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



# Milbemycin Oxime / Lufenuron / Praziquantel Formulation

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

1.1 Product identifier

Trade name : Milbemycin Oxime / Lufenuron / Praziguantel Formulation

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

Use of the Sub-

stance/Mixture

: Veterinary product

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Walton Manor, Walton

MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

### 1.4 Emergency telephone number

+1-908-423-6000

#### **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

## Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Skin sensitisation, Category 1 H317: May cause an allergic skin reaction. Reproductive toxicity, Category 1B H360D: May damage the unborn child.

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

exposure, Category 2 longed or repeated exposure.

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

gory 1

Long-term (chronic) aquatic hazard, Cat-

egory 1

H410: Very toxic to aquatic life with long lasting

effects.

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#### 2.2 Label elements

## Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)

Hazard pictograms :







Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H360D May damage the unborn child.

H373 May cause damage to organs through prolonged

or repeated exposure.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P201 Obtain special instructions before use. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye

protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/

attention.

P333 + P313 If skin irritation or rash occurs: Get medical

advice/ attention.

P391 Collect spillage.

Hazardous components which must be listed on the label:

Lufenuron (ISO)

#### 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.

Dust contact with the eyes can lead to mechanical irritation.

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

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

## **SECTION 3: Composition/information on ingredients**

#### 3.2 Mixtures

#### Components

			_
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		, ,

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	De alatuation of		
	Registration number		
Lufenuron (ISO)	103055-07-8 410-690-9 616-050-00-7	Skin Sens. 1; H317 Repr. 1B; H360D STOT RE 1; H372 (Central nervous system, Lungs, Liver, Stomach) Aquatic Acute 1; H400 Aquatic Chronic 1; H410  M-Factor (Acute aquatic toxicity): 10,000	>= 2.5 - < 10
		M-Factor (Chronic aquatic toxicity): 10	
Savorysel Bacon Flavor	Not Assigned	aquatic toxicity). 10	>= 1 - < 10
praziquantel	55268-74-1 259-559-6	Aquatic Chronic 3; H412	>= 2.5 - < 10
Milbemycin Oxime	129496-10-2	Acute Tox. 4; H302 Acute Tox. 4; H332 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	>= 0.25 - < 1
		aquatic toxicity): 10,000	
Substances with a workplace exposu		1	1
Starch	9005-25-8 232-679-6		>= 30 - < 50
Glycerine	56-81-5 200-289-5		>= 10 - < 20
Sucrose	57-50-1 200-334-9		>= 1 - < 10

For explanation of abbreviations see section 16.

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#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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

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

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

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

of water.

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse.

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

Get medical attention if irritation develops and persists.

If swallowed : If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water.

#### 4.2 Most important symptoms and effects, both acute and delayed

Risks : May cause an allergic skin reaction.

May damage the unborn child.

May cause damage to organs through prolonged or repeated

exposure.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation.

#### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

## **SECTION 5: Firefighting measures**

## 5.1 Extinguishing media

Suitable extinguishing media : Water spray

Alcohol-resistant foam

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Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Nitrogen oxides (NOx)

Metal oxides

Chlorine compounds

5.3 Advice for firefighters

Special protective equipment:

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment. Use water spray to cool unopened containers.

ose water spray to coor unopened containers.

Remove undamaged containers from fire area if it is safe to do

SO.

Evacuate area.

**SECTION 6: Accidental release measures** 

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Retail and dispose of contaminated wash water.

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

6.3 Methods and material for containment and cleaning up

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

tainer for disposal.

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

with compressed air).

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

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Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

### **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

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.

Do not breathe dust, fume, gas, mist, vapours 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 as-

sessment

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.

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

flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Contaminated work clothing should not be allowed out of the workplace.

Wash contaminated clothing before re-use.

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

use of administrative controls.

#### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers

Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

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

Strong oxidizing agents

Self-reactive substances and mixtures

Organic peroxides

Explosives Gases

7.3 Specific end use(s)

Specific use(s) : No data available

### **SECTION 8: Exposure controls/personal protection**

### 8.1 Control parameters

#### **Occupational Exposure Limits**

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Starch	9005-25-8	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40
Glycerine	56-81-5	TWA (Mist)	10 mg/m3	GB EH40
Lufenuron (ISO)	103055-07-	TWA	60 µg/m3 (OEB 3)	Internal
	8			
	Further information: DSEN			
		Wipe limit	100 μg/100 cm2	Internal
Sucrose	57-50-1	TWA	10 mg/m3	GB EH40
		STEL	20 mg/m3	GB EH40
Savorysel Bacon	Not As-	Wipe limit	OEB 2 (>= 100 < 1000	Internal
Flavor	signed		μg/m3)	
praziquantel	55268-74-1	TWA	0.5 mg/m3 (OEB 2)	Internal
Milbemycin Oxime	129496-10- 2	TWA	0.1 mg/m3 (OEB2)	Internal

### **Derived No Effect Level (DNEL)**

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068.62 mg/m3
	Workers	Inhalation	Acute systemic effects	2068.62 mg/m3
	Workers	Skin contact	Long-term systemic effects	295.52 mg/kg bw/day
	Workers	Skin contact	Acute systemic effects	295.52 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic	443.28 mg/m3

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		I	effects	
	Consumers	Inhalation	Acute systemic ef- fects	443.28 mg/m3
	Consumers	Skin contact	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Skin contact	Acute systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	126.65 mg/kg bw/day
	Consumers	Ingestion	Acute systemic effects	126.65 mg/kg bw/day
Glycerine	Workers	Inhalation	Long-term local ef- fects	56 mg/m3
	Consumers	Ingestion	Long-term systemic effects	229 mg/kg bw/day
	Consumers	Inhalation	Long-term local effects	33 mg/m3

#### **Predicted No Effect Concentration (PNEC)**

Substance name	Environmental Compartment	Value
Lufenuron (ISO)	Water	0.2 μg/l
praziquantel	Water	0.03 mg/l
Sodium chloride	Fresh water	5 mg/l
	Sewage treatment plant	500 mg/l
	Soil	4.86 mg/kg dry weight (d.w.)
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.)

#### 8.2 Exposure controls

### **Engineering measures**

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

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

Minimize open handling.

#### Personal protective equipment

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a

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potential for direct contact to the face with dusts, mists, or

aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

Skin and body protection : Work uniform or laboratory coat.

Additional body garments should be used based upon the task

being performed (e.g., sleevelets, apron, gauntlets, disposable

suits) to avoid exposed skin surfaces.

Use appropriate degowning techniques to remove potentially

contaminated clothing.

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

sure assessment demonstrates exposures outside the rec-

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

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

### **SECTION 9: Physical and chemical properties**

#### 9.1 Information on basic physical and chemical properties

Appearance : solid Colour : brown

Odour : characteristic
Odour Threshold : No data available

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, han-

dling or other means.

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

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Density : No data available

Solubility(ies)

Water solubility : soluble

Partition coefficient: n-

octanol/water

: Not applicable

Auto-ignition 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.

9.2 Other information

Flammability (liquids) : Not applicable

Molecular weight : No data available

Particle size : No data available

## **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

Not classified as a reactivity hazard.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

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

dling or other means.

Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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### **SECTION 11: Toxicological information**

#### 11.1 Information on toxicological effects

Information on likely routes of:

exposure

: Inhalation Skin contact

> Ingestion Eye contact

**Acute toxicity** 

Not classified based on available information.

**Components:** 

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/m3

Test atmosphere: dust/mist

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

Savorysel Bacon Flavor:

Acute oral toxicity : Remarks: Based on available data, the classification criteria

are not met.

Acute inhalation toxicity : Remarks: Not classified due to lack of data.

Acute dermal toxicity : Remarks: Based on available data, the classification criteria

are not met.

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

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

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

Sucrose:

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

Skin corrosion/irritation

Not classified based on available information.

**Components:** 

Lufenuron (ISO):

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

Savorysel Bacon Flavor:

Remarks : Based on data from similar materials

May irritate skin.

praziquantel:

Species : Rabbit
Method : Draize Test
Remarks : slight irritation

Milbemycin Oxime:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Glycerine:

Species : Rabbit

Result : No skin irritation

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#### Serious eye damage/eye irritation

Not classified based on available information.

#### **Components:**

Lufenuron (ISO):

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

Savorysel Bacon Flavor:

Remarks : Based on data from similar materials

May irritate eyes.

praziquantel:

Species : Rabbit
Method : Draize Test
Result : Mild eye irritation

Milbemycin Oxime:

Species : Rabbit

Result : No eye irritation

Starch:

Species : Rabbit

Result : No eye irritation

Glycerine:

Species : Rabbit

Result : No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

#### Respiratory sensitisation

Not classified based on available information.

#### **Components:**

#### Lufenuron (ISO):

Test Type : Maximisation Test

Species : Guinea pig

Assessment : May cause sensitisation by skin contact.

Result : Sensitiser

#### Savorysel Bacon Flavor:

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Remarks : Not classified due to lack of data.

praziquantel:

Test Type : Maximisation Test

Exposure routes : Dermal Species : Guinea pig

Result : Not a skin sensitizer.

Milbemycin Oxime:

Exposure routes : Skin contact
Species : Guinea pig
Result : negative

Starch:

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

#### Germ cell mutagenicity

Not classified based on available information.

#### **Components:**

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

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

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

lar cells Species: Rat Result: negative

Germ cell mutagenicity- As-

sessment

Weight of evidence does not support classification as a germ

cell mutagen.

Savorysel Bacon Flavor:

Genotoxicity in vitro : Remarks: Not classified due to lack of data.

Genotoxicity in vivo : Remarks: Not classified due to lack of data.

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

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

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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

Sucrose:

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

Result: negative

Carcinogenicity

Not classified based on available information.

**Components:** 

Lufenuron (ISO):

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

NOAEL : 250 mg/kg body weight

Result : negative

Remarks : No significant adverse effects were reported

Glycerine:

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

Reproductive toxicity

May damage the unborn child.

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**Components:** 

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 foetal develop-

ment

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-foetal toxicity: 8.3 mg/kg body weight

Result: foetal abnormalities

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

Savorysel Bacon Flavor:

Effects on fertility : Remarks: No data available

Effects on foetal develop-

ment

Remarks: No data available

praziquantel:

Effects on fertility : Test Type: Fertility

Species: Rat

Remarks: No significant adverse effects were reported

Test Type: Fertility Species: Mouse

Remarks: No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Remarks: No significant adverse effects were reported

Test Type: Development

Species: Mouse

Remarks: No significant adverse effects were reported

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



# Milbemycin Oxime / Lufenuron / Praziquantel Formulation

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Milbemycin Oxime:

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

Species: Dog

**Application Route: Ingestion** 

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Ingestion

Result: negative

Test Type: Embryo-foetal development

Species: Dog

Application Route: Ingestion

Result: negative

Glycerine:

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

Species: Rat

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

#### STOT - single exposure

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

May cause damage to organs through prolonged or repeated exposure.

#### **Components:**

Lufenuron (ISO):

Exposure routes : Oral

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

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



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

centrations of 10 mg/kg bw or less.

Milbemycin Oxime:

Exposure routes : 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:** 

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

Species : Rat

NOAEL : 1.93 mg/kg
Application Route : oral (feed)
Exposure time : 2 yr

Symptoms : central nervous system effects, Convulsions

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

Target Organs : 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 yr

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

Savorysel Bacon Flavor:

Remarks : Not classified due to lack of data.

praziquantel:

Species : Rat

NOAEL : 1,000 mg/kg

Application Route : Oral

Remarks : No significant adverse effects were reported

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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

Starch:

Species : Rat

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

Method : OECD Test Guideline 410

Glycerine:

 Species
 : Rat

 NOAEL
 : 0.167 mg/l

 LOAEL
 : 0.622 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 13 Weeks

Species : Rat

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

Application Route : Ingestion Exposure time : 2 yr

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

#### **Aspiration toxicity**

Not classified based on available information.

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#### **Experience with human exposure**

**Components:** 

Lufenuron (ISO):

General Information : Remarks: May be harmful if swallowed.

May cause neurotoxic effects.

Savorysel Bacon Flavor:

General Information : Remarks: Based on data from similar materials

May irritate skin. May irritate eyes.

praziquantel:

Inhalation : Symptoms: Headache, Tiredness, Dizziness, Gastrointestinal

discomfort, decrease body temperature, Allergic reactions

Milbemycin Oxime:

Ingestion : Symptoms: Salivation, Convulsions, Diarrhoea, Weakness,

Vomiting, Tremors, Coma

Remarks: Based on Animal Evidence

**Further information** 

**Components:** 

Savorysel Bacon Flavor:

Remarks : No toxicology information is available.

#### **SECTION 12: Ecological information**

#### 12.1 Toxicity

## **Components:**

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)): >  $29,000 \mu g/l$ 

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

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## Milbemycin Oxime / Lufenuron / Praziquantel Formulation

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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

M-Factor (Acute aquatic tox-

icity)

10,000

Toxicity to fish (Chronic tox-

icity)

NOEC: 80 µg/l

Exposure time: 33 d

Species: Oncorhynchus mykiss (rainbow trout)

Method: OECD Test Guideline 210

NOEC: 20 µg/l Exposure time: 359 d

Species: Oncorhynchus mykiss (rainbow trout)

Method: OECD Test Guideline 229

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 8.38 µg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

NOEC: 90 μg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

NOEC: 2 µg/l Exposure time: 21 d

Species: Chironomus riparius (harlequin fly)

Method: OECD Test Guideline 211

M-Factor (Chronic aquatic

toxicity)

10

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

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



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

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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:

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

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 0.03 μg/l

Species: Daphnia magna (Water flea)

Exposure time: 48 h

Toxicity to algae/aquatic

plants

: EC50 : > 87  $\mu$ g/l

NOEC: 0.01 µg/l

Exposure time: 72 h

M-Factor (Acute aquatic tox-

icity)

10,000

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

M-Factor (Chronic aquatic

10,000

toxicity)

**Glycerine:** 

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

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

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

Exposure time: 48 h

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

Exposure time: 16 h

Method: DIN 38 412 Part 8

#### 12.2 Persistence and degradability

#### **Components:**

Glycerine:

Biodegradability Result: Readily biodegradable.

Biodegradation: 92 % Exposure time: 30 d

Method: OECD Test Guideline 301D

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#### 12.3 Bioaccumulative potential

**Components:** 

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

praziquantel:

Partition coefficient: n-

: log Pow: 2.012 pH: 7

octanol/water

Milbemycin Oxime:

Bioaccumulation : Bioconcentration factor (BCF): 440

Partition coefficient: n-

octanol/water

: log Pow: 7

Glycerine:

Partition coefficient: n-

octanol/water

log Pow: -1.75

Sucrose:

Partition coefficient: n-

octanol/water

Pow: < 1

12.4 Mobility in soil

Components:

Lufenuron (ISO):

Distribution among environ-

log Koc: 5.38

mental compartments

Method: OECD Test Guideline 106

12.5 Results of PBT and vPvB assessment

**Product:** 

Assessment : This substance/mixture contains no components considered

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

0.1% or higher.

12.6 Other adverse effects

**Product:** 

Endocrine disrupting poten-

tial

This substance/mixture does not contain components considered to have endocrine disrupting properties for environment

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according to UK REACH Article 57(f).

### **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

According to the European Waste Catalogue, Waste Codes

are not product specific, but application specific.

Waste codes should be assigned by the user, preferably in

discussion with the waste disposal authorities.

Do not dispose of waste into sewer.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

### **SECTION 14: Transport information**

#### 14.1 UN number

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

### 14.2 UN proper shipping name

**ADN** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Milbemycin Oxime, Lufenuron (ISO))

**ADR** : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Milbemycin Oxime, Lufenuron (ISO))

RID : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Milbemycin Oxime, Lufenuron (ISO))

IMDG : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,

N.O.S.

(Milbernycin Oxime, Lufenuron (ISO))

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

(Milbemycin Oxime, Lufenuron (ISO))

#### 14.3 Transport hazard class(es)

Class Subsidiary risks

**ADN** : 9

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 ADR
 : 9

 RID
 : 9

 IMDG
 : 9

 IATA
 : 9

### 14.4 Packing group

ADN

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

**ADR** 

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

**RID** 

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

**IMDG** 

Packing group : III Labels : 9

EmS Code : F-A, S-F

IATA (Cargo)

Packing instruction (cargo : 956

aircraft)

Packing instruction (LQ) : Y956 Packing group : III

Labels : Miscellaneous

IATA (Passenger)

Packing instruction (passen- : 956

ger aircraft)

Packing instruction (LQ) : Y956
Packing group : III

Labels : Miscellaneous

14.5 Environmental hazards

ADN

Environmentally hazardous : yes

**ADR** 

Environmentally hazardous : yes

**RID** 

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Environmentally hazardous : yes

**IMDG** 

Marine pollutant : yes

IATA (Passenger)

Environmentally hazardous : yes

IATA (Cargo)

Environmentally hazardous : yes

#### 14.6 Special precautions for user

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

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

Remarks : Not applicable for product as supplied.

#### **SECTION 15: Regulatory information**

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

Relevant EU provisions transposed through retained EU law

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

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

concern (SVHC) for Authorisation

The Persistent Organic Pollutants Regulations (retained : Not applicable

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

ain)

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

layer

UK REACH List of substances subject to authorisation : Not applicable

(Annex XIV)

GB Export and import of hazardous chemicals - Prior : Not applicable

Informed Consent (PIC) Regulation

Control of Major Accident Hazards Regulations 2015 (COMAH)

Quantity 1 Quantity 2

E1 ENVIRONMENTAL 100 t 200 t

**HAZARDS** 

#### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

#### **SECTION 16: Other information**

Other information : Items where changes have been made to the previous version

are highlighted in the body of this document by two vertical

lines.

#### **Full text of H-Statements**

H302 : Harmful if swallowed.

H317 : May cause an allergic skin reaction.

H332 : Harmful if inhaled.

H360D : May damage the unborn child.

H372 : Causes damage to organs through prolonged or repeated

exposure.

H372 : Causes damage to organs through prolonged or repeated

exposure if swallowed.

H400 : Very toxic to aquatic life.

H410 : Very toxic to aquatic life with long lasting effects.H412 : Harmful to aquatic life with long lasting effects.

#### Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity Skin Sens. : Skin sensitisation

STOT RE : Specific target organ toxicity - repeated exposure GB EH40 : UK. EH40 WEL - Workplace Exposure Limits

GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - 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

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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 mixture: Classification procedure:

Skin Sens. 1	H317	Calculation method
Repr. 1B	H360D	Calculation method
STOT RE 2	H373	Calculation method
Aquatic Acute 1	H400	Calculation method
Aquatic Chronic 1	H410	Calculation method

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

GB / EN