATORY INFORMATION**

#### **CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

#### SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Sodium selenate	13410-01-0	100	41666

#### SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards Acute toxicity (any route of exposure)

> Carcinogenicity Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

**SARA 313** This material does not contain any chemical components with

> known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

#### **US State Regulations**

# Pennsylvania Right To Know

Water 7732-18-5 Levamisole hydrochloride 16595-80-5 oxfendazole 53716-50-0 Disodium [[N,N'-ethylenediylbis[N-14025-21-9 (carboxylatomethyl)glycinato]](4-)-

N,N',O,O',ON,ON']zincate(2-)

Cobalt disodium ethylenediaminetetraacetate 15137-09-4 Sodium selenate 13410-01-0

#### **California Permissible Exposure Limits for Chemical Contaminants**

Silicon, amorphous 112945-52-5

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

according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

Version Revision Date: SDS Number: Date of last issue: 07/03/2024 4.0 07/06/2024 10822840-00009 Date of first issue: 07/28/2022

AICS : not determined

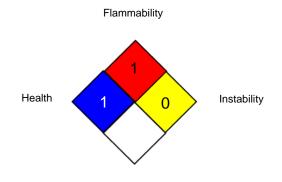
DSL : not determined

IECSC : not determined

#### **SECTION 16. OTHER INFORMATION**

#### **Further information**

#### **NFPA 704:**



Special hazard

#### HMIS® IV:



HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Lim-

its for Air Contaminants

OSHA Z-3 : USA. Occupational Exposure Limits (OSHA) - Table Z-3 Min-

eral Dusts

US WEEL : USA. Workplace Environmental Exposure Levels (WEEL)

ACGIH / TWA : 8-hour, time-weighted average

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour

workday during a 40-hour workweek

OSHA Z-1 / TWA : 8-hour time weighted average OSHA Z-3 / TWA : 8-hour time weighted average

US WEEL / TWA : 8-hr TWA

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Haz-

according to the OSHA Hazard Communication Standard



# Levamisole / Oxfendazole Selenised Formulation

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ardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

Sources of key data used to compile the Material Safety

Data Sheet

Revision Date : 07/06/2024

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

cy, http://echa.europa.eu/

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

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.

US / Z8