

Levamisole / Oxfendazole Formulation

Version 5.0 Revision Date: 2023/12/05 SDS Number: 10808161-00005 Date of last issue: 2023/09/30
Date of first issue: 2022/07/05

1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Levamisole / Oxfendazole Formulation
Other means of identification : Scanda (A007130)

Supplier's company name, address and phone number

Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.
Menuuma factory
Telephone : 048-588-8411
E-mail address : EHSDATASTEWARD@msd.com
Emergency telephone number : +1-908-423-6000


Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product
Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION**GHS classification of chemical product**

Reproductive toxicity : Category 1B
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 2

GHS label elements

Hazard pictograms : 
Signal word : Danger
Hazard statements : H360FD May damage fertility. May damage the unborn child.
H400 Very toxic to aquatic life.
H411 Toxic to aquatic life with long lasting effects.
Precautionary statements : **Prevention:**

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P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification

None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
levamisole hydrochloride	16595-80-5	8	
oxfendazole	53716-50-0	>= 2.5 - < 10	
Polyethylene glycol stearate	9004-99-3	>= 1 - < 10	
Citric acid	77-92-9	>= 1 - < 10	2-1318
Silicon, amorphous	112945-52-5	> 0 - < 10	1-548

4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.
 When symptoms persist or in all cases of doubt seek medical advice.

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

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

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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.
Most important symptoms and effects, both acute and delayed	:	May damage fertility. May damage the unborn child.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	:	Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire-fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion products	:	Carbon oxides
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.

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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.

7. HANDLING AND STORAGE

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.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
Keep container tightly closed.
Take care to prevent spills, waste and minimize release to the environment. |
| Avoidance of contact | : | Oxidizing agents |
| 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. |

Storage

- | | | |
|-----------------------------|---|--|
| Conditions for safe storage | : | Keep in properly labelled 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 |
| Packaging material | : | Unsuitable material: None known. |

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

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

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).
 All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
 Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
 Minimize open handling.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type
 Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.
 Eye protection : Wear safety glasses with side shields or goggles.
 If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

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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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state : Aqueous solution

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Boiling point, initial boiling point and boiling range : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit
Upper explosion limit / Up- per flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : 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

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Density and / or relative density
Relative density : No data available

Density : No data available

Relative vapour density : 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

10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components:**levamisole hydrochloride:**

Acute oral toxicity : LD50 (Rat): 180 mg/kg
LD50 (Mouse): 223 mg/kg

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	LD50 (Rabbit): 458 mg/kg
Acute inhalation toxicity	: Remarks: No data available
Acute dermal toxicity	: Remarks: No data available

oxfendazole:

Acute oral toxicity	: LD50 (Rat): > 6,000 mg/kg
	LD50 (Dog): 1,600 mg/kg
	LD50 (sheep): 250 mg/kg

Polyethylene glycol stearate:

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

Acute oral toxicity	: LD50 (Mouse): 5,400 mg/kg
Acute dermal toxicity	: LD50 (Rat): > 2,000 mg/kg Method: OECD Test Guideline 402 Assessment: The substance or mixture has no acute dermal toxicity

Silicon, amorphous:

Acute oral toxicity	: LD50 (Rat): > 5,000 mg/kg Method: OECD Test Guideline 401 Remarks: Based on data from similar materials
Acute inhalation toxicity	: LC50 (Rat): > 2.08 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity Remarks: Based on data from similar materials
Acute dermal toxicity	: LD50 (Rabbit): > 5,000 mg/kg Remarks: Based on data from similar materials

Skin corrosion/irritation

Not classified based on available information.

Components:**levamisole hydrochloride:**

Remarks	: No data available
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Species : Rabbit
Result : No skin irritation

Polyethylene glycol stearate:

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

Citric acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Silicon, amorphous:

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:**levamisole hydrochloride:**

Remarks : No data available

oxfendazole:

Species : Rabbit
Result : No eye irritation

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

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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

Polyethylene glycol stearate:

||Test Type : Open epicutaneous test
||Exposure routes : Skin contact
||Species : Guinea pig
||Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:**levamisole hydrochloride:**

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

Test Type: Chromosome aberration test in vitro
Result: negative

oxfendazole:

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

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow
cytogenetic test, chromosomal analysis)
Species: Mouse
Application Route: Oral
Result: positive

Polyethylene glycol stearate:

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

Citric acid:

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

Test Type: in vitro micronucleus test

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		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

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

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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

Reproductive toxicity

May damage fertility. May damage the unborn child.

Components:**levamisole hydrochloride:**

Effects on fertility	: Test Type: Three-generation reproduction toxicity study Species: Rat Application Route: Oral Result: No significant adverse effects were reported
Effects on foetal development	: Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 20 mg/kg body weight Result: Fetotoxicity
	: Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: LOAEL: 40 mg/kg body weight Result: Fetotoxicity
Reproductive toxicity - Assessment	: Some evidence of adverse effects on development, based on animal experiments.

oxfendazole:

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat, male Application Route: Oral Fertility: NOAEL: 17 mg/kg body weight Target Organs: Testes Result: Effects on fertility
	: Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral Fertility: NOAEL: 0.9 mg/kg body weight Target Organs: Liver Result: No effects on fertility

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		<p>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</p>
	Effects on foetal development	<p>: Test Type: Embryo-foetal development Species: Rat Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: positive, Fetal effects</p> <p>Test Type: Embryo-foetal development Species: Rat Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: positive, Embryo-foetal toxicity</p> <p>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</p> <p>Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral Developmental Toxicity: NOAEL: 0.625 mg/kg body weight</p>
	Reproductive toxicity - Assessment	<p>: 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.</p>

Citric acid:

	Effects on foetal development	<p>: Test Type: One-generation reproduction toxicity study Species: Rat Application Route: Ingestion Result: negative</p>
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Silicon, amorphous:

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

Repeated dose toxicity**Components:****levamisole hydrochloride:**

|| Species : Rat
|| NOAEL : 2.5 mg/kg
|| Application Route : Oral
|| Exposure time : 18 Months
|| Target Organs : Testis

|| Species : Dog
|| LOAEL : 20 mg/kg
|| Application Route : Oral
|| Exposure time : 18 Months
|| Target Organs : Blood

|| Species : Dog
|| LOAEL : 40 mg/kg
|| Application Route : Oral
|| Exposure time : 3 Months

oxfendazole:

|| Species : Rat
|| NOAEL : 11 mg/kg
|| Application Route : Oral
|| Exposure time : 2 Weeks
|| Target Organs : Blood, Liver, Testis

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Species	: Rat
NOAEL	: 3.8 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: Liver, Testis

Species	: Mouse
NOAEL	: 750 mg/kg
Application Route	: Oral
Exposure time	: 1 Months
Target Organs	: Liver

Species	: Mouse
NOAEL	: 37.5 mg/kg
Application Route	: Oral
Exposure time	: 3 Months
Target Organs	: Liver

Species	: Dog
NOAEL	: 6 mg/kg
Application Route	: Oral
Exposure time	: 1 Months
Remarks	: No significant adverse effects were reported

Species	: Dog
NOAEL	: 11 mg/kg
Application Route	: Oral
Exposure time	: 2 Weeks
Target Organs	: Lymph nodes, thymus gland

Species	: Dog
NOAEL	: 13.5 mg/kg
Application Route	: Oral
Exposure time	: 12 Months
Target Organs	: Liver

Citric acid:

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

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

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Aspiration toxicity

Not classified based on available information.

Experience with human exposure**Components:****levamisole hydrochloride:**

Ingestion	:	Symptoms: Nausea, Vomiting, Headache, Dizziness, hypotension
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12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****levamisole hydrochloride:**

Toxicity to fish	:	LC50 (<i>Oryzias latipes</i> (Japanese medaka)): 37.3 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (<i>Daphnia magna</i> (Water flea)): 64 mg/l Exposure time: 48 h Method: OECD Test Guideline 202

oxfendazole:

Toxicity to fish	:	LC50 (<i>Lepomis macrochirus</i> (Bluegill sunfish)): > 2.7 mg/l Exposure time: 96 h LC50 (<i>Oncorhynchus mykiss</i> (rainbow trout)): > 2.5 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (<i>Daphnia magna</i> (Water flea)): 0.059 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (<i>Pseudokirchneriella subcapitata</i> (green algae)): > 4 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 NOEC (<i>Pseudokirchneriella subcapitata</i> (green algae)): > 4 mg/l Exposure time: 72 h Method: OECD Test Guideline 201
M-Factor (Acute aquatic toxicity)	:	10
Toxicity to daphnia and other aquatic invertebrates (Chronic)	:	NOEC (<i>Daphnia magna</i> (Water flea)): 0.023 mg/l Exposure time: 21 d

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Acute toxicity) Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1

Polyethylene glycol stearate:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 10,000 mg/l
Exposure time: 96 h
Method: DIN 38412

Toxicity to microorganisms : EC10 (Bacteria): > 10,000 mg/l
Exposure time: 16 h

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

Persistence and degradability**Components:****oxfendazole:**

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

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Polyethylene glycol stearate:

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

Citric acid:

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

Bioaccumulative potential**Components:****oxfendazole:**

Partition coefficient: n-octanol/water : log Pow: 1.95

Citric acid:

Partition coefficient: n-octanol/water : log Pow: -1.72

Mobility in soil**Components:****oxfendazole:**

Distribution among environmental compartments : log Koc: 3.2

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS**Disposal methods**

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

14. TRANSPORT INFORMATION**International Regulations**

UNRTDG

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UN number : UN 3082
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxfendazole)
 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)
 Class : 9
 Packing group : III
 Labels : Miscellaneous
 Packing instruction (cargo aircraft) : 964
 Packing instruction (passenger aircraft) : 964
 Environmentally hazardous : yes

IMDG-Code

UN number : UN 3082
 Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (oxfendazole)
 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.

National Regulations

Refer to section 15 for specific national regulation.

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.

ERG Code : 171

15. REGULATORY INFORMATION**Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

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Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law**Harmful Substances Prohibited from Manufacture**

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Not applicable

Substances Subject to be Notified Names

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
levamisole hydrochloride	>0 - <10	From April 1st, 2025
Amorphous silica (silica gel, precipitated silica)	>0 - <10	From April 1st, 2026

Substances Subject to be Indicated Names

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
levamisole hydrochloride	From April 1st, 2025
silica gel	From April 1st, 2026

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances

Not applicable

Ordinance on Prevention of Lead Poisoning

Not applicable

Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

Ordinance on Prevention of Organic Solvent Poisoning

Not applicable

Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

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Poisonous and Deleterious Substances Control Law

Deleterious substance

Chemical name	Cabinet Order Number
(S)-2,3,5,6-Tetrahydro-6-phenylimidazo[2,1-b]thiazole, its salts and preparations containing some of them	71.3

Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

High Pressure Gas Safety Act

Not applicable

Explosive Control Law

Not applicable

Vessel Safety Law

Miscellaneous dangerous substances and articles (Article 2 and 3 of rules on shipping and storage of dangerous goods and its Attached Table 1)

Aviation Law

Miscellaneous dangerous substances and articles (Article 194 of The Enforcement Rules of Aviation Law and its Attached Table 1)

Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z)

Pack transportation : Classified as marine pollutant

Narcotics and Psychotropics Control Act

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

Waste Disposal and Public Cleansing Law

Industrial waste

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

AICS : not determined

DSL : not determined

IECSC : not determined

16. OTHER INFORMATION**Further information**

Sources of key data used to compile the Safety Data : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agen-

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

Date format : yyyy/mm/dd

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

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

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

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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