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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

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

1.1 Product identifier

Trade name : Praziquantel Formulation

Product code : Hadaclean 5%, Hadaclean A

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

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

EUH210 Safety data sheet available on request.

EUH208 Contains Dimethyl octadienol, 3,7-Dimethyl 2,6-octadienal. May produce an

allergic reaction.

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

2.3 Other hazards

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

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

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

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
praziquantel	55268-74-1 259-559-6	Aquatic Chronic 3; H412	>= 2,5 - < 10
Dimethyl octadienol	78-70-6 201-134-4 603-235-00-2	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1B; H317	>= 0,1 - < 1
3,7-Dimethyl 2,6-octadienal	5392-40-5 226-394-6 605-019-00-3	Skin Irrit. 2; H315 Eye Irrit. 2; H319 Skin Sens. 1; H317	>= 0,1 - < 1

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,

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



Praziquantel Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025 2.1 07.07.2025 11512495-00003 Date of first issue: 19.02.2025

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 : 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 : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting.

Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

May produce an allergic reaction.

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)

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

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.

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.

Local authorities should be advised if significant spillages

cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

Avoid dispersal of dust in the air (i.e., clearing dust surfaces

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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 : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

and bonding, or inert atmospheres.

Local/Total ventilation : Use only with adequate ventilation. Advice on safe handling : Do not get on skin or clothing.

Avoid breathing dust, fume, gas, mist, vapours or spray.

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

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges.

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. Contaminated work clothing should not be allowed out of the workplace.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store in accordance with

the particular national regulations.

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

Strong oxidizing agents

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
praziquantel	55268-74-1	TWA	0.5 mg/m3 (OEB 2)	Internal

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

	` '	•	` '	
Substance name	End Use	Exposure routes	Potential health ef-	Value
			fects	
Dimethyl octadienol	Workers	Inhalation	Long-term systemic	24,58 mg/m3
			effects	

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

	Workers	Skin contact	Long-term systemic effects	3,5 mg/kg bw/day
	Workers	Skin contact	Long-term local ef- fects	3 mg/cm2
	Workers	Skin contact	Acute local effects	3 mg/cm2
	Consumers	Inhalation	Long-term systemic effects	4,33 mg/m3
	Consumers	Skin contact	Long-term systemic effects	1,25 mg/kg bw/day
	Consumers	Skin contact	Long-term local ef- fects	1,5 mg/cm2
	Consumers	Skin contact	Acute local effects	1,5 mg/cm2
	Consumers	Ingestion	Long-term systemic effects	2,49 mg/kg bw/day
3,7-Dimethyl 2,6- octadienal	Workers	Inhalation	Long-term systemic effects	9 mg/m3
	Workers	Skin contact	Long-term systemic effects	1,7 mg/kg bw/day
	Workers	Skin contact	Long-term local ef- fects	0,140 mg/cm2
	Consumers	Inhalation	Long-term systemic effects	2,7 mg/m3
	Consumers	Skin contact	Long-term systemic effects	1 mg/kg bw/day
	Consumers	Skin contact	Long-term local ef- fects	0,140 mg/cm2
	Consumers	Ingestion	Long-term systemic effects	0,6 mg/kg bw/day

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
praziquantel	Fresh water	0,03 mg/l
	Marine water	0,03 mg/l
Dimethyl octadienol	Fresh water	0,2 mg/l
	Freshwater - intermittent	2 mg/l
	Marine water	0,02 mg/l
	Sewage treatment plant	10 mg/l
	Fresh water sediment	2,22 mg/kg dry weight (d.w.)
	Marine sediment	0,222 mg/kg dry weight (d.w.)
	Soil	0,327 mg/kg dry weight (d.w.)
	Secondary Poisoning	7,8 mg/kg food
3,7-Dimethyl 2,6-octadienal	Fresh water	0,007 mg/l
	Freshwater - intermittent	0,068 mg/l
	Marine water	0,001 mg/l
	Sewage treatment plant	1,6 mg/l
	Fresh water sediment	0,125 mg/kg dry weight (d.w.)
	Marine sediment	0,013 mg/kg dry weight (d.w.)

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

Soil 0,021 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

Use feasible engineering controls to minimize exposure to compound.

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

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

Skin and body protection

: Work uniform or laboratory coat.

Respiratory protection

If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to NS EN 143

Filter type : Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : Crystalline solid

Colour : No data available

Odour : No data available

Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower : No data available

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



Praziquantel Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025 2.1 07.07.2025 11512495-00003 Date of first issue: 19.02.2025

flammability limit

Flash point : Not applicable

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : Not applicable

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics

Particle size : No data available

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : Not applicable

Molecular weight : No data available

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 : May form explosive dust-air mixture during processing, han-

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of:

exposure

Inhalation Skin contact

Ingestion

Eye contact

Acute toxicity

Not classified based on available information.

Components:

praziquantel:

Acute oral toxicity : LD50 (Rat): 2.480 mg/kg

LD50 (Mouse): 2.454 mg/kg

LD50 (Dog): > 200 mg/kg

LD50 (Rabbit): 1.050 mg/kg

Dimethyl octadienol:

Acute oral toxicity : LD50 (Rat): 2.790 mg/kg

Method: OECD Test Guideline 401

Remarks: The test was conducted equivalent or similar to

guideline

Acute inhalation toxicity : LC50 (Mouse): > 3,2 mg/l

Exposure time: 90 min Test atmosphere: vapour

Remarks: No test guideline followed

Acute dermal toxicity : LD50 (Rabbit): 5.610 mg/kg

Method: OECD Test Guideline 402

Remarks: The test was conducted equivalent or similar to

guideline

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

3,7-Dimethyl 2,6-octadienal:

Acute oral toxicity : LD50 (Rat, female): 4.895 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 0,68 mg/l

Exposure time: 7 h

Test atmosphere: vapour

Acute dermal toxicity : LD50 (Rabbit): 2.250 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

praziquantel:

Species : Rabbit
Method : Draize Test
Remarks : slight irritation

Dimethyl octadienol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : Skin irritation

Remarks : The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

Species : Rabbit Result : Skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Components:

praziquantel:

Species: RabbitMethod: Draize TestResult: Mild eye irritation

Dimethyl octadienol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Remarks : The test was conducted equivalent or similar to guideline

3,7-Dimethyl 2,6-octadienal:

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Components:

praziquantel:

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Dimethyl octadienol:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact Species : Mouse

Method : OECD Test Guideline 429

Result : positive

Remarks : The test was conducted according to guideline

Assessment : Probability or evidence of low to moderate skin sensitisation

rate in humans

3,7-Dimethyl 2,6-octadienal:

Test Type : Human repeat insult patch test (HRIPT)

Exposure routes : Skin contact Result : positive

Assessment : Probability or evidence of skin sensitisation in humans

Germ cell mutagenicity

Not classified based on available information.

Components:

praziquantel:

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

Result: negative

Test Type: Chromosomal aberration Test system: Chinese hamster cells

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat Result: negative

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

Dimethyl octadienol:

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

Method: OECD Test Guideline 471

Result: negative

Remarks: The test was conducted equivalent or similar to

guideline

Test Type: In vitro mammalian cell gene mutation test

Method: OECD Test Guideline 476

Result: negative

Remarks: The test was conducted equivalent or similar to

guideline

Test Type: Chromosome aberration test in vitro

Method: OECD Test Guideline 473

Result: negative

Remarks: The test was conducted equivalent or similar to

guideline

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Method: OECD Test Guideline 474

Result: negative

Remarks: The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

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

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

Test Type: In vitro sister chromatid exchange assay in mam-

malian cells Result: positive

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

cytogenetic assay) Species: Mouse

Application Route: Ingestion

Result: negative

Carcinogenicity

Not classified based on available information.

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



Praziquantel Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025 2.1 07.07.2025 11512495-00003 Date of first issue: 19.02.2025

Components:

praziquantel:

Species : Hamster
Application Route : Oral
Exposure time : 80 weeks

NOAEL : 100 mg/kg body weight

Result : negative

Remarks : No significant adverse effects were reported

Species : Rat
Application Route : Oral
Exposure time : 104 weeks

NOAEL : 250 mg/kg body weight

Result : negative

Remarks : No significant adverse effects were reported

3,7-Dimethyl 2,6-octadienal:

Species : Mouse
Application Route : Ingestion
Exposure time : 104 - 105 weeks

Result : negative

Reproductive toxicity

Not classified based on available information.

Components:

praziquantel:

Effects on fertility : Test Type: Fertility

Species: Rat

Remarks: No significant adverse effects were reported

Test Type: Fertility Species: Mouse

Remarks: No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Remarks: No significant adverse effects were reported

Test Type: Development

Species: Mouse

Remarks: No significant adverse effects were reported

Dimethyl octadienol:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Remarks: No test guideline followed

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

3,7-Dimethyl 2,6-octadienal:

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

Species: Rat

Application Route: Ingestion Method: OECD Test Guideline 443

Result: negative

Effects on foetal develop-

ment

Test Type: One-generation reproduction toxicity study

Species: Rat

Application Route: Ingestion

Method: OECD Test Guideline 443

Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

praziquantel:

Species : Rat

NOAEL : 1.000 mg/kg

Application Route : Oral

Remarks : No significant adverse effects were reported

Species : Dog NOAEL : 60 mg/kg LOAEL : 180 mg/kg

Application Route : Oral

Target Organs : Gastrointestinal tract

Remarks : No significant adverse effects were reported

Dimethyl octadienol:

Species : Rat, male

NOAEL : >= 497,9 mg/kg

Application Route : Ingestion

Exposure time : 96 Days

Method : OECD Test Guideline 408

Remarks : The test was conducted according to guideline

Species : Rat
NOAEL : 250 mg/kg
Application Route : Skin contact
Exposure time : 91 Days

Method : OECD Test Guideline 411

Remarks : The test was conducted equivalent or similar to guideline

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



Praziquantel Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025 2.1 07.07.2025 11512495-00003 Date of first issue: 19.02.2025

3,7-Dimethyl 2,6-octadienal:

Species : Rat, female LOAEL : 335 mg/kg Application Route : Ingestion Exposure time : 14 Weeks

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Not classified based on available information.

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

Experience with human exposure

Components:

praziquantel:

Inhalation : Symptoms: Headache, Tiredness, Dizziness, Gastrointestinal

discomfort, decrease body temperature, Allergic reactions

SECTION 12: Ecological information

12.1 Toxicity

Components:

praziquantel:

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 29,2 mg/l

Exposure time: 96 hrs

Method: OECD Test Guideline 203

LC50 (Danio rerio (zebra fish)): 31,6 mg/l

Exposure time: 96 hrs

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 35 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50 (activated sludge): > 1.000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition of activated sludge

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



Praziquantel Formulation

Version Revision Date: SDS Number: Date of last issue: 14.04.2025 2.1 07.07.2025 11512495-00003 Date of first issue: 19.02.2025

Method: OECD Test Guideline 209

Dimethyl octadienol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 27,8 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Remarks: The test was conducted according to guideline

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 59 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: The test was conducted according to guideline

Toxicity to algae/aquatic

plants

ErC50 (Desmodesmus subspicatus (green algae)): 156,7 mg/l

Exposure time: 96 h

EC10 (Desmodesmus subspicatus (green algae)): 54,3 mg/l

Exposure time: 96 h

Toxicity to microorganisms : EC10 (activated sludge): > 100 mg/l

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 6,78 mg/l

Exposure time: 96 h Method: DIN 38412

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 6,8 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

Exposure time. 40 fr

ErC50 (Desmodesmus subspicatus (green algae)): 103,8 mg/l Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): 3 mg/l

Exposure time: 72 h

Toxicity to microorganisms : EC50 (activated sludge): 160 mg/l

Exposure time: 30 min

Method: OECD Test Guideline 209

12.2 Persistence and degradability

Components:

Dimethyl octadienol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: 64,2 % Exposure time: 28 d

Method: OECD Test Guideline 301D

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

Remarks: The test was conducted according to guideline

3,7-Dimethyl 2,6-octadienal:

Biodegradability : Result: Readily biodegradable.

Biodegradation: > 90 % Exposure time: 28 d

Method: Directive 67/548/EEC Annex V, C.4.D.

12.3 Bioaccumulative potential

Components:

praziquantel:

Partition coefficient: n-

octanol/water

log Pow: 2,012

pH: 7

Dimethyl octadienol:

Partition coefficient: n-

octanol/water

log Pow: 2,84

Method: OECD Test Guideline 107

Remarks: The test was conducted equivalent or similar to

guideline

3,7-Dimethyl 2,6-octadienal:

Partition coefficient: n-

octanol/water

log Pow: 2,76

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

12.7 Other adverse effects

No data available

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

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 or ID number

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADN : Not regulated as a dangerous good
ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Conditions of restriction for the following entries should be considered: Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

ces of Very High : Not applicable

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EU) No 2024/590 on substances that de-

plete the ozone layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (ÉU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

: Not applicable

Not applicable

Not applicable

Not applicable

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

Not applicable

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

AICS : not determined

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



Praziquantel Formulation

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 14.04.2025

 2.1
 07.07.2025
 11512495-00003
 Date of first issue: 19.02.2025

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

H315 : Causes skin irritation.

H317 : May cause an allergic skin reaction. H319 : Causes serious eye irritation.

H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Aquatic Chronic : Long-term (chronic) aquatic hazard

Eye Irrit. : Eye irritation
Skin Irrit. : Skin irritation
Skin Sens. : Skin sensitisation

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

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



Praziquantel Formulation

Version **Revision Date:** SDS Number: Date of last issue: 14.04.2025 07.07.2025 11512495-00003 Date of first issue: 19.02.2025 2.1

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 Agen-

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

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.

NO / EN