

Versio 4.1	n Revision Date: 26.06.2024		OS Number: 92846-00013	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
SECT	ION 1: Identification of	the	substance/mixt	ure and of the company/undertaking
1.1 Pro	oduct identifier			
Tr	ade name	:	Pyrantel Pamoate	e / Moxidectin Formulation
1.2 Re	levant identified uses of t	he s	substance or mixt	ure and uses advised against
-	se of the Sub- ance/Mixture	:	Veterinary produc	t
	ecommended restrictions	:	Not applicable	
1.3 De	tails of the supplier of the	saf	ety data sheet	
	ompany	:	MSD 20 Spartan Road 1619 Spartan, So	outh Africa
Te	elephone	:	+27119239300	
	mail address of person sponsible for the SDS	:	EHSDATASTEW.	ARD@msd.com
1.4 Em	nergency telephone numb	er		

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through pro- longed or repeated exposure.
Short-term (acute) aquatic hazard, Cate- gory 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Cat- egory 1	H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

:

Hazard pictograms



Signal word

Hazard statements

H373 May cause damage to organs through prolonged or repeated exposure.



Version 4.1	Revision Date: 26.06.2024	SDS Nun 4892846		Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
		H410	Very toxic	to aquatic life with long lasting effects.
Precau	itionary statements	· Preve	ntion:	
		P273	Avoid rele	ase to the environment.
		Respo	onse:	
		P314 P391	Get medic Collect sp	al advice/ attention if you feel unwell. illage.

Hazardous components which must be listed on the label:

Moxidectin

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 4,4'-methylenebis[3-hydroxy-2-	CAS-No. EC-No. Index-No. Registration number 22204-24-6	Classification	Concentration (% w/w) >= 30 - < 50
naphthoic] acid, compound with (E)- 1,4,5,6-tetrahydro-1-methyl-2-[2-(2- thienyl)vinyl]pyrimidine (1:1)	244-837-1		>= 30 - < 30
Moxidectin	113507-06-5	Acute Tox. 3; H301 Acute Tox. 4; H332 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000	>= 1 - < 2,5
Ethanol#	64-17-5 200-578-6 603-002-00-5	Flam. Liq. 2; H225 Eye Irrit. 2; H319	>= 0,1 - < 1



Vers 4.1		Revision Date: 26.06.2024		92846-00013	Date of last issue: (Date of first issue:		
l							
		anation of abbreviatio tarily-disclosed substa					
SEC	CTION 4	: First aid measure	es				
4.1 [Descripti	on of first aid meas	ures	5			
	General	advice	:	vice immediately.	-	nwell, seek medical ad- s of doubt seek medical	
	Protectio	on of first-aiders	:	and use the recon		ion to self-protection, rotective equipment (see section 8).	
	If inhaled	t	:	If inhaled, remove Get medical atten			
	In case o	of skin contact	:	of water. Remove contamir Get medical atten Wash clothing bet	nated clothing and sh tion.		
	In case o	of eye contact	:		ater as a precaution tion if irritation devel		
	If swallow	wed	:	If swallowed, DO Get medical atten Rinse mouth thore		Э.	
4.2	Most imp	ortant symptoms ar	nd e	ffects, both acute	and delayed		
	Risks		:	May cause damaged avec a mage damaged by the set of the	ge to organs through	prolonged or repeated	
4.3 I	ndicatio	n of any immediate ı	mec	lical attention and	special treatment	needed	
	Treatme	nt	:	Treat symptomation	cally and supportivel	у.	
SEC	SECTION 5: Firefighting measures						
5.1 E	Extinguis	shing media					
	-	extinguishing media	:	Water spray Alcohol-resistant f Carbon dioxide (C Dry chemical			

Unsuitable extinguishing : None known.



Vers 4.1	ion	Revision Date: 26.06.2024		92846-00013	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
	media				
	-	-			xture pustion products may be a hazard to health.
	Hazardous combustion prod- ucts		:	Carbon oxides Nitrogen oxides (NOx) Sulphur oxides	
		f or firefighters protective equipment ghters	:	In the event of fire Use personal prot	e, wear self-contained breathing apparatus. ective equipment.
	Specific ods	extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do

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	:	Soak up with inert absorbent material. For large spills, provide dyking or other appropriate contain- ment 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 dis- posal 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.



Vers 4.1	sion	Revision Date: 26.06.2024	-	0S Number: 92846-00013	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019				
SEC	CTION	7: Handling and sto	orag	je					
7.1	7.1 Precautions for safe handling								
	Techni	cal measures	:	CONTROLS/PER					
Local/Total ventilation Advice on safe handling Hygiene measures		::	CONTROLS/PERSONAL PROTECTION section. Use only with adequate ventilation. 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. 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						
7.2		ons for safe storage,	incl	• • •					
	•	ements for storage and containers	:	Keep in properly the particular nati	abelled containers. Store in accordance with onal regulations.				
	Advice	on common storage	:	Strong oxidizing a	stances and mixtures				
7.3	Specific	c 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,	22204-24-6	TWA	250 µg/m3 (OEB 2)	Internal



Version 4.1	Revision Da 26.06.2024			Date of last issue: 02.04.2024 Date of first issue: 17.09.2019	
(E)-1 tetra meth thier	pound with 1,4,5,6- hydro-1- hyl-2-[2-(2- hyl)vinyl]pyrimi (1:1)				
Мох	idectin	113507-06- 5	TWA	10 µg/m3 (OEB 3)	Internal
			Wipe limit	100 µg/100 cm ²	Internal
Etha	nol	64-17-5	OEL- RL STEL/C	2.000 ppm	ZA OEL
			nation: Occupation	al Exposure Limits - Restricted	I Limits For

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

Substance name	End Use	Exposure routes	Potential health ef- fects	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 ef- fects	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) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
Moxidectin	Water	0,3 ng/l
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



Version	Revision Date:	SDS Number:	Date of last issue: 02.04.2024
4.1	26.06.2024	4892846-00013	Date of first issue: 17.09.2019

	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
	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

vices).	e compound to uncontrolled areas (e.g., open-face containment de-
Minimize open handling.	
Personal protective equipment	nent
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.
Filter type	: Combined particulates and organic vapour type (A-P)

9.1 Information on basic physical and chemical properties



Vers 4.1	sion	Revision Date: 26.06.2024		S Number: 2846-00013	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
	Appear Colour Odour Odour	ance Threshold	: : :	paste yellow No data available No data available	
	рН		:	No data available)
	Melting	point/freezing point	:	No data available)
	Initial b range	oiling point and boiling	:	No data available)
	Flash p	point	:	Not applicable	
	Evapor	ation rate	:	Not applicable	
	Flamm	ability (solid, gas)	:	Not applicable	
		explosion limit / Upper ability limit	:	No data available	
		explosion limit / Lower ability limit	:	No data available	
	Vapour	pressure	:	Not applicable	
	Relativ	e vapour density	:	Not applicable	
	Relativ	e density	:	No data available	9
	Density	/	:	No data available	9
		er solubility n coefficient: n-	:	No data available Not applicable)
	Auto-ig	nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	9
	Viscosi Visc	ty cosity, kinematic	:	Not applicable	
	Explosi	ive properties	:	Not explosive	
	Oxidizi	ng properties	:	The substance or	mixture is not classified as oxidizing.
9.2	Other ir	nformation			
	Flamm	ability (liquids)	:	No data available	
	Molecu	llar weight	:	No data available	9
	Particle	e size	:	Not applicable	



Version 4.1	Revision Date: 26.06.2024	SDS Number: 4892846-00013	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
SECTION	10: Stability and	reactivity	
10.1 Reac Not cl	tivity lassified as a reactivity	y hazard.	
	nical stability e under normal condit	ions.	
10.3 Poss	ibility of hazardous	reactions	
	rdous reactions		strong oxidizing agents.
	litions to avoid		
Condi	itions to avoid	: None known.	
	npatible materials	A	
Mater	ials to avoid	: Oxidizing ager	lts
	rdous decompositio	•	
No ha	azardous decompositio	on products are known	•
	0	information	
11.1 Infori	mation on toxicologi nation on likely routes	ical effects	
11.1 Inforn Inform expos Acute	mation on toxicologi nation on likely routes	ical effects of : Skin contact Ingestion Eye contact	
11.1 Inforn Inform expos Acute	mation on toxicologi nation on likely routes sure e toxicity lassified based on ava	ical effects of : Skin contact Ingestion Eye contact	
11.1 Inforn Inform expos Acute Not cl <u>Produ</u>	mation on toxicologi nation on likely routes sure e toxicity lassified based on ava	ical effects of : Skin contact Ingestion Eye contact ailable information.	stimate: > 2.000 mg/kg ation method
11.1 Inform Inform expose Acute Not cl <u>Produ</u> Acute	mation on toxicologination on likely routes sure toxicity lassified based on ava	ical effects of : Skin contact Ingestion Eye contact ailable information. : Acute toxicity e Method: Calcul	ation method stimate: > 5 mg/l 4 h re: dust/mist
11.1 Inform Inform expose Acute Not cl <u>Produ</u> Acute	mation on toxicologi nation on likely routes sure e toxicity lassified based on ava uct: oral toxicity	ical effects of : Skin contact Ingestion Eye contact ailable information. : Acute toxicity e Method: Calcul : Acute toxicity e Exposure time: Test atmosphere	ation method stimate: > 5 mg/l 4 h re: dust/mist
11.1 Inform Inform expose Acute Not cl Produ Acute Acute Acute 4,4'-n	mation on toxicologi nation on likely routes sure e toxicity lassified based on ava <u>uct:</u> e oral toxicity e inhalation toxicity	ical effects of : Skin contact Ingestion Eye contact ailable information. : Acute toxicity e Method: Calcul : Acute toxicity e Exposure time: Test atmospher Method: Calcul	ation method stimate: > 5 mg/l 4 h re: dust/mist
11.1 Inform Inform expose Acute Not cl <u>Produ</u> Acute Acute Acute <u>Comp</u> 4,4'-m methy	mation on toxicologi nation on likely routes sure a toxicity lassified based on ava <u>uct:</u> a oral toxicity inhalation toxicity	ical effects of : Skin contact Ingestion Eye contact ailable information. : Acute toxicity e Method: Calcul : Acute toxicity e Exposure time: Test atmospher Method: Calcul	ation method stimate: > 5 mg/l 4 h re: dust/mist ation method , compound with (E)-1,4,5,6-tetrahydro-1-
11.1 Inform Inform expose Acute Not cl <u>Produ</u> Acute Acute Acute <u>Comp</u> 4,4'-m methy	mation on toxicologi nation on likely routes sure e toxicity lassified based on ava <u>uct:</u> e oral toxicity e inhalation toxicity <u>ponents:</u> nethylenebis[3-hydro yl-2-[2-(2-thienyl)vin	 ical effects of : Skin contact Ingestion Eye contact ailable information. : Acute toxicity e Method: Calcul : Acute toxicity e Exposure time: Test atmospher Method: Calcul 	ation method stimate: > 5 mg/l 4 h re: dust/mist ation method , compound with (E)-1,4,5,6-tetrahydro-1-
11.1 Inform Inform expose Acute Not cl <u>Produ</u> Acute Acute Acute <u>Comp</u> 4,4'-m methy	mation on toxicologi nation on likely routes sure e toxicity lassified based on ava <u>uct:</u> e oral toxicity e inhalation toxicity <u>ponents:</u> nethylenebis[3-hydro yl-2-[2-(2-thienyl)vin	 ical effects of : Skin contact Ingestion Eye contact ailable information. : Acute toxicity e Method: Calcul : Acute toxicity e Exposure time: Test atmospher Method: Calcul 	ation method stimate: > 5 mg/l 4 h re: dust/mist ation method , compound with (E)-1,4,5,6-tetrahydro-1- 4.000 mg/kg > 24.000 mg/kg
11.1 Inform Inform expose Acute Not cl Produ Acute Acute Acute 4,4'-m methy Acute	mation on toxicologi nation on likely routes sure e toxicity lassified based on ava <u>uct:</u> e oral toxicity e inhalation toxicity <u>ponents:</u> nethylenebis[3-hydro yl-2-[2-(2-thienyl)vin	 ical effects of : Skin contact Ingestion Eye contact ailable information. : Acute toxicity e Method: Calcul : Acute toxicity e Exposure time: Test atmospher Method: Calcul oxy-2-naphthoic] acid yl]pyrimidine (1:1): : LD50 (Rat): > 2 LD50 (Mouse): 	ation method stimate: > 5 mg/l 4 h re: dust/mist ation method , compound with (E)-1,4,5,6-tetrahydro-1- 4.000 mg/kg > 24.000 mg/kg

SAFETY DATA SHEET



Pyrantel Pamoate / Moxidectin Formulation

sion	Revision Date: 26.06.2024		92846-00013	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
Acute	oral toxicity	:	LD50 (Rat): 106 n	ng/kg
			LD50 (Mouse): 42	2 - 84 mg/kg
Acute i	nhalation toxicity	:	LC50 (Rat): 3,28 r Exposure time: 5 Test atmosphere:	h
			LC50 (Rat): 2,87 - Test atmosphere:	
Acute of	dermal toxicity	:	LD50 (Rabbit): > 2 Remarks: No sign	2.000 mg/kg ificant adverse effects were reported
	oxicity (other routes of stration)	:	LD50 (Rat): 394 n Application Route	
			LD50 (Mouse): 84 Application Route	
			LD50 (Rat): > 640 Application Route	
			LD50 (Mouse): 26 Application Route	
Ethand	ol:			
Acute of	oral toxicity	:	LD50 (Rat): 10.47 Method: OECD Te	
Acute i	nhalation toxicity	:	LC50 (Rat, male): Exposure time: 4 Test atmosphere:	h
Acute	dermal toxicity	:	LD50 (Rabbit): > 7	15.800 mg/kg
	orrosion/irritation	hle	information	
	onents:	010		
Moxid	ectin:			
Specie Result		:	Rabbit Mild skin irritation	
Ethand	ol:			
Specie Methoo		:	Rabbit OECD Test Guide	sline 404

Serious eye damage/eye irritation

Not classified based on available information.



Components: Moxidectin: Species : Rabbit Result : Moderate eye irritation Ethanol: : Species : Rabbit Method : OECD Test Guideline 405 Result : Irritation to eyes, reversing within 21 days Respiratory or skin sensitisation Skin sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Components: Moxidectin: : Test Type : Buchler Test Exposure routes : Dermal Species : Guinea pig Result : Not a skin sensitizer. Ethanol: : Test Type : Skin contact Species : Skin contact Species : Skin contact Species : Mouse ear swelling test (MEST) Exposure routes : Skin contact Species : Mouse ear swelling test (MEST) Exposure routes : Skin contact Species : Mouse ear swelling test (MEST) Exposure routes : Skin contact	ersion 1	Revision Date: 26.06.2024	SDS Numbe 4892846-000		Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
Species : Rabbit Result : Moderate eye irritation Ethanol: : Species : Rabbit Method : OECD Test Guideline 405 Result : Irritation to eyes, reversing within 21 days Respiratory or skin sensitisation Skin sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Components: Moxidectin: : Test Type : Buehler Test Exposure routes : Guinea pig Result : Not a skin sensitizer. Ethanol: : Test Type : Mouse ear swelling test (MEST) Exposure routes : Skin contact Species : Mouse Result : negative Gern cell mutagenicity Not assified based on available information. Components: : A.4methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-imethyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1): Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative : Test Type: In vitro mammalian cell gene mutation test	Com	ponents:			
Result : Moderate eye irritation Ethanol: Species : Rabbit Method : OECD Test Guideline 405 Result : Irritation to eyes, reversing within 21 days Respiratory or skin sensitisation Skin sensitisation Skin sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Soport Sepiratory sensitisation Not classified based on available information. Components: Moxidectin: Test Type Test Type : Buehler Test Exposure routes : Dermal Species : Ounce apig Result : Not a skin sensitizer. Ethanol: : Species Test Type : Mouse Result : negative Germ cell mutagenicity Not classified based on available information. Components: : Mouse 4.4'-methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-1 methyl-2-[2(2-thienyl)vinyl[pyrimidine (1:1): Genotox	Moxi	dectin:			
Ethanol: Species :: Result :: CDECD Test Guideline 405 Result :: Respiratory or skin sensitisation Skin sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Components: Moxidectin: Test Type :: Species :: Species :: Species :: Suit :: Test Type :: Result :: Not classified based on available information. Components: Moxidectin: Test Type :: Result : Not a skin sensitizer. Ethanol: Test Type :: Result : Moxidectin Calous if ide based on available information. Components: A.4-methylenebis[3-hydroxy-2-naphthoic] acid, compound					
Species : Rabbit Method : OECD Test Guideline 405 Result : Irritation to eyes, reversing within 21 days Respiratory or skin sensitisation Skin sensitisation Skin sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Components: Moxidectin: Test Type Species Components: Moxidectin: Test Type Species Counce a skin sensitizer. Ethanol: Exposure routes Species Mouse Result Species Mouse Result Species Mouse Result Not a skin sensitizer. Dermal Specice <td>Resu</td> <td>lt</td> <td>: Moderate</td> <td>e eye irrita</td> <td>ation</td>	Resu	lt	: Moderate	e eye irrita	ation
Method : OECD Test Guideline 405 Result : Irritation to eyes, reversing within 21 days Respiratory or skin sensitisation Skin sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Components: Moxidectin: . Test Type : Besult : Species : Mouse ear swelling test (MEST) Exposure routes : System contes : Most : Result : Result : 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 mutati	Ethar	nol:			
Result : Irritation to eyes, reversing within 21 days Respiratory or skin sensitisation Skin sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Components: Moxidectin: Test Type ::::::::::::::::::::::::::::::::::::					
Skin sensitisation Not classified based on available information. Respiratory sensitisation Not classified based on available information. Components: Moxidectin: Test Type ::: Buehler Test Exposure routes :: Dermal Species ::: Guinea pig Result :: Not a skin sensitizer. Ethanol: :: Test Type :: Mouse ear swelling test (MEST) Exposure routes :: Skin contact Species :: Mouse Result :: negative Germ cell mutagenicity Not classified based on available information. 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 Moxidectin: : Genotoxicity in vitro :: Test Type: Bacterial reverse mutation assay (AMES) Result: negative Moxidectin: : Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative <td></td> <td></td> <td></td> <td></td> <td></td>					
Not classified based on available information. Respiratory sensitisation Not classified based on available information. Components: Moxidectin: Test Type : Buehler Test Exposure routes : Dermal Species : Guinea pig Result : Not a skin sensitizer. Ethanol: Test Type : Mouse ear swelling test (MEST) Exposure routes : Skin contact Species : Mouse 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 Moxidectin: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Result: negative	Resp	iratory or skin sensit	tisation		
Respiratory sensitisation Not classified based on available information. Components: Moxidectin: Test Type : Busidectins: Species : Species : Busidectins: Species : Species : Species : Result : Not a skin sensitizer. Ethanol: Test Type : Species : Species : Synour routes : Skin contact Species : Result : 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 Moxidectin: Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test Result: negative Choti	Skin	sensitisation			
Not classified based on available information. Components: Moxidectin: Test Type : Buehler Test Exposure routes : Dermal Species : Guinea pig Result : Not a skin sensitizer. Ethanol: Test Type : Mouse ear swelling test (MEST) Exposure routes : Skin contact Species : Mouse 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 Moxidectin: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative	Not c	lassified based on ava	ilable informatio	on.	
Components: Moxidectin: Test Type :: Buehler Test Exposure routes :: Dermal Species :: Gern 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 Moxidectin: Genotoxicity in vitro Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In	Resp	iratory sensitisation			
Moxidectin: Test Type : Buehler Test Exposure routes : Dermal Species : Guinea pig Result : Not a skin sensitizer. Ethanol: . Test Type : Mouse ear swelling test (MEST) Exposure routes : Skin contact Species : Mouse Result : negative Germ cell mutagenicity Not classified based on available information. 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 Moxidectin: : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Moxidectin: : Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative	Not c	lassified based on ava	ilable informatio	on.	
Test Type : Buehler Test Exposure routes : Dermal Species : Guinea pig Result : Not a skin sensitizer. Ethanol: : Not a skin sensitizer. Test Type : Mouse ear swelling test (MEST) Exposure routes : Skin contact Species : Mouse 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 Result: negative Moxidectin: : Test Type: Bacterial reverse mutation assay (AMES) Result: negative : Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative	<u>Com</u>	ponents:			
Exposure routes : Dermal Species : Guinea pig Result : Not a skin sensitizer. Ethanol: Test Type : Mouse ear swelling test (MEST) Exposure routes : Skin contact Species : Mouse Result : negative Germ cell mutagenicity Not classified based on available information. <u>Components:</u> 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 Moxidectin: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative	Moxi	dectin:			
Species : Guinea pig Result : Not a skin sensitizer. Ethanol: : Test Type : Mouse ear swelling test (MEST) Exposure routes : Skin contact Species : Mouse 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 Moxidectin: : Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Moxidectin: : Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative				Test	
Result : Not a skin sensitizer. Ethanol:				nia	
Test Type : Mouse ear swelling test (MEST) Exposure routes : Skin contact Species : Mouse Result : negative Germ cell mutagenicity . negative 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 Moxidectin: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative					er.
Exposure routes : Skin contact Species : Mouse 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 Moxidectin: : Genotoxicity in vitro : Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Moxidectin: : : Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative	Ethar	nol:			
Species : Mouse 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 Moxidectin: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Moxidectin: : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Mesult: negative : Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative					g test (MEST)
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 Moxidectin: Genotoxicity in vitro Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Moxidectin: : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Moxidectin: : Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative				itact	
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 Moxidectin: : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative					
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 Moxidectin: : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Moxidectin: : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative	Germ	o cell mutagenicity			
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 Moxidectin: : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Moxidectin: : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative			ilable informatio	on.	
methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negativeMoxidectin:Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negativeSenotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negativeTest Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative	Com	ponents:			
Moxidectin: Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative					ompound with (E)-1,4,5,6-tetrahydro-1-
Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative	Geno	toxicity in vitro			ial reverse mutation assay (AMES)
Result: negative Test Type: In vitro mammalian cell gene mutation test Test system: Chinese hamster ovary cells Result: negative	Moxi	dectin:			
Test system: Chinese hamster ovary cells Result: negative	Geno	toxicity in vitro			ial reverse mutation assay (AMES)
Test Type: in vitro assay			Test syst	tem: Chin	
			Test Typ	e: in vitro	assay

NÓAEL



Pyrantel Pamoate / Moxidectin Formulation

ersion 1	26.06.2024	48	OS Number: 92846-00013	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
			Test system: Es Result: negative	
Geno	toxicity in vivo	:	Test Type: Chro Species: Rat Cell type: Bone Result: negative	
			Test Type: Uns mammalian live Species: Rat Cell type: Liver Result: negative	cells
Ethar	ol.			
	toxicity in vitro	:		terial reverse mutation assay (AMES) Test Guideline 471 e
				itro mammalian cell gene mutation test Test Guideline 476 e
			Test Type: Chro Result: negative	omosome aberration test in vitro e
Geno	toxicity in vivo	:	Test Type: Mar cytogenetic ass Species: Rat Application Rou Result: negative	ute: Ingestion
Carci	nogenicity			
	assified based on av	ailable	information.	
<u>Comp</u>	oonents:			
Moxio	dectin:			
Speci		:	Mouse	
	cation Route	:	Oral 2 Years	
NOAE			2 Years 4,5 mg/kg body	r weight
Resul		:	negative	
Speci	es	:	Rat	
	cation Route	:	Oral	
Expos	sure time	:	2 Years 4,5 mg/kg body	weight
Resul		:	negative	weight
Speci		:	Dog	
	cation Route	:	Oral	
Expos NOAF	sure time		1 Years 0.5 mg/kg body	weight

: 0,5 mg/kg body weight



ersion .1	Revision Date: 26.06.2024	SDS Number: 4892846-0001	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
Resul	t	: negative	
	oductive toxicity assified based on avai	lable information	
<u>Comp</u>	oonents:		
	nethylenebis[3-hydro /I-2-[2-(2-thienyl)viny		acid, compound with (E)-1,4,5,6-tetrahydro-1-
Effect ment	s on foetal develop-	Species: F Application Developm	n Route: Oral ental Toxicity: NOAEL: 3.000 mg/kg body weight effects on fertility and early embryonic develop-
		Species: F Application Developm	n Route: Oral ental Toxicity: NOAEL: 1.000 mg/kg body weight effects on fertility and early embryonic develop-
	lectin:		
Effect	s on fertility	Species: F Application General T Symptoms Result: No	Two-generation reproduction toxicity study at a Route: Oral oxicity F1: LOAEL: 0,8 mg/kg body weight : Reduced foetal weight, foetal mortality effects on fertility, Some evidence of adverse ef- evelopment, based on animal experiments.
		Species: F Applicatior General T Symptoms Result: No	Three-generation reproduction toxicity study at n Route: Oral oxicity F1: LOAEL: 0,8 mg/kg body weight : Reduced foetal weight, foetal mortality effects on fertility, Some evidence of adverse ef- evelopment, based on animal experiments.
Effect ment	s on foetal develop-	Species: F Application General T Embryo-fo Result: Sk	Embryo-foetal development at n Route: Oral oxicity Maternal: LOAEL: 10 mg/kg body weight etal toxicity: LOAEL: 10 mg/kg body weight eletal malformations The effects were seen only at maternally toxic dos
		Species: F Application General T	Embryo-foetal development abbit n Route: Oral oxicity Maternal: LOAEL: 5 mg/kg body weight ental Toxicity: NOAEL: 10 mg/kg body weight



Version 4.1	Revision Date: 26.06.2024		OS Number: 92846-00013	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
			Result: No terat	ogenic effects, No embryotoxic effects
Repro sessr	oductive toxicity - As- nent	:	Some evidence animal experime	of adverse effects on development, based on ents.
Ethar	nol:			
Effect	ts on fertility	:	Test Type: Two Species: Mouse Application Rou Result: negative	te: Ingestion
	Γ - single exposure lassified based on ava	ilable	information.	
STOT	- repeated exposure	•		
May o	cause damage to orga	ns thr	ough prolonged c	or repeated exposure.
<u>Com</u>	ponents:			
Moxi	dectin:			
	et Organs ssment	:	Central nervous Causes damage exposure.	system to organs through prolonged or repeated
Repe	ated dose toxicity			
-	ated dose toxicity ponents:			
<u>Com</u> 4,4'-n	ponents:			compound with (E)-1,4,5,6-tetrahydro-1-
<u>Com</u> 4,4'-n meth Speci	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny ies		imidine (1:1): Dog	compound with (E)-1,4,5,6-tetrahydro-1-
<u>Com</u> 4,4'-n meth Speci NOAI	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny jes EL		imidine (1:1): Dog 10 mg/kg	, compound with (E)-1,4,5,6-tetrahydro-1-
<u>Com</u> 4,4'-n meth Speci NOAE LOAE	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny ies EL		imidine (1:1): Dog 10 mg/kg 30 mg/kg	compound with (E)-1,4,5,6-tetrahydro-1-
<u>Comj</u> 4,4'-n meth Speci NOAE LOAE Applie	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny jes EL		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d	
<u>Comj</u> 4,4'-n meth Speci NOAE LOAE Applie	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny es EL EL cation Route sure time		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d	compound with (E)-1,4,5,6-tetrahydro-1-
Comj 4,4'-n meth Speci NOAE LOAE Applic Expos Rema	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny es EL EL cation Route sure time arks		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d	
Comj 4,4'-n meth Speci NOAE LOAE Applic Expos Rema Speci NOAE	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny es EL EL cation Route sure time arks es EL		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ad Dog 600 mg/kg	
Comj 4,4'-n meth Speci NOAE LOAE Applie Expos Rema Speci NOAE Applie	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny es EL EL cation Route sure time arks EL cation Route		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ad Dog 600 mg/kg Oral	
Comj 4,4'-n meth Speci NOAE LOAE Applie Expos Rema Speci NOAE Applie	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny es EL EL cation Route sure time arks EL cation Route sure time		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ad Dog 600 mg/kg Oral 19 d	
Comj 4,4'-n meth Speci NOAE LOAE Applic Expos Rema Speci NOAE Applic Expos Rema	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny ies EL EL cation Route sure time arks EL cation Route sure time sure time arks		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ad Dog 600 mg/kg Oral 19 d No significant ad	dverse effects were reported
Comj 4,4'-n meth Speci NOAE LOAE Applic Expos Rema Speci NOAE Applic Expos	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny ies EL EL cation Route sure time arks EL cation Route sure time arks		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ad Dog 600 mg/kg Oral 19 d	dverse effects were reported
Comj 4,4'-n meth Speci NOAE LOAE Applic Expos Rema Speci NOAE Applic Expos Rema	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny es EL EL cation Route sure time arks EL cation Route sure time arks EL cation Route sure time arks		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ad Dog 600 mg/kg Oral 19 d No significant ad Dog 600 mg/kg Oral Oral Og 600 mg/kg Oral	dverse effects were reported
Comj 4,4'-n meth Speci NOAE LOAE Applic Expos Rema Speci NOAE Applic Expos Rema	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny ies EL EL cation Route sure time arks EL cation Route sure time arks EL cation Route sure time arks		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ac Dog 600 mg/kg Oral 19 d No significant ac Dog 600 mg/kg Oral 30 d	dverse effects were reported
Comj 4,4'-n meth Speci NOAE LOAE Applic Expos Rema Speci NOAE Applic Expos Rema	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny ies EL EL cation Route sure time arks EL cation Route sure time arks EL cation Route sure time arks		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ad Dog 600 mg/kg Oral 19 d No significant ad Dog 600 mg/kg Oral 30 d No significant ad	dverse effects were reported
Comj 4,4'-n meth Speci NOAE LOAE Applic Expos Rema Speci NOAE Applic Expos Rema	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny ies EL EL cation Route sure time arks EL cation Route sure time arks EL cation Route sure time arks EL cation Route sure time arks		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ad Dog 600 mg/kg Oral 19 d No significant ad Dog 600 mg/kg Oral 30 d No significant ad Dog 000 mg/kg Oral 000 mg/kg 000 mg	dverse effects were reported
Comj 4,4'-n meth Speci NOAE LOAE Applid Expos Rema Speci NOAE Applid Expos Rema Speci NOAE Applid Expos Rema	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny ies EL EL cation Route sure time arks EL cation Route sure time arks EL cation Route sure time arks EL cation Route sure time arks		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ad Dog 600 mg/kg Oral 19 d No significant ad Dog 600 mg/kg Oral 30 d No significant ad	dverse effects were reported
Comj 4,4'-n meth Speci NOAE Applid Expos Rema Speci NOAE Applid Expos Rema Speci NOAE Applid Expos Rema	ponents: nethylenebis[3-hydro yl-2-[2-(2-thienyl)viny ies EL EL cation Route sure time arks EL cation Route sure time arks EL cation Route sure time arks EL cation Route sure time arks		imidine (1:1): Dog 10 mg/kg 30 mg/kg Ingestion 3 d No significant ad Dog 600 mg/kg Oral 19 d No significant ad Dog 600 mg/kg Oral 30 d No significant ad Dog 600 mg/kg Oral 30 d No significant ad	dverse effects were reported



sion	Revision Date: 26.06.2024	SDS Number:Date of last issue: 02.04.20244892846-00013Date of first issue: 17.09.2019
Moxid	dectin:	
Speci	es	: Mouse
NOAE		: 3,9 mg/kg
LOAE		: 15,4 mg/kg
	cation Route	: Oral
	sure time	: 4 Weeks
Symp		: Tremors
Cymp		
Speci		: Rat
NOAE		: 3,9 mg/kg
LOAE		: 7,9 mg/kg
	cation Route	: Oral
	sure time	: 13 Weeks
	et Organs	: Central nervous system
Symp	toms	: Tremors, Salivation
Speci	es	: Dog
NOAE		: 0,3 mg/kg
LOAE		: 0,9 mg/kg
-	cation Route	: Oral
	sure time	: 90 Days
	et Organs	: Central nervous system
Symp		: Tremors, Lachrymation, Salivation
Creat		
Speci NOAE		: Dog
-		: 1,15 mg/kg : Oral
	cation Route	: 52 Weeks
	sure time et Organs	
Symp		Central nervous systemTremors, Lachrymation
Symp	101115	. Tremois, Lacinymation
Ethar	nol:	
Speci		: Rat
NOAE		: 1.730 mg/kg
LOAE		: 3.200 mg/kg
	cation Route	: Ingestion
	sure time	: 90 Days
•	ation toxicity	
Not cl	assified based on av	ailable information.
Expe	rience with human	exposure
<u>Comp</u>	oonents:	
		roxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1 nyl]pyrimidine (1:1):
Inges	tion	: Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhoea, Headache, Dizziness, Fever
Moxid	dectin:	
Inhala	ation	: Remarks: No human information is available.
-		



Version	Revision Date: 26.06.2024	SDS Number:	Date of last issue: 02.04.2024
4.1		4892846-00013	Date of first issue: 17.09.2019
• • • • • •	contact contact stion	: Remarks: No h	uman information is available. uman information is available. uman information is available.

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
	•	
Moxidectin: Toxicity to fish	:	LC50 (Lepomis macrochirus (Bluegill sunfish)): 0,0006 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
		LC50 (Oncorhynchus mykiss (rainbow trout)): 0,0002 mg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 0,00003 mg/l Exposure time: 48 h Method: OECD Test Guideline 202
Toxicity to algae/aquatic plants	:	EC50 (Pseudokirchneriella subcapitata (green algae)): 0,087 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
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



Versi 4.1	ion	Revision Date: 26.06.2024		OS Number: 92846-00013	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
	Toxicity	y to microorganisms	:	EC50 (Protozoa): 5.800 mg/l Exposure time: 4 h	
	Toxicity icity)	y to fish (Chronic tox-	:	NOEC: >= 79 mg Exposure time: 10 Species: Oryzias	
i		/ to daphnia and other invertebrates (Chron- ity)	:	NOEC: 9,6 mg/l Exposure time: 9 d Species: Daphnia magna (Water flea)	
12.2	Persis	tence and degradabil	ity		
	Compo	onents:			
	Ethanc Biodeg	bl: radability	:	Result: Readily b Biodegradation: Exposure time: 20	84 %
12.3	Bioaco	cumulative potential			
	Compo	onents:			
	Moxide Partitio octanol	n coefficient: n-	:	log Pow: 4,7	
	Ethanc Partitio octanol	n coefficient: n-	:	log Pow: -0,35	
		ty in soil a available			
12.5	Result	s of PBT and vPvB as	sse	ssment	
	Produc Assess		:	to be either persis	nixture contains no components considered stent, bioaccumulative and toxic (PBT), or nd very bioaccumulative (vPvB) at levels of
12.6	Other	adverse effects			
	Produc Endocr tial	<u>ct:</u> ine disrupting poten-	:	ered to have ende REACH Article 57	ixture does not contain components consid- ocrine disrupting properties according to 7(f) or Commission Delegated regulation or Commission Regulation (EU) 2018/605 at higher.



Version	Revision Date:	SDS Number:	Date of last issue: 02.04.2024
4.1	26.06.2024	4892846-00013	Date of first issue: 17.09.2019

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product Contaminated packaging	:	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. Empty containers should be taken to an approved waste han-
Contaminated packaging	·	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			
ΙΑΤΑ	:	UN 3077			
14.2 UN proper shipping name					
ADN	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Moxidectin)			
ADR	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Moxidectin)			
RID	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Moxidectin)			
IMDG	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Moxidectin)			
ΙΑΤΑ	:	Environmentally hazardous substance, solid, n.o.s. (Moxidectin)			
14.3 Transport hazard class(es)					
		Class Subsidiary risks			
ADN	:	9			
ADR	:	9			
RID	:	9			
IMDG	:	9			
ΙΑΤΑ	:	9			



Version 4.1	Revision Date: 26.06.2024	SDS Number: 4892846-00013	Date of last issue: 02.04.2024 Date of first issue: 17.09.2019
14.4 Pac	king group		
Clas	king group ssification Code ard Identification Number	: III : M7 : 90 : 9	
Clas Haz Lab	king group ssification Code ard Identification Number	: III : M7 : 90 : 9 : (-)	
Clas	king group ssification Code ard Identification Number	: III : M7 : 90 : 9	
Lab	king group	: III : 9 : F-A, S-F	
Pac airci Pac	king instruction (LQ) king group	: 956 : Y956 : III : Miscellaneous	
Pac ger Pac	A (Passenger) king instruction (passen- aircraft) king instruction (LQ) king group els	: 956 : Y956 : III : Miscellaneous	
14.5 Env	vironmental hazards		
ADI Envi	N ironmentally hazardous	: yes	
ADF		: yes	
RID	-	: yes	
IMD		: yes	
ΙΑΤ	A (Passenger) ironmentally hazardous	: yes	
ΙΑΤ	A (Cargo) ironmentally hazardous	: yes	



Version	Revision Date:	SDS Number:	Date of last issue: 02.04.2024
4.1	26.06.2024	4892846-00013	Date of first issue: 17.09.2019

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

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.

CTION 16: Other informati	ion	
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.
H301	:	Toxic if swallowed.
H319	:	Causes serious eye irritation.
H332	:	Harmful if inhaled.
H361d	:	Suspected of damaging the unborn child.
H372	:	Causes damage to organs through prolonged or repeated exposure.
H400	:	Very toxic to aquatic life.
H410	:	Very toxic to aquatic life with long lasting effects.
Full text of other abbreviati	ons	
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
Repr.	:	Reproductive toxicity
STOT RE	:	Specific target organ toxicity - repeated exposure
ZA OEL	:	South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits
ZA OEL / OEL- RL STEL/C	:	Occupational Exposure Limit Restricted limit - Short term oc-



Version	Revision Date:	SDS Number:	Date of last issue: 02.04.2024
4.1	26.06.2024	4892846-00013	Date of first issue: 17.09.2019

cupational exposure limits / ceiling limits

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

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 mix	Classification procedure:	
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



Version	Revision Date:	SDS Number:	Date of last issue: 02.04.2024
4.1	26.06.2024	4892846-00013	Date of first issue: 17.09.2019

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.

ZA / EN