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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 10808193-00008 Date of first issue: 05.07.2022

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

1.1 Product identifier

Trade name : Levamisole / Oxfendazole Formulation

Other means of identification : Scanda (A007130)

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

Use of the Sub-

stance/Mixture

: Veterinary product

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Reproductive toxicity, Category 1B H360FD: May damage fertility. May damage the

unborn child.

Short-term (acute) aquatic hazard, Cate-

gory 1

H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Cat-H411

H411: Toxic to aquatic life with long lasting effects.

egory 2

2.2 Label elements

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

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

Hazard pictograms :



*

Signal word : Danger

Hazard statements : H360FD May damage fertility. May damage the unborn

child.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use. 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.

Hazardous components which must be listed on the label: oxfendazole

2.3 Other hazards

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

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. 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	>= 3 - < 10
oxfendazole	53716-50-0 258-714-5	Repr. 1B; H360FD STOT RE 2; H373 (Liver, Testis) Aquatic Acute 1;	>= 2.5 - < 10

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



Levamisole / Oxfendazole Formulation

_				-
5.1	28.09.2024	10808193-00008	Date of first issue: 05.07.2022	
Version	Revision Date:	SDS Number:	Date of last issue: 06.07.2024	

		H400 Aquatic Chronic 1; H410	
		M-Factor (Acute aquatic toxicity): 10 M-Factor (Chronic aquatic toxicity): 1	
Citric acid	77-92-9 201-069-1 607-750-00-3	Eye Irrit. 2; H319 STOT SE 3; H335	>= 1 - < 10
Substances with a workplace	e exposure limit :		
Silicon, amorphous	112945-52-5		>= 1 - < 10

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

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

vice 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, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May damage fertility. May damage the unborn child.

4.3 Indication of any immediate medical attention and special treatment needed

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

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 meth-

ohe

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

SO.

Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so.

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

barriers).

Retain and dispose of contaminated wash water.

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

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

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 absor-

bent.

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures : See Engineering measures under EXPOSURE

CONTROLS/PERSONAL PROTECTION section.

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

ventilation.

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

Do not breathe mist or vapours.

Do not swallow.

Avoid contact with eyes.

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

sessment

Keep container tightly closed.

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 contami-

nated clothing before re-use.

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

use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national

regulations.

Advice on common storage : Do not store with the following product types:

Strong oxidizing agents

Self-reactive substances and mixtures

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

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 hydro- chloride	16595-80-5	TWA	20 μg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	200 μg/100 cm ²	Internal
oxfendazole	53716-50-0	TWA	40 μg/m3 (OEB 3)	Internal
		Wipe limit	400 μg/100 cm ²	Internal
Silicon, amorphous	112945-52-	TWA (inhalable	6 mg/m3	GB EH40
	5	dust)	(Silica)	
		TWA (Respirable dust)	2.4 mg/m3 (Silica)	GB EH40

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Citric acid	Fresh water	0.44 mg/l
	Marine water	0.044 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	34.6 mg/kg dry weight (d.w.)
	Marine sediment	3.46 mg/kg dry weight (d.w.)
	Soil	33.1 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less guick 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

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 10808193-00008 Date of first issue: 05.07.2022

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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to BS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : Aqueous solution
Colour : No data available
Odour : No data available
Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : No data available

Relative vapour density : No data available

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : No data available Partition coefficient: n- : Not applicable

octanol/water

Auto-ignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Explosive properties : Not explosive

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

9.2 Other information

Flammability (liquids) : No data available

Molecular weight : No data available

Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 10808193-00008 Date of first issue: 05.07.2022

SECTION 11: Toxicological information

11.1 Information on toxicological effects

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

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

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

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

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

Skin corrosion/irritation

Not classified based on available information.

Components:

levamisole hydrochloride:

Remarks : No data available

oxfendazole:

Species : Rabbit

Result : No skin irritation

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Silicon, amorphous:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Not classified based on available information.

Components:

levamisole hydrochloride:

Remarks : No data available

oxfendazole:

Species : Rabbit

Result : No eye irritation

Citric acid:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

Silicon, amorphous:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Remarks : Based on data from similar materials

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

levamisole hydrochloride:

Remarks : No data available

Germ cell mutagenicity

Not classified based on available information.

Components:

levamisole hydrochloride:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

oxfendazole:

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

Result: negative

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

cytogenetic test, chromosomal analysis)

Species: Mouse Application Route: Oral

Result: positive

Citric acid:

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

Result: negative

Test Type: in vitro micronucleus test

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 10808193-00008 Date of first issue: 05.07.2022

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
Exposure time : 2 Years

Symptoms : No adverse effects

Target Organs : Liver

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 10808193-00008 Date of first issue: 05.07.2022

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 develop-

ment

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 - 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

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 10808193-00008 Date of first issue: 05.07.2022

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 fertility, 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

Silicon, amorphous:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: Based on data from similar materials

STOT - single exposure

Not classified based on available information.

Components:

Citric acid:

Assessment : May cause respiratory irritation.

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

STOT - repeated exposure

Not classified based on available information.

Components:

levamisole hydrochloride:

Target Organs : Blood, Testis

Assessment : May cause damage to organs through prolonged or repeated

exposure.

oxfendazole:

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

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

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

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

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

levamisole hydrochloride:

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 10808193-00008 Date of first issue: 05.07.2022 5.1

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

tension

SECTION 12: Ecological information

12.1 Toxicity

Components:

levamisole hydrochloride:

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

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

oxfendazole:

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

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

ma/l

Exposure time: 72 h

Method: OECD Test Guideline 201

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

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox- :

icity)

10

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 0.023 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

1

Citric acid:

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

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 10808193-00008 Date of first issue: 05.07.2022

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

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-

log Pow: 1.95

octanol/water

Citric acid:

Partition coefficient: n- : log Pow: -1.72

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 10808193-00008 Date of first issue: 05.07.2022

octanol/water

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 Other adverse effects

Product:

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

according to UK REACH Article 57(f).

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

ADN : UN 3082
ADR : UN 3082
RID : UN 3082
IMDG : UN 3082
IATA : UN 3082

14.2 UN proper shipping name

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxfendazole)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxfendazole)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxfendazole)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID,

N.O.S.

(oxfendazole)

IATA : Environmentally hazardous substance, liquid, n.o.s.

(oxfendazole)

14.3 Transport hazard class(es)

Class Subsidiary risks

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

ADN

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

ADR

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

RID

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

IMDG

Packing group : III Labels : 9

EmS Code : F-A, S-F

IATA (Cargo)

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 10808193-00008 Date of first issue: 05.07.2022

Packing instruction (cargo 964

aircraft)

Packing instruction (LQ) Y964 Packing group Ш

Labels Miscellaneous

IATA (Passenger)

Packing instruction (passen-964

ger aircraft)

Packing instruction (LQ) Y964 Packing group Ш

Labels Miscellaneous

14.5 Environmental hazards

Environmentally hazardous yes

Environmentally hazardous yes

Environmentally hazardous yes

IMDG

Marine pollutant yes

IATA (Passenger)

Environmentally hazardous yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

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

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

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) Conditions of restriction for the following entries should be considered:

Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 5.1 28.09.2024 10808193-00008 Date of first issue: 05.07.2022

restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or

not.

Not applicable

Not applicable

UK REACH Candidate list of substances of very high

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained : Not applicable

Regulation (EU) 2019/1021 as amended for Great Brit-

aın)

Regulation (EC) on substances that deplete the ozone

layer

UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2
E1 ENVIRONMENTAL 100 t 200 t

HAZARDS

Other regulations:

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

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

Full text of H-Statements

H301 : Toxic if swallowed.

H319 : Causes serious eye irritation. H335 : May cause respiratory irritation.

H360FD : May damage fertility. May damage the unborn child.

H361d : Suspected of damaging the unborn child.

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



Levamisole / Oxfendazole Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 28.09.2024 10808193-00008 Date of first issue: 05.07.2022 5.1 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

Eye Irrit. : Eye irritation

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure STOT SE : Specific target organ toxicity - single exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice: IARC - International Agency for Research on Cancer: IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals: OECD - Organization for Economic Co-operation and Development: OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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



Levamisole / Oxfendazole Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.07.2024

 5.1
 28.09.2024
 10808193-00008
 Date of first issue: 05.07.2022

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 Agen-

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

Classification of the mixture: Classification procedure:

Repr. 1B H360FD Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 2 H411 Calculation method

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

GB / EN