

## Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 30.09.2023
3.3	28.09.2024	7567913-00010	Date of first issue: 20.11.2020

#### SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Milbemycin Oxime / Lufenuron / Praziquantel Formulation			
Manufacturer or supplier's details					
Company name of supplier	:	MSD			
Address	:	126 E. Lincoln Avenue			
		Rahway, New Jersey U.S.A. 07065			
Telephone	:	908-740-4000			
Emergency telephone	:	1-908-423-6000			
E-mail address	:	EHSDATASTEWARD@msd.com			
Recommended use of the chemical and restrictions on use					
Recommended use	:	Veterinary product			
Restrictions on use	:	Not applicable			

### **SECTION 2. HAZARDS IDENTIFICATION**

GHS Classification Skin sensitization	:	Category 1
Reproductive toxicity	:	Category 1B
Specific target organ toxicity - repeated exposure (Oral)	:	Category 1 (Central nervous system, Lungs, Liver, Stomach)
GHS label elements		
Hazard pictograms	:	
Signal Word	:	Danger
Hazard Statements	:	H317 May cause an allergic skin reaction. H360D May damage the unborn child. H372 Causes damage to organs (Central nervous system, Lungs, Liver, Stomach) through prolonged or repeated exposure if swallowed.
Precautionary Statements	:	<ul> <li>Prevention:</li> <li>P201 Obtain special instructions before use.</li> <li>P202 Do not handle until all safety precautions have been read and understood.</li> <li>P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ spray.</li> <li>P264 Wash skin thoroughly after handling.</li> <li>P270 Do not eat, drink or smoke when using this product.</li> <li>P272 Contaminated work clothing should not be allowed out of the workplace.</li> <li>P280 Wear protective gloves/ protective clothing/ eye protection/</li> </ul>



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		face protection.		
	<b>Response:</b> P302 + P352 IF ON SKIN: Wash with plenty of water. P308 + P313 IF exposed or concerned: Get medical a attention. P333 + P313 If skin irritation or rash occurs: Get medi attention. P362 + P364 Take off contaminated clothing and was reuse.		exposed or concerned: Get medical advice/ kin irritation or rash occurs: Get medical advice/	
		<b>Storage:</b> P405 Store locke	ed up.	
	<b>Disposal:</b> P501 Dispose of contents/ container to an approved posal plant.			
Other	hazards			

#### Other hazards

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

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch	9005-25-8	>= 30 -< 50
Glycerine	56-81-5	>= 10 -< 20
Lufenuron (ISO)	103055-07-8	>= 5 -< 10
Sucrose	57-50-1	>= 5 -< 10
Savorysel Bacon Flavor	Not Assigned	>= 5 -< 10
Praziquantel	55268-74-1	>= 1 -< 5
Sodium chloride	7647-14-5	>= 1 -< 5
Milbemycin Oxime	129496-10-2	>= 0.1 -< 1

#### **SECTION 4. FIRST AID MEASURES**

General advice	:	In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.



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In case of eye contact If swallowed		<ul> <li>If in eyes, rinse well with water.</li> <li>Get medical attention if irritation develops and persists.</li> <li>If swallowed, DO NOT induce vomiting.</li> <li>Get medical attention.</li> <li>Rinse mouth thoroughly with water.</li> </ul>			
Most important symptoms and effects, both acute and delayed		: May cause an May damage th Causes damage exposure if swa Contact with du	<ul> <li>May cause an allergic skin reaction.</li> <li>May damage the unborn child.</li> <li>Causes damage to organs through prolonged or repeated exposure if swallowed.</li> <li>Contact with dust can cause mechanical irritation or drying of the skin.</li> </ul>		
	ion of first-aiders o physician	<ul> <li>Dust contact w</li> <li>First Aid respo and use the re- when the poter</li> </ul>	ith the eyes can lead to mechanical irritation. nders should pay attention to self-protection, commended personal protective equipment ntial for exposure exists (see section 8). natically and supportively.		

#### SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	None known.
Specific hazards during fire fighting	:	Exposure to combustion products may be a hazard to health.
Hazardous combustion prod- ucts	:	Carbon oxides Nitrogen oxides (NOx) Metal oxides Chlorine compounds
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.
Special protective equipment for fire-fighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec- :		Use personal protective equipment.	
tive equipment and emer-		Follow safe handling advice (see section 7) and personal	
gency procedures		protective equipment recommendations (see section 8).	
Environmental precautions	:	Avoid release to the environment. Prevent further leakage or spillage if safe to do so.	



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					se of contaminated wash water. should be advised if significant spillages ed.
	Methods and materials for containment and cleaning up		:	container for disp Avoid dispersal of with compressed Dust deposits sho surfaces, as these released into the Local or national disposal of this m employed in the of determine which in Sections 13 and 1	dust in the air (i.e., clearing dust surfaces

#### SECTION 7. HANDLING AND STORAGE

Technical measures	:	Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
Local/Total ventilation	:	
Advice on safe handling	:	Do not get on skin or clothing. Do not breathe dust, fume, gas, mist, vapors or spray. Do not swallow. Avoid contact with eyes. Wash skin thoroughly after handling. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment Keep container tightly closed. 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. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the
Hygiene measures	:	<ul> <li>environment.</li> <li>If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.</li> <li>When using do not eat, drink or smoke.</li> <li>Contaminated work clothing should not be allowed out of the workplace.</li> <li>Wash contaminated clothing before re-use.</li> <li>The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures,</li> </ul>



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Conditions for safe storage		<ul> <li>industrial hygiene monitoring, medical surveillance and the use of administrative controls.</li> <li>Keep in properly labeled containers.</li> <li>Store locked up.</li> <li>Keep tightly closed.</li> <li>Store in accordance with the particular national regulations.</li> </ul>			
Materials to avoid		: Do not store with the following product types: Strong oxidizing agents Self-reactive substances and mixtures Organic peroxides Explosives Gases			

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Starch	9005-25-8	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010- STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Glycerine	56-81-5	VLE-PPT (Mist)	10 mg/m <sup>3</sup>	NOM-010- STPS-2014
Lufenuron (ISO)	103055-07-8	TWA	60 µg/m3 (OEB 3)	Internal
· · · ·	Further inform	ation: DSEN		
		Wipe limit	100 µg/100 cm2	Internal
Sucrose	57-50-1	VLE-PPT	10 mg/m <sup>3</sup>	NOM-010- STPS-2014
		TWA	10 mg/m <sup>3</sup>	ACGIH
Savorysel Bacon Flavor	Not Assigned	Wipe limit	OEB 2 (>= 100 < 1000 µg/m3)	Internal
Praziquantel	55268-74-1	TWA	0.5 mg/m3 (OEB 2)	Internal
Milbemycin Oxime	129496-10-2	TWA	0.1 mg/m3 (OEB2)	Internal

#### Ingredients with workplace control parameters

design and operated in accordance with GMP principles to protect products, workers, and the environment. Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices). Minimize open handling.
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### Personal protective equipment

Respiratory protection	:	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the
Filter type	:	recommended guidelines, use respiratory protection. Combined particulates and organic vapor type



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Hand	protection			
Ма	terial	:	Chemical-resista	nt gloves
	marks rotection	If the work enviro mists or aerosols Wear a faceshiel		gloving. ses with side shields or goggles. nment or activity involves dusty conditions, , wear the appropriate goggles. d or other full face protection if there is a t contact to the face with dusts, mists, or
Skin a	nd body protection	:	task being perfor disposable suits)	arments should be used based upon the med (e.g., sleevelets, apron, gauntlets, to avoid exposed skin surfaces. degowning techniques to remove potentially

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid
Color	:	brown
Odor	:	characteristic
Odor Threshold	:	No data available
рН	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Flammability (liquids)	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable



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Relative density		:	No data available	e	
I	Density		:	No data available	9
:	Solubility(ies) Water solubility		:	soluble	
	Partition octanol	n coefficient: n-	:	Not applicable	
		nition temperature	:	No data available	9
I	Decomposition temperature		:	No data available	e
,	Viscosi Visc	ty cosity, kinematic	:	Not applicable	
I	Explosi	ve properties	:	Not explosive	
(	Oxidizir	ng properties	:	The substance o	r mixture is not classified as oxidizing.
I	Molecu	lar weight	:	No data available	9
	Particle Particle	e characteristics e size	:	No data available	e

#### SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials	:	Heat, flames and sparks. Avoid dust formation. Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

#### SECTION 11. TOXICOLOGICAL INFORMATION

#### Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

#### Acute toxicity

Not classified based on available information.

#### Product:



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,	Acute o	oral toxicity	:	Acute toxicity estin Method: Calculation	mate: > 5,000 mg/kg on method
,	Acute o	dermal toxicity	:	Acute toxicity estine Method: Calculation	mate: > 5,000 mg/kg on method
<u>(</u>	Compo	onents:			
:	Starch	:			
/	Acute o	oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
/	Acute o	dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
(	Glycer	ine:			
/	Acute o	oral toxicity	:	LD50 (Rat): > 5,00	00 mg/kg
/	Acute o	dermal toxicity	:	LD50 (Guinea pig	): > 5,000 mg/kg
1	Lufenı	ıron (ISO):			
		oral toxicity	:	LD50 (Rat): > 2,00	00 mg/kg
				LD50 (Mouse): > 2	2,000 mg/kg
/	Acute i	nhalation toxicity	:	LC50 (Rat): 2,350 Test atmosphere:	
/	Acute o	dermal toxicity	:	LD50 (Rabbit): > 2	2,000 mg/kg
:	Sucros	Se:			
/	Acute o	oral toxicity	:	LD50 (Rat): 29,70	0 mg/kg
:	Savor	vsel Bacon Flavor:			
	-	oral toxicity	:	Remarks: Based of are not met.	on available data, the classification criteria
1	Acute i	nhalation toxicity	:	Remarks: Not clas	ssified due to lack of data.
	Acute o	dermal toxicity	:	Remarks: Based of are not met.	on available data, the classification criteria
I	Praziq	uantel:			
1	Acute of	oral toxicity	:	LD50 (Rat): 2,480	mg/kg
				LD50 (Mouse): 2,4	154 mg/kg
				LD50 (Dog): > 200	) mg/kg
				LD50 (Rabbit): 1,0	050 mg/kg



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Sodiu	um chloride:			
Acute	e oral toxicity	:	LD50 (Rat): 3,5	50 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 4 Exposure time: Test atmospher	1 h _
Acute	e dermal toxicity	:	LD50 (Rabbit): :	> 5,000 mg/kg
Milbe	emycin Oxime:			
	oral toxicity	:	LD50 (Rat): 532	2 - 863 mg/kg
			LD50 (Mouse):	722 - 946 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): 1,20 Exposure time: Test atmospher	4 h
Aouto	e dermal toxicity	:	LD50 (Rat): > 2	,000 mg/kg
<b>Skin</b> Not cl	corrosion/irritation lassified based on ava ponents:	ilable	information.	
Skin Not cl <u>Com</u> Glyce Speci	corrosion/irritation lassified based on ava ponents: erine: les	ilable :	Rabbit	
Skin Not cl <u>Com</u> Glyce	corrosion/irritation lassified based on ava ponents: erine: les	ilable : :		1
Skin Not cl Com Glyce Speci Resul	corrosion/irritation lassified based on ava <u>ponents:</u> erine: les lt nuron (ISO):	ilable : :	Rabbit No skin irritatior	1
Skin Not cl Com Glyce Speci Resul Lufer Speci	corrosion/irritation lassified based on ava <u>ponents:</u> erine: les lt <b>nuron (ISO)</b> : les	ilable : :	Rabbit No skin irritatior Rabbit	1
Skin Not cl Com Glyce Speci Resul	corrosion/irritation lassified based on ava <u>ponents:</u> erine: les lt <b>huron (ISO)</b> : les od	ilable : : :	Rabbit No skin irritatior	
Skin Not cl Com Glyce Speci Resul Lufer Speci Metho Resul	corrosion/irritation lassified based on ava <u>ponents:</u> erine: les lt <b>huron (ISO)</b> : les od	ilable : :	Rabbit No skin irritatior Rabbit Draize Test	
Skin Not cl Com Glyce Speci Resul Lufer Speci Metho Resul	corrosion/irritation lassified based on ava ponents: erine: les lt huron (ISO): les od lt rysel Bacon Flavor:	ilable : : :	Rabbit No skin irritation Rabbit Draize Test No skin irritation	ı İrom similar materials
Skin Not cl Com Glyce Speci Resul Lufer Speci Metho Resul Savo Rema	corrosion/irritation lassified based on ava ponents: erine: les lt huron (ISO): les od lt rysel Bacon Flavor:	ilable : : :	Rabbit No skin irritation Rabbit Draize Test No skin irritation Based on data f	ı İrom similar materials
Skin Not cl Com Glyce Speci Resul Lufer Speci Metho Resul Savo Rema	corrosion/irritation lassified based on ava ponents: erine: les lt nuron (ISO): les od lt rysel Bacon Flavor: arks quantel: les od	ilable : : : :	Rabbit No skin irritation Rabbit Draize Test No skin irritation Based on data f	ı İrom similar materials
Skin Not cl Com Glyce Speci Resul Lufer Speci Metho Resul Savo Rema	corrosion/irritation lassified based on ava ponents: erine: les lt nuron (ISO): les od lt rysel Bacon Flavor: arks quantel: les od	ilable : : : :	Rabbit No skin irritation Rabbit Draize Test No skin irritation Based on data f May irritate skin Rabbit Draize Test	ı İrom similar materials

### Milbemycin Oxime:



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ersion 3	Revision Date: 28.09.2024		S Number: 67913-00010	Date of last issue: 30.09.2023 Date of first issue: 20.11.2020
Species Method Result		:	Rabbit OECD Test Guid No skin irritation	
	ous eye damage/eye classified based on av			
<u>Com</u>	<u>nponents:</u>			
Star	ch:			
Spee	cies	:	Rabbit	
Resi		:	No eye irritation	
Glyc	cerine:			
Spee	cies	:	Rabbit	
Res	ult	:	No eye irritation	
Lufe	enuron (ISO):			
Spee	cies		Rabbit	
Res		:	No eye irritation	
Meth	od	:	Draize Test	
Save	orysel Bacon Flavor:			
Rem	narks	:	Based on data fi May irritate eyes	rom similar materials s.
Praz	ziquantel:			
Spee		:	Rabbit	
Res		:	Mild eye irritation	n
Meth	od	:	Draize Test	
Sod	ium chloride:			
Spee		:	Rabbit	
Res	ult	:	No eye irritation	
Milb	emycin Oxime:			
Spee		:	Rabbit	
Res	ult	:	No eye irritation	
Res	piratory or skin sens	itizatio	n	
_	sensitization			
May	cause an allergic skin	reactio	on.	
Pos	niratory consitization			

### **Respiratory sensitization**

Not classified based on available information.



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Comp	oonents:		
<b>Starcl</b> Test T Route Specie Result	Type s of exposure es	: Maximization : Skin contact : Guinea pig : negative	Test
Lufen	uron (ISO):		
Test T Specie Asses Result	es ssment	: Maximization : Guinea pig : May cause se : Sensitizer	Test nsitization by skin contact.
Savor	rysel Bacon Flavor:		
Rema	irks	: Not classified	due to lack of data.
Test T	es of exposure	: Maximization : Dermal : Guinea pig : Not a skin ser	
	ım chloride:		
Test T Route Specie Result	es of exposure es	: Local lymph n : Skin contact : Mouse : negative	ode assay (LLNA)
Milbe	mycin Oxime:		
Route Specie Result		: Skin contact : Guinea pig : negative	
	cell mutagenicity assified based on av	ailable information.	
Comp	oonents:		
<b>Starcl</b> Genot	<b>h:</b> toxicity in vitro	: Test Type: Ba Result: negati	cterial reverse mutation assay (AMES) ve
Glyce	erine:		
-	toxicity in vitro	: Test Type: In Result: negati	vitro mammalian cell gene mutation test ve



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		Result: neg	ative
		Test Type: Result: neg	Chromosome aberration test in vitro ative
			DNA damage and repair, unscheduled DNA syn- ammalian cells (in vitro) ative
Lufe	nuron (ISO):		
Geno	otoxicity in vitro	: Test Type: Result: neg	
			Mouse Lymphoma n: Chinese hamster cells ative
			Cytogenetic assay n: Chinese hamster ovary cells ative
		thesis in ma	DNA damage and repair, unscheduled DNA syn- ammalian cells (in vitro) n: rat hepatocytes ative
		Test systen Result: neg	n: Human lymphocytes ative
Geno	otoxicity in vivo	: Test Type: cytogenetic Species: M Result: neg	ouse
		Test Type: lar cells Species: Ra Result: neg	
	n cell mutagenicity - ssment	: Weight of e cell mutage	vidence does not support classification as a germ n.
Sucr	ose:		
Geno	otoxicity in vitro	: Test Type: Result: neg	In vitro mammalian cell gene mutation test ative
	rysel Bacon Flavor:		
Geno	otoxicity in vitro	: Remarks: N	lot classified due to lack of data.
Geno	otoxicity in vivo	: Remarks: N	lot classified due to lack of data.



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Prazi	iquantel:			
	toxicity in vitro	:	Test Type: Bac Result: negativ	terial reverse mutation assay (AMES) e
				omosomal aberration hinese hamster cells e
Genc	otoxicity in vivo	:	Test Type: Mic Species: Rat Result: negativ	
Sodi	um chloride:			
Geno	otoxicity in vitro	:	Test Type: In v Result: positive	itro mammalian cell gene mutation test
			Test Type: Bac Result: negativ	terial reverse mutation assay (AMES) e
			Test Type: Sac (in vitro) Result: positive	charomyces cerevisiae, gene mutation assay
				A damage and repair, unscheduled DNA syn- nalian cells (in vitro)
			Test Type: Chr Result: positive	omosome aberration test in vitro
			Test Type: Chr Result: negativ	omosome aberration test in vitro e
Geno	otoxicity in vivo	:		ivo micronucleus test
			Species: Mous Application Ro Result: negativ	ute: Intraperitoneal injection
				agenicity (in vivo mammalian bone-marrow t, chromosomal analysis)
				ute: Intraperitoneal injection
	n cell mutagenicity - ssment	:	Weight of evide cell mutagen.	ence does not support classification as a germ
Milbe	emycin Oxime:			
	otoxicity in vitro	:	Test Type: Bac Result: negativ	terial reverse mutation assay (AMES) e
			Test Type: Chr	omosome aberration test in vitro



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		Result: neg	ative
Genot	oxicity in vivo	: Test Type: cytogenetic Species: M Result: neg	ouse
	nogenicity assified based on ava	lable information.	
Comp	onents:		
Glyce	rine:		
Specie	es	: Rat	
	ation Route	: Ingestion	
	ure time	: 2 Years	
Result		: negative	
Lufen	uron (ISO):		
Specie	es	: Rat	
Applic	ation Route	: Ingestion	
	ure time	: 18 month(s	)
Result		: negative	
Carcin ment	ogenicity - Assess-	: Weight of e cinogen	vidence does not support classification as a ca
Prazio	uantel:		
Specie	es	: Hamster	
Applic	ation Route	: Oral	
	ure time	: 80 weeks	
NOAE	L		body weight
Result		: negative	
Rema	rks	: No significa	int adverse effects were reported
Specie	es	: Rat	
	ation Route	: Oral	
	ure time	: 104 weeks	
NOAE			body weight
Result		: negative	when the second se
Rema	rks	: No significa	int adverse effects were reported
	m chloride:		
Specie		: Rat	
	ation Route	: Ingestion	
	ure time	: 2 Years	
Result		: negative	

May damage the unborn child.



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	Compo	onents:			
	Glycer	ine:			
	-	on fertility	:	Test Type: Two-g Species: Rat Application Route Result: negative	eneration reproduction toxicity study : Ingestion
	Effects	on fetal development	:	Test Type: Embry Species: Rat Application Route Result: negative	ro-fetal development : Ingestion
	Lufenu	uron (ISO):			
		on fertility	:	Species: Rat Application Route General Toxicity F Early Embryonic I weight	eneration reproduction toxicity study :: Oral Parent: NOAEL: 8.3 mg/kg wet weight Development: NOAEL: 20.9 mg/kg body sting did not show any effects on fertility.
	Effects	on fetal development	:	Developmental To Symptoms: No ac	: Oral Maternal: NOAEL: 500 mg/kg body weight oxicity: NOAEL: 1,000 mg/kg body weight
				Species: Rat Application Route General Toxicity	Maternal: NOAEL: 20.9 mg/kg body weight city.: 8.3 mg/kg body weight
	Reproc sessme	ductive toxicity - As- ent	:	Clear evidence of animal experimen	adverse effects on development, based on ts.
	Savor	ysel Bacon Flavor:			
	-	on fertility	:	Remarks: No data	a available
	Effects	on fetal development	:	Remarks: No data	a available
	Prazia	uantel:			
	-	on fertility	:	Test Type: Fertilit Species: Rat Remarks: No sigr	y nificant adverse effects were reported
				Test Type: Fertilit	у



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				Species: Mouse Remarks: No sign	ificant adverse effects were reported
E	Effects	on fetal development	:	Test Type: Develo Species: Rat Remarks: No sign	opment ificant adverse effects were reported
				Test Type: Develo Species: Mouse Remarks: No sign	opment ificant adverse effects were reported
N	Milberr	nycin Oxime:			
E	Effects	on fertility	:	Test Type: One-g Species: Dog Application Route Result: negative	eneration reproduction toxicity study : Ingestion
E	Effects	on fetal development	:	Test Type: Embry Species: Rat Application Route Result: negative	o-fetal development : Ingestion
				Test Type: Embry Species: Rabbit Application Route Result: negative	o-fetal development : Ingestion
				Test Type: Embry Species: Dog Application Route Result: negative	o-fetal development : Ingestion
		<b>single exposure</b> ssified based on availa	blo	information	
		onents:			
L		ıron (ISO):	:	The substance or organ toxicant, sir	mixture is not classified as specific target ngle exposure.
s	отот-и	repeated exposure			
C	Causes	• •			Lungs, Liver, Stomach) through prolonged
<u>c</u>	Compo	onents:			
L	ufenu	iron (ISO):			
Т		of exposure Organs ment	:		ystem, Lungs, Liver, Stomach e significant health effects in animals at con- mg/kg bw or less.



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	l <b>ilbemycin Ox</b> outes of expos			Ingestion	
Та	arget Organs ssessment		:	Central nervous s	significant health effects in animals at con-
R	epeated dose	toxicity			
<u>C</u>	omponents:				
St	tarch:				
	pecies		:	Rat	
	OAEL pplication Rout	te	:	>= 2,000 mg/kg Skin contact	
E	xposure time		:	28 Days	
M	lethod		:	OECD Test Guide	line 410
G	lycerine:				
	pecies OAEL		:	Rat 0.167 mg/l	
	OAEL		:	0.622 mg/l	
	pplication Rout	te	:	inhalation (dust/m	ist/fume)
E	xposure time		•	13 Weeks	
	pecies OAEL		:	Rat	allen a
	DAEL	te	:	8,000 - 10,000 mg Ingestion	укд
	xposure time		:	2 y	
	pecies		:	Rabbit	
	OAEL pplication Rout	to	:	5,040 mg/kg Skin contact	
	xposure time	le	:	45 Weeks	
1.	ufenuron (ISO	)) <b>.</b>			
	pecies	·)-	:	Rat	
N	OAEL		:	5.34 mg/kg	
	pplication Rout	te	:	oral (feed) 4 Months	
	arget Organs		:		ystem, digestive system
S	ymptoms		:	central nervous sy	stem effects
	pecies		:	Rat	
	OAEL pplication Rout	te	:	1.93 mg/kg oral (feed)	
E	xposure time		:	2 y	
S	ymptoms		:	central nervous sy	vstem effects, Convulsions
	pecies		:	Mouse	
N	OAEL		:	2.12 mg/kg	



## Milbemycin Oxime / Lufenuron / Praziquantel Formulation

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Expos	cation Route sure time t Organs toms		us system, Liver, Prostate us system effects, Convulsions
Expos Targe Symp	EL cation Route sure time t Organs toms <b>rysel Bacon Flavor:</b>	: Convulsions,	us system, Liver, Lungs Fatality, Irregularities due to lack of data.
Renia		. Not classifica	
Speci NOAE Applic Rema	EL cation Route urks	-	adverse effects were reported
	EL EL cation Route t Organs	: Dog : 60 mg/kg : 180 mg/kg : Oral : Gastrointestir : No significant	al tract adverse effects were reported
Speci LOAE Applic		: Rat : 2,533 mg/kg : Ingestion : 2 y	
Milbe	mycin Oxime:		
Specie NOAE LOAE Applic	es EL EL cation Route sure time	: Rat : 3 mg/kg : 15 mg/kg : Ingestion : 90 Days : Liver disorder	s, Blood disorders
	L cation Route sure time	: Dog : 8.6 mg/kg : Ingestion : 3 Days : Tremors	
Acnir	ation toxicity		

### Aspiration toxicity

Not classified based on available information.



# Milbemycin Oxime / Lufenuron / Praziquantel Formulation

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E	Experie	ence with human exp	osi	ıre	
<u>c</u>	Compo	<u>nents:</u>			
L	Lufenu	ron (ISO):			
C	General	Information	:	Remarks: May be May cause neuro	e harmful if swallowed. toxic effects.
S	Savory	sel Bacon Flavor:			
C	General	Information	:	Remarks: Based May irritate skin. May irritate eyes.	on data from similar materials
F	Praziqu	antel:			
lı	Inhalatio	n	:		ache, Tiredness, Dizziness, Gastrointestinal ase body temperature, Allergic reactions
Ν	Milbem	ycin Oxime:			
lı	Ingestio	n	:	Vomiting, Tremor	ation, Convulsions, Diarrhea, Weakness, s, Coma on Animal Evidence
F	Further	information			
<u>c</u>	Compo	nents:			
S	Savory	sel Bacon Flavor:			
F	Remark	S	:	No toxicology info	prmation is available.

### SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity
-------------

Com	ponents:

Gly	C	eriı	ne:	

Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): 54,000 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 1,955 mg/l Exposure time: 48 h
Toxicity to microorganisms	:	NOEC (Pseudomonas putida): > 10,000 mg/l Exposure time: 16 h Method: DIN 38 412 Part 8
Lufenuron (ISO):		
Toxicity to fish	:	LC50 (Oncorhynchus mykiss (rainbow trout)): > 73,100 µg/l Exposure time: 96 h Method: OECD Test Guideline 203
		LC50 (Oncorhynchus mykiss (rainbow trout)): > 29,000 µg/l Exposure time: 96 h



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				Method: OECD Te	est Guideline 203
				LC50 (Oncorhync Exposure time: 96 Method: OECD Te	
		to daphnia and other invertebrates	:	EC50 (Americamy Exposure time: 96 Method: US-EPA	Sh Sh
				EC50 (Daphnia m Exposure time: 48 Method: OECD Te	
	Toxicity plants	to algae/aquatic	:	EC50 (Raphidoce µg/l Exposure time: 72 Method: OECD Te	
				EC50 (Scenedesr Exposure time: 72 Method: OECD Te	
	Toxicity icity)	to fish (Chronic tox-	:	NOEC (Oncorhyn Exposure time: 33 Method: OECD Te	
				NOEC (Oncorhyn Exposure time: 35 Method: OECD Te	
		to daphnia and other invertebrates (Chron- ty)	:	NOEC (Daphnia n Exposure time: 21 Method: OECD Te	
				NOEC (Daphnia n Exposure time: 21 Method: OECD Te	
				NOEC (Chironom Exposure time: 21 Method: OECD Te	
	<b>Praziqι</b> Toxicity		:	LC50 (Carassius a Exposure time: 96 Method: OECD Te	
				LC50 (Danio rerio Exposure time: 96 Method: OECD Te	
	Toxicity	to daphnia and other	:	EC50 (Daphnia m	agna (Water flea)): 35 mg/l



sion	Revision Date: 28.09.2024			Date of last issue: 30.09.2023 Date of first issue: 20.11.2020
aquatic invertebrates				
Toxicity to microorganisms		:	EC50 (activated sludge): > 1,000 mg/l Exposure time: 3 h Test Type: Respiration inhibition of activated sludge Method: OECD Test Guideline 209	
Sodiun	n chloride:			
		:		acrochirus (Bluegill sunfish)): 5,840 mg/l 3 h
		:		agna (Water flea)): 4,136 mg/l 3 h
Toxicity plants	/ to algae/aquatic	:		
Toxicity icity)	v to fish (Chronic tox-	:		es promelas (fathead minnow)): 252 mg/l 3 d
aquatic	invertebrates (Chron-	:		oulex (Water flea)): 314 mg/l d
		:	EC10: > 1,000 mg	ŋ/l
Milhow	wain Ovima			
	-	:		hus mykiss (rainbow trout)): 0.16 µg/l Sh
	•	:	· ·	agna (Water flea)): 0.03 µg/l 3 h
Toxicity plants	∕ to algae/aquatic	:	EC50: > 87 µg/l Exposure time: 72	2 h
aquatic	invertebrates (Chron-	:	NOEC (Daphnia r	nagna (Water flea)): 0.01 µg/l
Persistence and degradability				
Compo	onents:			
Glycer	ine:			
Biodeg	radability	:	Biodegradation: 9 Exposure time: 30	92 %
	Sodium Toxicity Toxicity aquatic Toxicity plants Toxicity Toxicity aquatic ic toxicity Toxicity Toxicity Toxicity aquatic ic toxicity Toxicity aquatic Toxicity aquatic Toxicity Plants Toxicity aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic Toxicity Aquatic	28.09.2024 aquatic invertebrates Toxicity to microorganisms Sodium chloride: Toxicity to fish Toxicity to daphnia and other aquatic invertebrates Toxicity to algae/aquatic plants Toxicity to fish (Chronic tox- icity) Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity) Toxicity to microorganisms Milbemycin Oxime: Toxicity to fish Toxicity to fish Toxicity to fish Toxicity to daphnia and other aquatic invertebrates Toxicity to daphnia and other aquatic invertebrates Toxicity to algae/aquatic plants	28.09.2024750aquatic invertebratesToxicity to microorganisms:Toxicity to microorganisms::Sodium chloride: Toxicity to fish::Toxicity to daphnia and other aquatic invertebrates::Toxicity to algae/aquatic plants::Toxicity to fish (Chronic tox- icity)::Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity):Toxicity to daphnia and other ic toxicity):Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity):Toxicity to daphnia and other aquatic invertebrates:Toxicity to daphnia and other aquatic invertebrates:Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity):Toxicity to algae/aquatic plants:Toxicity to algae/aquatic plants:Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity):Persistence and degradability:Components: Glycerine::	28.09.20247567913-00010aquatic invertebratesExposure time: 48 Method: OECD To Toxicity to microorganismsToxicity to microorganisms:EC50 (activated s Exposure time: 31 Test Type: Respir Method: OECD ToSodium chloride::Toxicity to fish:LC50 (Lepomis m Exposure time: 96Toxicity to daphnia and other aquatic invertebrates:Toxicity to algae/aquatic plants:EC50: > 2,000 mg Exposure time: 96Toxicity to fish (Chronic tox- ic toxicity):NOEC (Pimephale Exposure time: 31Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity):NOEC (Daphnia p Exposure time: 21Toxicity to daphnia and other aquatic invertebrates (Chron- ic toxicity):NOEC (Daphnia p Exposure time: 21Toxicity to daphnia and other aquatic invertebrates:Toxicity to algae/aquatic plants:Toxicity to algae/aquatic plants:Components: Glycerine: Biodegradability:Biodegradability:Result: Readily bi Biodegradation: S Exposure time: 30



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	Bioace	cumulative potential			
	<u>Comp</u>	onents:			
	Glyce	rine:			
		on coefficient: n- ol/water	:	log Pow: -1.75	
	Lufen	uron (ISO):			
	Bioaco	cumulation	:	Bioconcentration	s macrochirus (Bluegill sunfish) factor (BCF): 28 est Guideline 305
		on coefficient: n- ol/water	:	log Pow: 5.12	
	Sucro	se:			
		on coefficient: n- ol/water	:	Pow: < 1	
	Praziq	juantel:			
		on coefficient: n- ol/water	:	log Pow: 2.012 pH: 7	
	Milber	nycin Oxime:			
	Bioacc	cumulation	:	Bioconcentration	factor (BCF): 440
		on coefficient: n- ol/water	:	log Pow: 7	
	Mobili	ty in soil			
	<u>Comp</u>	onents:			
	Lufen	uron (ISO):			
		ution among environ- l compartments	:		est Guideline 106
	Other	adverse effects			
	No dat	a available			

### SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer. Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.



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#### **SECTION 14. TRANSPORT INFORMATION**

#### International Regulations

UNRTDG		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
		N.O.S.
		(Milbemycin Oxime, Lufenuron (ISO))
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes
IATA-DGR		
UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Milbemycin Oxime, Lufenuron (ISO))
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passen-	:	956
ger aircraft)		
Environmentally hazardous	:	yes
IMDG-Code		
UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
		N.O.S.
		(Milbemycin Oxime, Lufenuron (ISO))
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

#### Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **Domestic regulation**

<b>NOM-002-SCT</b> UN number Proper shipping name	:	UN 3077 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime, Lufenuron (ISO))
Class	:	9
Packing group	:	III
Labels	:	9

#### 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



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Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### **SECTION 15. REGULATORY INFORMATION**

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

Federal Law for the control of chemical precursors, : Not applicable essential chemical products and machinery for producing capsules, tablets and pills.

#### The ingredients of this product are reported in the following inventories:

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

#### **SECTION 16. OTHER INFORMATION**

Revision Date Date format	:	28.09.2024 dd.mm.yyyy
Full text of other abbreviation	ns	
		USA. ACGIH Threshold Limit Values (TLV) Mexico. Norm NOM-010-STPS-2014 on Chemicals Polluting the Work Environment - Identification, Assessment and Con- trol - Appendix 1 Occupational Exposure Limits
		8-hour, time-weighted average Time weighted average limit value

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; 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; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect



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Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; 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; WHMIS - Workplace Hazardous Materials Information System

Sources of key data used to	:
compile the Material Safety	
Data Sheet	

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

The information is considered as correct, but not exhaustive, and will be used only as a guide, which is based in the current knowledge of the substance or mixture, and is applicable to proper safety precautions for the product.

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