according to the Hazardous Products Regulations



# Milbemycin Oxime / Lufenuron / Praziquantel Formulation

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#### **SECTION 1. IDENTIFICATION**

Product name : Milbernycin Oxime / Lufenuron / Praziquantel Formulation

Other means of identification : No data available

#### Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc Address : 37 McCarville Street

Charlottetown, PE C1E 2A7

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.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 in accordance with the Hazardous Products Regulations

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 : Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P261 Avoid breathing dust, fume, gas, mist, vapors or spray.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

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P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves, protective clothing, eye protection

and face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.

P308 + P313 IF exposed or concerned: Get medical attention. P333 + P313 If skin irritation or rash occurs: Get medical atten-

tion.

P362 + P364 Take off contaminated clothing and wash it before

reuse.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste

disposal plant.

#### 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	Common Name/Synonym	CAS-No.	Concentration (% w/w)
Starch	Sago starch	9005-25-8	>= 30 - < 60 *
Glycerine	1,2,3- Propanetriol	56-81-5	>= 10 - < 30 *
Lufenuron (ISO)	No data availa- ble	103055-07-8	>= 5 - < 10 *
Sucrose	.alphaD- Glucopyra- noside, .beta D- fructofuranosyl	57-50-1	>= 5 - < 10 *
Praziquantel	4H-pyrazino- [2,1-a]- isoquinolin-4- one, 2- (cyclohexylcar- bonyl)- 1,2,3,6,7,11b- hexahydro-	55268-74-1	>= 1 - < 5 *
Milbemycin Oxime	No data availa- ble	129496-10-2	>= 0.1 - < 1 *

according to the Hazardous Products Regulations



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\* Actual concentration or concentration range is withheld as a trade secret

#### **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 contact, immediately flush skin with soap and plenty In case of skin contact

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

In case of eye contact : If in eyes, rinse well with water.

Get medical attention if irritation develops and persists.

Contact with dust can cause mechanical irritation or drying of

Dust contact with the eyes can lead to mechanical irritation.

If swallowed, DO NOT induce vomiting. If swallowed

Get medical attention.

Rinse mouth thoroughly with water.

Most important symptoms and effects, both acute and

delayed

May cause an allergic skin reaction.

May damage the unborn child.

Causes damage to organs through prolonged or repeated

exposure if swallowed.

First Aid responders should pay attention to self-protection, Protection of first-aiders

> and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

#### **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

Nitrogen oxides (NOx)

Metal oxides

Carbon oxides

Chlorine compounds

Specific extinguishing meth-Use extinguishing measures that are appropriate to local cir-

according to the Hazardous Products Regulations



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ods 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, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

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.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable

container for disposal.

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

with compressed air).

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items

employed in the cleanup of releases. You will need to

determine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

### **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 : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

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

Avoid breathing 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

according to the Hazardous Products Regulations



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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

environment.

Conditions for safe storage : Keep in properly labeled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

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**

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis		
Starch	9005-25-8	TWA	10 mg/m³	CA AB OEL		
		TWA (Total dust)	10 mg/m³	CA BC OEL		
		TWA (respirable dust fraction)	3 mg/m³	CA BC OEL		
		TWAEV (to- tal dust)	10 mg/m³	CA QC OEL		
		TWA	10 mg/m <sup>3</sup>	ACGIH		
Glycerine	56-81-5	TWA (Mist)	10 mg/m <sup>3</sup>	CA AB OEL		
		TWA (Mist)	10 mg/m <sup>3</sup>	CA BC OEL		
		TWA (Respirable mist)	3 mg/m³	CA BC OEL		
		TWAEV (Mist)	10 mg/m <sup>3</sup>	CA QC OEL		
Lufenuron (ISO)	103055-07-8	TWA	200 μg/m3 (OEB 2)	Internal		
	Further information: DSEN					
		Wipe limit	100 μg/100 cm2	Internal		
Sucrose	57-50-1	TWA	10 mg/m <sup>3</sup>	CA AB OEL		
		TWA (Total dust)	10 mg/m <sup>3</sup>	CA BC OEL		
		TWA (respirable dust	3 mg/m³	CA BC OEL		

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		fraction)		
		TWAEV	10 mg/m <sup>3</sup>	CA QC OEL
		TWA	10 mg/m <sup>3</sup>	ACGIH
Praziquantel	55268-74-1	TWA	0.5 mg/m3 (OEB 2)	Internal
Milbemycin Oxime	129496-10-2	TWA	0.1 mg/m3 (OEB2)	Internal

**Engineering measures** : Use feasible engineering controls to minimize exposure to

compound.

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to

protect products, workers, and the environment.

Personal protective equipment

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

exposure assessment demonstrates exposures outside the

recommended guidelines, use respiratory protection. Combined particulates and organic vapor type

Filter type
Hand protection

Material : Chemical-resistant gloves

Eye 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.

Skin and body protection

Hygiene measures

Work uniform or laboratory coat.

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

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

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

use of administrative controls.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : solid

Color : brown

Odor : characteristic

Odor Threshold : No data available

according to the Hazardous Products Regulations



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pH : 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

Relative density : No data available

Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

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

Molecular weight : No data available

Particle characteristics

Particle size : No data available

according to the Hazardous Products Regulations



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#### **SECTION 10. STABILITY AND REACTIVITY**

Reactivity : Not classified as a reactivity hazard. Chemical stability : Stable under normal conditions.

Possibility of hazardous reac- : May

tions

May form explosive dust-air mixture during processing,

handling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Oxidizing agents

Incompatible materials

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:** 

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

Method: Calculation method

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

Method: Calculation method

#### **Components:**

Starch:

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

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

Glycerine:

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

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

Lufenuron (ISO):

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg

LD50 (Mouse): > 2,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): 2,350 mg/m<sup>3</sup>

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Test atmosphere: dust/mist

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

Sucrose:

Acute oral toxicity : LD50 (Rat): 29,700 mg/kg

Praziquantel:

Acute oral toxicity : LD50 (Rat): 2,480 mg/kg

LD50 (Mouse): 2,454 mg/kg

LD50 (Dog): > 200 mg/kg

LD50 (Rabbit): 1,050 mg/kg

Milbemycin Oxime:

Acute oral toxicity : LD50 (Rat): 532 - 863 mg/kg

LD50 (Mouse): 722 - 946 mg/kg

Acute inhalation toxicity : LC50 (Rat): 1,200 mg/m³

Exposure time: 4 h

Test atmosphere: dust/mist

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

#### Skin corrosion/irritation

Not classified based on available information.

#### **Components:**

Glycerine:

Species : Rabbit

Result : No skin irritation

Lufenuron (ISO):

Species : Rabbit
Method : Draize Test
Result : No skin irritation

Praziquantel:

Species : Rabbit
Method : Draize Test
Remarks : slight irritation

Milbemycin Oxime:

Species : Rabbit

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Method : OECD Test Guideline 404

Result : No skin irritation

### Serious eye damage/eye irritation

Not classified based on available information.

Components:

Starch:

Species : Rabbit

Result : No eye irritation

Glycerine:

Species : Rabbit

Result : No eye irritation

Lufenuron (ISO):

Species : Rabbit

Result : No eye irritation

Method : Draize Test

Praziquantel:

Species : Rabbit

Result : Mild eye irritation
Method : Draize Test

Milbemycin Oxime:

Species : Rabbit

Result : No eye irritation

Respiratory or skin sensitization

Skin sensitization

May cause an allergic skin reaction.

Respiratory sensitization

Not classified based on available information.

**Components:** 

Starch:

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Lufenuron (ISO):

Test Type : Maximization Test

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Species : Guinea pig

Assessment : May cause sensitization by skin contact.

Result : Sensitizer

Praziquantel:

Test Type : Maximization Test

Routes of exposure : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Milbemycin Oxime:

Routes of exposure : Skin contact Species : Guinea pig Result : negative

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Starch:

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

Result: negative

Glycerine:

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

Result: negative

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

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

thesis in mammalian cells (in vitro)

Result: negative

Lufenuron (ISO):

Genotoxicity in vitro : Test Type: Ames test

Result: negative

Test Type: Mouse Lymphoma Test system: Chinese hamster cells

Result: negative

Test Type: Cytogenetic assay

Test system: Chinese hamster ovary cells

Result: negative

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

thesis in mammalian cells (in vitro) Test system: rat hepatocytes

Result: negative

Test system: Human lymphocytes

Result: negative

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

cytogenetic assay) Species: Mouse Result: negative

Test Type: Unscheduled DNA synthesis test (UDS) in testicu-

lar cells Species: Rat Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

Sucrose:

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

Result: negative

Praziquantel:

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

Result: negative

Test Type: Chromosomal aberration Test system: Chinese hamster cells

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat Result: negative

Milbemycin Oxime:

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

Result: negative

Test Type: Chromosome aberration test in vitro

Result: negative

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

cytogenetic assay) Species: Mouse Result: negative

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#### Carcinogenicity

Not classified based on available information.

#### **Components:**

#### Glycerine:

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

#### Lufenuron (ISO):

Species: RatApplication Route: IngestionExposure time: 18 month(s)Result: negative

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

#### Praziquantel:

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

NOAEL : 100 mg/kg body weight

Result : negative

Remarks : No significant adverse effects were reported

Species: RatApplication Route: OralExposure time: 104 weeks

NOAEL : 250 mg/kg body weight

Result : negative

Remarks : No significant adverse effects were reported

#### Reproductive toxicity

May damage the unborn child.

#### **Components:**

#### Glycerine:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

Species: Rat

Application Route: Ingestion

Result: negative

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Lufenuron (ISO):

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

Species: Rat

Application Route: Oral

General Toxicity Parent: NOAEL: 8.3 mg/kg wet weight Early Embryonic Development: NOAEL: 20.9 mg/kg body

weight

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

Effects on fetal development : Test Type: Development

Species: Rat

Application Route: Oral

General Toxicity Maternal: NOAEL: 500 mg/kg body weight Developmental Toxicity: NOAEL: 1,000 mg/kg body weight

Symptoms: No adverse effects.

Remarks: No significant adverse effects were reported

Test Type: Fertility/early embryonic development

Species: Rat

Application Route: Ingestion

General Toxicity Maternal: NOAEL: 20.9 mg/kg body weight

Embryo-fetal toxicity.: 8.3 mg/kg body weight

Result: Fetal abnormalities.

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

Praziquantel:

Effects on fertility : Test Type: Fertility

Species: Rat

Remarks: No significant adverse effects were reported

Test Type: Fertility Species: Mouse

Remarks: No significant adverse effects were reported

Effects on fetal development : Test Type: Development

Species: Rat

Remarks: No significant adverse effects were reported

Test Type: Development

Species: Mouse

Remarks: No significant adverse effects were reported

Milbemycin Oxime:

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

Species: Dog

Application Route: Ingestion

Result: negative

Effects on fetal development : Test Type: Embryo-fetal development

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Species: Rat

Application Route: Ingestion

Result: negative

Test Type: Embryo-fetal development

Species: Rabbit

Application Route: Ingestion

Result: negative

Test Type: Embryo-fetal development

Species: Dog

Application Route: Ingestion

Result: negative

#### STOT-single exposure

Not classified based on available information.

#### **Components:**

### Lufenuron (ISO):

Assessment : The substance or mixture is not classified as specific target

organ toxicant, single exposure.

#### STOT-repeated exposure

Causes damage to organs (Central nervous system, Lungs, Liver, Stomach) through prolonged or repeated exposure if swallowed.

### Components:

### Lufenuron (ISO):

Routes of exposure : Oral

Target Organs : Central nervous system, Lungs, Liver, Stomach

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

#### Milbemycin Oxime:

Routes of exposure : Ingestion

Target Organs : Central nervous system

Assessment : Shown to produce significant health effects in animals at con-

centrations of 10 mg/kg bw or less.

### Repeated dose toxicity

### **Components:**

#### Starch:

Species : Rat

NOAEL : >= 2,000 mg/kg
Application Route : Skin contact
Exposure time : 28 Days

Method : OECD Test Guideline 410

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Glycerine:

: Rat

NOAEL : 0.167 mg/l

LOAEL : 0.622 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

: Rat Species

: 8,000 - 10,000 mg/kg

Species: RatNOAEL: 8,000 - 10Application Route: IngestionExposure time: 2 y

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

Lufenuron (ISO):

Species Rat

NOAEL : 5.34 mg/kg Application Route : oral (feed)
Exposure time : 4 Months
Target Organs : Central nervous system, digestive system
Symptoms : central nervous system effects

Symptoms

: Rat

Species NOAEL Application Route Exposure time Symptoms NOAEL 1.93 mg/kg oral (feed)

Symptoms central nervous system effects, Convulsions

Species NOAEL Application Route Exposure time Target Organs Symptoms Mouse : 2.12 mg/kg : oral (feed) : 18 Months

: Central nervous system, Liver, Prostate Symptoms central nervous system effects, Convulsions

Species : Dog
NOAEL : 7.02 mg/kg
Application Route : oral (feed)
Exposure time : 1 y
Target Organs : Central ner
Symptoms : Convulsion Species : 7.02 mg/kg

: Central nervous system, Liver, Lungs Symptoms Convulsions, Fatality, Irregularities

Praziquantel:

Species Rat

NOAEL 1,000 mg/kg

Application Route Oral

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Remarks No significant adverse effects were reported

Species Dog NOAEL 60 mg/kg LOAEL 180 mg/kg Application Route Oral

Target Organs Gastrointestinal tract

Remarks No significant adverse effects were reported

Milbemycin Oxime:

Species Rat NOAEL 3 mg/kg LOAEL 15 mg/kg Application Route Ingestion Exposure time 90 Days

Symptoms Liver disorders, Blood disorders

Species Dog LOAEL 8.6 mg/kg Application Route Ingestion Exposure time 3 Days **Symptoms Tremors** 

**Aspiration toxicity** 

Not classified based on available information.

**Experience with human exposure** 

**Components:** 

Lufenuron (ISO):

Remarks: May be harmful if swallowed. General Information

May cause neurotoxic effects.

Praziquantel:

Inhalation Symptoms: Headache, Tiredness, Dizziness, Gastrointestinal

discomfort, decrease body temperature, Allergic reactions

Milbemycin Oxime:

Symptoms: Salivation, Convulsions, Diarrhea, Weakness, Ingestion

Vomiting, Tremors, Coma

Remarks: Based on Animal Evidence

**SECTION 12. ECOLOGICAL INFORMATION** 

**Ecotoxicity** 

**Components:** 

Glycerine:

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

Exposure time: 96 h

according to the Hazardous Products Regulations



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aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 1,955 mg/l

Exposure time: 48 h

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

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

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

Method: OECD Test Guideline 203

LC50 (Oncorhynchus mykiss (rainbow trout)): 370 μg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

EC50 (Americamysis): 0.042 µg/l

Exposure time: 96 h

Method: US-EPA OPPTS 850.1035

EC50 (Daphnia magna (Water flea)): 0.41 μg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Raphidocelis subcapitata (freshwater green alga)): 209

μg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Scenedesmus subspicatus): 17 μg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Oncorhynchus mykiss (rainbow trout)): 80 µg/l

Exposure time: 33 d

Method: OECD Test Guideline 210

NOEC (Oncorhynchus mykiss (rainbow trout)): 20 µg/l

Exposure time: 359 d

Method: OECD Test Guideline 229

Toxicity to daphnia and other:

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 8.38 µg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

NOEC (Daphnia magna (Water flea)): 90 μg/l

Exposure time: 21 d

according to the Hazardous Products Regulations



# Milbemycin Oxime / Lufenuron / Praziquantel **Formulation**

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Method: OECD Test Guideline 211

NOEC (Chironomus riparius (harlequin fly)): 2 µg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

Praziquantel:

Toxicity to fish : LC50 (Carassius auratus (goldfish)): 29.2 mg/l

Exposure time: 96 hrs

Method: OECD Test Guideline 203

LC50 (Danio rerio (zebra fish)): 31.6 mg/l

Exposure time: 96 hrs

Method: OECD Test Guideline 203

Toxicity to daphnia and other:

aquatic invertebrates

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

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l

Exposure time: 3 h

Test Type: Respiration inhibition of activated sludge

Method: OECD Test Guideline 209

Milbemycin Oxime:

: LC50 (Oncorhynchus mykiss (rainbow trout)): 0.16 μg/l Toxicity to fish

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 0.03 µg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50:  $> 87 \mu g/l$ 

Exposure time: 72 h

Toxicity to daphnia and other: aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 0.01 µg/l

Persistence and degradability

**Components:** 

Glycerine:

Biodegradability Result: Readily biodegradable.

Biodegradation: 92 % Exposure time: 30 d

Method: OECD Test Guideline 301D

according to the Hazardous Products Regulations



# Milbemycin Oxime / Lufenuron / Praziquantel **Formulation**

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Bioaccumulative potential

**Components:** 

Glycerine:

Partition coefficient: n-

octanol/water

: log Pow: -1.75

Lufenuron (ISO):

Bioaccumulation Species: Lepomis macrochirus (Bluegill sunfish)

> Bioconcentration factor (BCF): 28 Method: OECD Test Guideline 305

Partition coefficient: n-

octanol/water

: log Pow: 5.12

Sucrose:

Partition coefficient: n-

octanol/water

: Pow: < 1

Praziquantel:

Partition coefficient: n-

octanol/water

log Pow: 2.012

pH: 7

Milbemycin Oxime:

Bioaccumulation Bioconcentration factor (BCF): 440

Partition coefficient: n-

octanol/water

log Pow: 7

Mobility in soil

**Components:** 

Lufenuron (ISO):

Distribution among environ- : log Koc: 5.38

mental compartments

Method: OECD Test Guideline 106

Other adverse effects

No data 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.

according to the Hazardous Products Regulations



# Milbemycin Oxime / Lufenuron / Praziquantel Formulation

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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.

(Milbernycin Oxime, Lufenuron (ISO))

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo : 956

aircraft)

Packing instruction (passen-

ger aircraft)

Environmentally hazardous : yes

**IMDG-Code** 

UN number : UN 3077

Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

956

(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** 

**TDG** 

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
ERG Code : 171

Marine pollutant : yes(Milbemycin Oxime, Lufenuron (ISO))

according to the Hazardous Products Regulations



# Milbemycin Oxime / Lufenuron / Praziquantel Formulation

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#### 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.

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

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

AICS : not determined

DSL : not determined

IECSC : not determined

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

#### Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

CA AB OEL : Canada. Alberta, Occupational Health and Safety Code (table

2: OEL)

CA BC OEL : Canada. British Columbia OEL

CA QC OEL : Québec. Regulation respecting occupational health and safe-

ty, Schedule 1, Part 1: Permissible exposure values for air-

borne contaminants

ACGIH / TWA : 8-hour, time-weighted average CA AB OEL / TWA : 8-hour Occupational exposure limit CA BC OEL / TWA : 8-hour time weighted average

CA QC OEL / TWAEV : Time-weighted average exposure 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 Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New

according to the Hazardous Products Regulations



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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 Agen-

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

Revision Date : 06/20/2025 Date format : mm/dd/yyyy

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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

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