

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09.05.2025
5.2	08.07.2025	7602783-00014	Date of first issue: 20.11.2020

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

#### 1.1 Product identifier

Trade name : Milbemycin Oxime / Lufenuron / Praziquantel 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  
Drynam Road  
K67 P263 Dublin, Ireland

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)

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 exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.
Short-term (acute) aquatic hazard, Category 1	H400: Very toxic to aquatic life.
Long-term (chronic) aquatic hazard, Category 1	H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

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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.

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

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

Dust contact with the eyes can lead to mechanical irritation.  
Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No.	Classification	Concentration
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	EC-No. Index-No. Registration number		(% w/w)
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 M-Factor (Chronic aquatic toxicity): 10	$\geq 2.5 - < 10$
praziquantel	55268-74-1 259-559-6	Aquatic Chronic 3; H412	$\geq 2.5 - < 10$
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 aquatic toxicity): 10,000  Acute toxicity esti- mate  Acute oral toxicity: 500 mg/kg Acute inhalation tox- icity (dust/mist): 1.2 mg/l	$\geq 0.25 - < 1$

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 advice immediately.<br>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.<br>Get medical attention.  |
| In case of skin contact    | : | In case of contact, immediately flush skin with soap and plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : | If in eyes, rinse well with water.<br>Get medical attention if irritation develops and persists.  |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.   |

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

- |       |   |   |
|-------|---|---|
| Risks | : | Contact with dust can cause mechanical irritation or drying of the skin.<br>Dust contact with the eyes can lead to mechanical irritation.<br><br>May cause an allergic skin reaction.<br>May damage the unborn child.<br>May cause damage to organs through prolonged or repeated exposure. |
|-------|---|---|

#### 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<br>Alcohol-resistant foam |
|------------------------------|---|---------------------------------------|

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Carbon dioxide (CO<sub>2</sub>)  
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 products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
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 methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

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

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

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

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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 determine 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.<br>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.<br>Avoid breathing dust, fume, gas, mist, vapours or spray.<br>Do not swallow.<br>Avoid contact with eyes.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>Do not eat, drink or smoke when using this product.<br>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.<br>Wash contaminated clothing before re-use.<br>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	OELV - 8 hrs (TWA) (Respirable dust)	4 mg/m <sup>3</sup>	IE OEL
		OELV - 8 hrs (TWA) (inhalable dust)	10 mg/m <sup>3</sup>	IE OEL
Lufenuron (ISO)	103055-07-8	TWA	200 µg/m <sup>3</sup> (OEB 2)	Internal
Further information: DSEN				
		Wipe limit	100 µg/100 cm <sup>2</sup>	Internal
Sucrose	57-50-1	OELV - 8 hrs (TWA)	10 mg/m <sup>3</sup>	IE OEL
		OELV - 15 min (STEL)	20 mg/m <sup>3</sup>	IE OEL
praziquantel	55268-74-1	TWA	0.5 mg/m <sup>3</sup> (OEB 2)	Internal
Milbemycin Oxime	129496-10-2	TWA	0.1 mg/m <sup>3</sup> (OEB2)	Internal

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

Substance name	End Use	Exposure routes	Potential health effects	Value
Sodium chloride	Workers	Inhalation	Long-term systemic effects	2068.62 mg/m <sup>3</sup>
	Workers	Inhalation	Acute systemic effects	2068.62 mg/m <sup>3</sup>
	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/m <sup>3</sup>

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			effects	
	Consumers	Inhalation	Acute systemic effects	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 effects	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) according to Regulation (EC) No. 1907/2006

Substance name	Environmental Compartment	Value
Lufenuron (ISO)	Water	0.2 µg/l
praziquantel	Fresh water	0.03 mg/l
	Marine 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

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

### Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.



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Hand protection	
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
	Filter should conform to I.S. 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

Physical state	: solid
Colour	: brown
Odour	: characteristic
Odour Threshold	: No data available
Melting point/freezing point	: No data available
Initial boiling point and boiling range	: No data available
Flammability (solid, gas)	: May form explosive dust-air mixture during processing, 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
Flash point	: Not applicable
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
pH	: No data available
Viscosity	
Viscosity, kinematic	: Not applicable
Solubility(ies)	

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Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Vapour pressure : Not applicable

Relative density : No data available

Density : No data available

Relative vapour density : Not applicable

Particle characteristics  
Particle size : No data available

### 9.2 Other information

Explosives : Not explosive

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

Evaporation rate : Not applicable

Molecular weight : No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

Hazardous reactions : May form explosive dust-air mixture during processing, handling 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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

##### Acute toxicity

Not classified based on available information.

##### Components:

##### **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>
	Test atmosphere: dust/mist
Acute dermal toxicity	: LD50 (Rabbit): > 2,000 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/m <sup>3</sup>
	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:

##### **Lufenuron (ISO):**

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

### **praziquantel:**

Species	:	Rabbit
Method	:	Draize Test
Remarks	:	slight irritation

### **Milbemycin Oxime:**

Species	:	Rabbit
Method	:	OECD Test Guideline 404
Result	:	No skin irritation

### **Serious eye damage/eye irritation**

Not classified based on available information.

### **Components:**

#### **Lufenuron (ISO):**

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

#### **praziquantel:**

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

#### **Milbemycin Oxime:**

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

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### **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

### **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 synthesis 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 testicular cells Species: Rat Result: negative
Germ cell mutagenicity- Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

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### **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

### **Carcinogenicity**

Not classified based on available information.

### **Components:**

#### **Lufenuron (ISO):**

Species : Rat  
Application Route : Ingestion  
Exposure time : 18 month(s)  
Result : negative

Carcinogenicity - Assessment : Weight of evidence does not support classification as a carcinogen

#### **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

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Result : negative  
Remarks : No significant adverse effects were reported

### Reproductive toxicity

May damage the unborn child.

### 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 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-foetal toxicity: 8.3 mg/kg body weight  
Result: foetal abnormalities

Reproductive toxicity - Assessment : 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 foetal 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

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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 development : 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

### 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  
Assessment : Shown to produce significant health effects in animals at concentrations 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 concentrations of 10 mg/kg bw or less.



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### 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

##### **praziquantel:**

Species	: Rat
NOAEL	: 1,000 mg/kg
Application Route	: Oral
Remarks	: No significant adverse effects were reported

Species	: Dog
NOAEL	: 60 mg/kg
LOAEL	: 180 mg/kg
Application Route	: Oral
Target Organs	: Gastrointestinal tract
Remarks	: No significant adverse effects were reported

##### **Milbemycin Oxime:**

Species	: Rat
NOAEL	: 3 mg/kg
LOAEL	: 15 mg/kg
Application Route	: Ingestion

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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.

## 11.2 Information on other hazards

### Endocrine disrupting properties

Not classified based on available information.

### Product:

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

### Components:

#### Lufenuron (ISO):

General Information	: Remarks: May be harmful if swallowed. May cause neurotoxic effects.
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#### praziquantel:

Inhalation	: Symptoms: Headache, Tiredness, Dizziness, Gastrointestinal discomfort, decrease body temperature, Allergic reactions
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#### Milbemycin Oxime:

Ingestion	: Symptoms: Salivation, Convulsions, Diarrhoea, Weakness, Vomiting, Tremors, Coma Remarks: Based on Animal Evidence
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## 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
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		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
M-Factor (Acute aquatic toxicity)	:	10,000
Toxicity to fish (Chronic toxicity)	:	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 (Chronic 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)

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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

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  
Exposure time: 48 h

Toxicity to algae/aquatic plants : EC50 : > 87 µg/l  
Exposure time: 72 h

M-Factor (Acute aquatic toxicity) : 10,000

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0.01 µg/l  
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity) : 10,000

## **12.2 Persistence and degradability**

No data available

## **12.3 Bioaccumulative potential**

### **Components:**

#### **Lufenuron (ISO):**

Bioaccumulation : Species: Lepomis macrochirus (Bluegill sunfish)  
Bioconcentration factor (BCF): 28

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Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 5.12

### **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

## 12.4 Mobility in soil

### Components:

#### **Lufenuron (ISO):**

Distribution among environmental compartments : log Koc: 5.38  
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 Endocrine disrupting properties

### Product:

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

## 12.7 Other adverse effects

No data available

## 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.

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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 handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

### SECTION 14: Transport information

#### 14.1 UN number or ID number

ADN	: 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. (Milbemycin 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	
ADR	: 9	
RID	: 9	
IMDG	: 9	
IATA	: 9	

#### 14.4 Packing group

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### 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 aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

### IATA (Passenger)

Packing instruction (passenger aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

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### 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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable for product as supplied.

## SECTION 15: Regulatory information

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

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

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable  
Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable  
Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable  
Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Lufenuron (ISO)  
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

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

E1	ENVIRONMENTAL HAZARDS	Quantity 1 100 t	Quantity 2 200 t
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### Other regulations:

Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations,



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where applicable.

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

### 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.
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### 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
IE OEL	:	Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2
IE OEL / OELV - 8 hrs (TWA)	:	Occupational exposure limit value (8-hour reference period)
IE OEL / OELV - 15 min (STEL)	:	Occupational exposure limit value (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; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Test-

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ing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; 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 Agency, <http://echa.europa.eu/>

### Classification of the mixture:

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

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method
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

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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.

IE / EN