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



Pyrantel Pamoate / Ivermectin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 9374188-00014 Date of first issue: 27.08.2021 4.6

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

1.1 Product identifier

Trade name Pyrantel Pamoate / Ivermectin Formulation

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

Use of the Sub-: Veterinary product

stance/Mixture

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)

Specific target organ toxicity - single ex-

H371: May cause damage to organs.

posure, Category 2

Specific target organ toxicity - repeated H373: May cause damage to organs through pro-

exposure, Category 2 longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate-H400: Very toxic to aquatic life.

2.2 Label elements

Long-term (chronic) aquatic hazard, Cat-H410: Very toxic to aquatic life with long lasting

egory 1

2019/720, and UK SI 2020/1567)

effects.

Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI

1/27

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



Pyrantel Pamoate / Ivermectin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.6 28.09.2024 9374188-00014 Date of first issue: 27.08.2021

Hazard pictograms :



¥2

Signal word : Warning

Hazard statements : H371 May cause damage to organs.

H373 May cause damage to organs through prolonged

or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this prod-

uct.

P273 Avoid release to the environment.

Response:

P308 + P311 IF exposed or concerned: Call a POISON

CENTER/ doctor.

P391 Collect spillage.

Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:

Ivermectin

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: $38.3\,\%$

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)
4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1)	22204-24-6 244-837-1		>= 30 - < 50
Ivermectin	70288-86-7 274-536-0	Acute Tox. 2; H300 Acute Tox. 3; H311 STOT SE 1; H370	>= 1 - < 2.5

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



Pyrantel Pamoate / Ivermectin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 06.04.2024
4.6	28.09.2024	9374188-00014	Date of first issue: 27.08.2021

Ethanol# Substances with a workplace exposure	64-17-5 200-578-6 603-002-00-5	(Central nervous system) STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 ————————————————————————————————————	>= 0.1 - < 1
Propylene glycol	57-55-6		>= 10 - < 20
Chroning	200-338-0 56-81-5		>= 10 - < 20
Glycerine	200-289-5		>= 10 - < 20

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 if symptoms occur.

In case of skin contact : Wash with water and soap as a precaution.

^{#:} Voluntarily-disclosed substance

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

Get medical attention if symptoms occur.

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 unless directed to do

so by medical personnel. Get medical attention.

Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

4.2 Most important symptoms and effects, both acute and delayed

Risks : May cause damage to organs.

May cause damage to organs through prolonged or repeated

exposure.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Sulphur 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-

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

SO.

Evacuate area.

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

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. Retain and dispose of contaminated wash water.

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

6.3 Methods and material for containment and cleaning up

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

For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable 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 : Use only with adequate ventilation.

Advice on safe handling : Do not breathe dust, fume, gas, mist, vapours or spray.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Wash skin thoroughly after handling.

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

sessment

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

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

environment.

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

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

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. Store in

accordance with the particular national regulations.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides Explosives

Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
4,4'- methylenebis[3- hydroxy-2- naphthoic] acid, compound with (E)-1,4,5,6- tetrahydro-1- methyl-2-[2-(2- thienyl)vinyl]pyrimi dine (1:1)	22204-24-6	TWA	250 μg/m3 (OEB 2)	Internal
Propylene glycol	57-55-6	TWA (Total va- pour and parti- cles)	150 ppm 474 mg/m3	GB EH40
		TWA (particles)	10 mg/m3	GB EH40
Glycerine	56-81-5	TWA (Mist)	10 mg/m3	GB EH40
Ivermectin	70288-86-7	TWA	30 μg/m3 (OEB 3)	Internal
	Further information: Skin			
		Wipe limit	300 μg/100 cm2	Internal
Ethanol	64-17-5	TWA	1,000 ppm 1,920 mg/m3	GB EH40

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Glycerine	Workers	Inhalation	Long-term local ef- fects	56 mg/m3
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m3
Propylene glycol	Workers	Inhalation	Long-term local ef- fects	10 mg/m3
	Workers	Inhalation	Long-term systemic effects	168 mg/m3
	Consumers	Inhalation	Long-term local ef- fects	10 mg/m3
	Consumers	Inhalation	Long-term systemic effects	50 mg/m3
Ethanol	Workers	Inhalation	Long-term systemic effects	380 mg/m3
	Workers	Skin contact	Long-term systemic effects	267 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	114 mg/m3

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Glycerine	Fresh water	0.885 mg/l
	Marine water	0.0885 mg/l
	Intermittent use/release	8.85 mg/l
	Sewage treatment plant	1000 mg/l
	Fresh water sediment	3.3 mg/kg dry weight (d.w.)
	Marine sediment	0.33 mg/kg dry weight (d.w.)
	Soil	0.141 mg/kg dry weight (d.w.)
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l
	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)
Ethanol	Fresh water	0.96 mg/l
	Freshwater - intermittent	2.75 mg/l
	Marine water	0.79 mg/l
	Sewage treatment plant	580 mg/l

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

Fresh water sediment	3.6 mg/kg dry weight (d.w.)
Marine sediment	2.9 mg/kg dry weight (d.w.)
Soil	0.63 mg/kg dry weight (d.w.)
Oral (Secondary Poisoning)	380 mg/kg food

8.2 Exposure controls

Engineering measures

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).

Minimize open handling.

Personal protective equipment

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

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

aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Equipment should conform to BS EN 14387

Filter type : Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : paste Colour : yellow

Odour : No data available Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

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



Pyrantel Pamoate / Ivermectin Formulation

Date of last issue: 06.04.2024 Version Revision Date: SDS Number: 4.6 28.09.2024 9374188-00014 Date of first issue: 27.08.2021

Initial boiling point and boiling :

range

No data available

Flash point Not applicable

Evaporation rate Not applicable

Flammability (solid, gas) No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower :

flammability limit

No data available

Not applicable Vapour pressure

Relative vapour density Not applicable

Relative density No data available

Density No data available

Solubility(ies)

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

octanol/water

No data available Auto-ignition temperature

Decomposition temperature No data available

Viscosity

Viscosity, kinematic Not applicable

Explosive properties Not explosive

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

9.2 Other information

Flammability (liquids) Not applicable

Molecular weight No data available

Particle size Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of : Skin contact

exposure 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

Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg

Method: Calculation method

Components:

4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Acute oral toxicity : LD50 (Rat): > 24,000 mg/kg

LD50 (Mouse): > 24,000 mg/kg

LD50 (Dog): 2,000 mg/kg

Ivermectin:

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

LD50 (Mouse): 25 mg/kg

LD50 (Monkey): > 24 mg/kg

Target Organs: Central nervous system

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



Pyrantel Pamoate / Ivermectin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.6 28.09.2024 9374188-00014 Date of first issue: 27.08.2021

Symptoms: Vomiting, Dilatation of the pupil Remarks: No mortality observed at this dose.

Acute inhalation toxicity : LC50 (Rat): 5.11 mg/l

Exposure time: 1 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): 406 mg/kg

LD50 (Rat): > 660 mg/kg

Ethanol:

Acute oral toxicity : LD50 (Rat): 10,470 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat, male): 116.9 mg/l

Exposure time: 4 h
Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): > 15,800 mg/kg

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist

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

Assessment: The substance or mixture has no acute dermal

toxicity

Glycerine:

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

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

Skin corrosion/irritation

Not classified based on available information.

Components:

Ivermectin:

Species : Rabbit

Result : No skin irritation

Ethanol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Glycerine:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Ivermectin:

Species : Rabbit

Result : Mild eye irritation

Ethanol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : No eye irritation

Glycerine:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

Ivermectin:

Exposure routes : Dermal Species : Humans

Result : Does not cause skin sensitisation.

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

Ethanol:

Test Type : Mouse ear swelling test (MEST)

Exposure routes : Skin contact
Species : Mouse
Result : negative

Propylene glycol:

Test Type : Maximisation Test
Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Germ cell mutagenicity

Not classified based on available information.

Components:

4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

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

Result: negative

Ivermectin:

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

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)
Test system: human diploid fibroblasts

Result: negative

Test Type: Mouse Lymphoma

Result: negative

Ethanol:

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

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Rat

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



Pyrantel Pamoate / Ivermectin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.6 28.09.2024 9374188-00014 Date of first issue: 27.08.2021

Application Route: Ingestion

Result: negative

Propylene glycol:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo

cytogenetic assay) Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Glycerine:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

Test Type: DNA damage and repair, unscheduled DNA syn-

thesis in mammalian cells (in vitro)

Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Ivermectin:

Species : Rat Application Route : Oral

NOAEL : 1.5 mg/kg body weight

Result : negative

Remarks : Based on data from similar materials

Species : Mouse Application Route : Oral

NOAEL : 2.0 mg/kg body weight

Result : negative

Remarks : Based on data from similar materials

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

Propylene glycol:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

Glycerine:

Species: RatApplication Route: IngestionExposure time: 2 YearsResult: negative

Reproductive toxicity

Not classified based on available information.

Components:

4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Oral

Developmental Toxicity: NOAEL: 3,000 mg/kg body weight Result: No effects on fertility and early embryonic develop-

ment were detected.

Test Type: Embryo-foetal development

Species: Rabbit Application Route: Oral

Developmental Toxicity: NOAEL: 1,000 mg/kg body weight Result: No effects on fertility and early embryonic develop-

ment were detected.

Ivermectin:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral

Fertility: NOAEL: 0.6 mg/kg body weight

Result: Animal testing did not show any effects on fertility.

Effects on foetal develop-

ment

Test Type: Development

Species: Mouse

Application Route: Oral

Developmental Toxicity: NOAEL: 0.2 mg/kg body weight Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally

toxic doses

Test Type: Development

Species: Rat

Application Route: Oral

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

Developmental Toxicity: LOAEL: 0.4 mg/kg body weight Result: Embryotoxic effects and adverse effects on the off-

spring were detected.

Remarks: The mechanism or mode of action may not be rele-

vant in humans.

Test Type: Development

Species: Rabbit

Application Route: Oral

Result: Teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally

toxic doses

Ethanol:

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

Species: Mouse

Application Route: Ingestion

Result: negative

Propylene glycol:

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

Species: Mouse

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

Glycerine:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

STOT - single exposure

May cause damage to organs.

Components:

Ivermectin:

Target Organs : Central nervous system
Assessment : Causes damage to organs.

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Ivermectin:

Target Organs : Central nervous system

Assessment : Causes damage to organs through prolonged or repeated

exposure.

Repeated dose toxicity

Components:

4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Species : Dog
NOAEL : 10 mg/kg
LOAEL : 30 mg/kg
Application Route : Ingestion
Exposure time : 3 d

Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 600 mg/kg
Application Route : Oral
Exposure time : 19 d

Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 600 mg/kg
Application Route : Oral
Exposure time : 30 d

Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 600 mg/kg
Application Route : Oral
Exposure time : 90 d

Remarks : No significant adverse effects were reported

Ivermectin:

Species : Dog
NOAEL : 0.5 mg/kg
LOAEL : 1 mg/kg
Application Route : Oral
Exposure time : 14 Weeks

Target Organs : Central nervous system

Symptoms : Dilatation of the pupil, Tremors, Lack of coordination, anorexia

Species : Monkey NOAEL : 1.2 mg/kg

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



Pyrantel Pamoate / Ivermectin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.6 28.09.2024 9374188-00014 Date of first issue: 27.08.2021

Application Route : Oral Exposure time : 2 Weeks

Remarks : No significant adverse effects were reported

Species : Rat

NOAEL : 0.4 mg/kg

LOAEL : 0.8 mg/kg

Application Route : Oral

Exposure time : 3 Months

Target Organs : spleen, Bone marrow, Kidney

Ethanol:

Species : Rat

NOAEL : 1,730 mg/kg LOAEL : 3,200 mg/kg Application Route : Ingestion Exposure time : 90 Days

Propylene glycol:

Species : Rat, male NOAEL : >= 1,700 mg/kg

Application Route : Ingestion Exposure time : 2 yr

Glycerine:

 Species
 : Rat

 NOAEL
 : 0.167 mg/l

 LOAEL
 : 0.622 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

Species : Rat

NOAEL : 8,000 - 10,000 mg/kg

Application Route : Ingestion Exposure time : 2 yr

Species : Rabbit
NOAEL : 5,040 mg/kg
Application Route : Skin contact
Exposure time : 45 Weeks

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea,

Headache, Dizziness, Fever

Ivermectin:

Skin contact : Remarks: Can be absorbed through skin.

Eye contact : Remarks: May irritate eyes.

Ingestion : Symptoms: Drowsiness, Dilatation of the pupil, Tremors, Vom-

iting, anorexia, Lack of coordination

SECTION 12: Ecological information

12.1 Toxicity

Components:

4,4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Ivermectin:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 0.003 mg/l

Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 0.0048 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.000025 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 9.1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 9.1

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

10,000

M-Factor (Chronic aquatic

toxicity)

10,000

Ethanol:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 14,200 mg/l

Exposure time: 96 h

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



Pyrantel Pamoate / Ivermectin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 28.09.2024 9374188-00014 Date of first issue: 27.08.2021 4.6

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 5,012 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Chlorella vulgaris (Fresh water algae)): 275 mg/l

Exposure time: 72 h

EC10 (Chlorella vulgaris (Fresh water algae)): 11.5 mg/l

Exposure time: 72 h

Toxicity to microorganisms EC50 (Protozoa): 5,800 mg/l

Exposure time: 4 h

Toxicity to fish (Chronic tox-

icity)

NOEC: >= 79 mg/l

Exposure time: 100 d

Species: Oryzias latipes (Japanese medaka)

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 9.6 mg/l Exposure time: 9 d

Species: Daphnia magna (Water flea)

Propylene glycol:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to microorganisms NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 h

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 13,020 mg/l Exposure time: 7 d

Species: Ceriodaphnia dubia (water flea)

Glycerine:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 1,955 mg/l

Exposure time: 48 h

NOEC (Pseudomonas putida): > 10,000 mg/l Toxicity to microorganisms

> Exposure time: 16 h Method: DIN 38 412 Part 8

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

12.2 Persistence and degradability

Components:

Ivermectin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 50 % Exposure time: 240 d

Ethanol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 84 % Exposure time: 20 d

Propylene glycol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Glycerine:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 92 % Exposure time: 30 d

Method: OECD Test Guideline 301D

12.3 Bioaccumulative potential

Components:

Ivermectin:

Bioaccumulation : Bioconcentration factor (BCF): 74

Partition coefficient: n-

octanol/water

log Pow: 3.22

Ethanol:

Partition coefficient: n-

octanol/water

log Pow: -0.35

Propylene glycol:

Partition coefficient: n-

: log Pow: -1.07

octanol/water

Method: Regulation (EC) No. 440/2008, Annex, A.8

Glycerine:

Partition coefficient: n-

octanol/water

log Pow: -1.75

12.4 Mobility in soil

No data available

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

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 3077
ADR : UN 3077
RID : UN 3077
IMDG : UN 3077
IATA : UN 3077

14.2 UN proper shipping name

ADN : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Ivermectin)

ADR : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Ivermectin)

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

(Ivermectin)

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S. (Ivermectin)

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

(Ivermectin)

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 : M7
Hazard Identification Number : 90
Labels : 9

ADR

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9
Tunnel restriction code : (-)

RID

Packing group : III
Classification Code : M7
Hazard Identification Number : 90
Labels : 9

IMDG

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

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

Packing instruction (LQ) : Y956

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



Pyrantel Pamoate / Ivermectin Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 4.6 28.09.2024 9374188-00014 Date of first issue: 27.08.2021

Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

14.6 Special precautions for user

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

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

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17) : Not applicable

UK REACH Candidate list of substances of very high : Not applicable

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained : Not applicable

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

ain)

Regulation (EC) on substances that deplete the ozone : Not applicable

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

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

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:

DSL : not determined

AICS : 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

H225 : Highly flammable liquid and vapour.

H300 : Fatal if swallowed.

H311 : Toxic in contact with skin.
H319 : Causes serious eye irritation.

H370 : Causes damage to organs if swallowed.

H372 : Causes 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.

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 Flam. Liq. : Flammable liquids

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 -

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021

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

Further information

Sources of key data used to compile the Safety Data

Sheet

Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, http://echa.europa.eu/

Classification of the mixture:

Classification procedure:

STOT SE 2 H371 Calculation method
STOT RE 2 H373 Calculation method
Aquatic Acute 1 H400 Calculation method
Aquatic Chronic 1 H410 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

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



Pyrantel Pamoate / Ivermectin Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 06.04.2024

 4.6
 28.09.2024
 9374188-00014
 Date of first issue: 27.08.2021