

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

---

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

#### 1.1 Product identifier

Trade name : Milbemycin Oxime / Lufenuron 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  
exposure, Category 1 H372: Causes damage to organs through pro-  
longed or repeated exposure.

Short-term (acute) aquatic hazard, Cate-  
gory 1 H400: Very toxic to aquatic life.

Long-term (chronic) aquatic hazard, Cat-  
egory 1 H410: Very toxic to aquatic life with long lasting  
effects.

# SAFETY DATA SHEET

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




## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

### 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.  
H372 Causes 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.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% 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	>= 30 - < 50

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version 6.1      Revision Date: 09.05.2025      SDS Number: 9374592-00010      Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

		(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	
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	$\geq 1 - < 2.5$
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		$\geq 10 - < 20$
Starch	9005-25-8 232-679-6		$\geq 1 - < 10$

For explanation of abbreviations see section 16.

### 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.  
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.

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

---

- |                         |   |   |
|-------------------------|---|---|
| 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  | : | Flush eyes with water as a precaution.<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 | : | May cause an allergic skin reaction.<br>May damage the unborn child.<br>Causes 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<br>Carbon dioxide (CO <sub>2</sub> )<br>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<br>Nitrogen oxides (NO <sub>x</sub> )<br>Metal oxides |

### 5.3 Advice for firefighters

- |   |   |  |
|---|---|--|
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |
| Specific extinguishing method                 | : | Use extinguishing measures that are appropriate to local cir-  |

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

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.

### 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.  
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 container for disposal.  
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 : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

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, 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 assessment  
Keep container tightly closed.

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version 6.1      Revision Date: 09.05.2025      SDS Number: 9374592-00010      Date of last issue: 14.04.2025  
Date of first issue: 27.08.2021

Hygiene measures : Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.  
If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. 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.

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
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
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40
		STEL (inhalable dust)	20 mg/m <sup>3</sup>	GB EH40
Starch	9005-25-8	TWA (inhalable dust)	10 mg/m <sup>3</sup>	GB EH40
		TWA (Respirable dust)	4 mg/m <sup>3</sup>	GB EH40

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

Milbemycin Oxime	129496-10-2	TWA	0.1 mg/m3 (OEB2)	Internal
------------------	-------------	-----	------------------	----------

### Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Lufenuron (ISO)	Water	0.2 µg/l

## 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.
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. Equipment should conform to BS EN 143
Filter type	: Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Appearance	: solid
Colour	: brown
Odour	: odourless
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)	: No data available
Flammability (liquids)	: Not applicable

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

---

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
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

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	:	Can react with strong oxidizing agents.
---------------------	---	---

### 10.4 Conditions to avoid

Conditions to avoid	:	None known.
---------------------	---	-------------



# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Information on likely routes of exposure : 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 inhalation toxicity : Acute toxicity estimate: > 5 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

#### 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

##### **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

##### **Cellulose:**

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

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

---

Acute inhalation toxicity : LC50 (Rat): > 5.8 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist

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

### Starch:

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

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

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Lufenuron (ISO):

Species	: Rabbit
Method	: Draize Test
Result	: No skin 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

#### Milbemycin Oxime:

Species	: Rabbit
Result	: No eye irritation

### Starch:

Species	: Rabbit
Result	: No eye irritation

### Respiratory or skin sensitisation

#### Skin sensitisation

May cause an allergic skin reaction.

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

---

### 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

#### 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 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

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

---

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.

### 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

### Cellulose:

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

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)  
Species: Mouse  
Application Route: Ingestion  
Result: negative

### Starch:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
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- : Weight of evidence does not support classification as a car-

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

ment

cinogen

### Cellulose:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	72 weeks
Result	:	negative

### 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.

#### 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

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

---

Test Type: Embryo-foetal development  
Species: Rabbit  
Application Route: Ingestion  
Result: negative

Test Type: Embryo-foetal development  
Species: Dog  
Application Route: Ingestion  
Result: negative

### Cellulose:

Effects on fertility : Test Type: One-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Result: negative

Effects on foetal development : Test Type: Fertility/early embryonic 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

Causes 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.

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

---

### 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

##### **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

##### **Cellulose:**

Species	: Rat
NOAEL	: >= 9,000 mg/kg
Application Route	: Ingestion
Exposure time	: 90 Days

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

### Starch:

Species	:	Rat
NOAEL	:	>= 2,000 mg/kg
Application Route	:	Skin contact
Exposure time	:	28 Days
Method	:	OECD Test Guideline 410

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Lufenuron (ISO):

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

#### Milbemycin Oxime:

Ingestion	:	Symptoms: Salivation, Convulsions, Diarrhoea, Weakness, Vomiting, Tremors, Coma Remarks: Based on Animal Evidence
-----------	---	---

## 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 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
----------------------------------	---	--



# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

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)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

### 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)

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

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

### Cellulose:

Toxicity to fish : LC50 (Oryzias latipes (Japanese medaka)): > 100 mg/l  
Exposure time: 48 h  
Remarks: Based on data from similar materials

### 12.2 Persistence and degradability

#### Components:

#### Cellulose:

Biodegradability : Result: Readily biodegradable.

### 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

#### 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 Other adverse effects

#### Product:

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment 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 handling 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.  
(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	

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

<b>ADR</b>	:	9
<b>RID</b>	:	9
<b>IMDG</b>	:	9
<b>IATA</b>	:	9

### 14.4 Packing group

<b>ADN</b>	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9

<b>ADR</b>	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9
Tunnel restriction code	: (-)

<b>RID</b>	
Packing group	: III
Classification Code	: M7
Hazard Identification Number	: 90
Labels	: 9

<b>IMDG</b>	
Packing group	: III
Labels	: 9
EmS Code	: F-A, S-F

<b>IATA (Cargo)</b>	
Packing instruction (cargo aircraft)	: 956
Packing instruction (LQ)	: Y956
Packing group	: III
Labels	: Miscellaneous

<b>IATA (Passenger)</b>	
Packing instruction (passenger aircraft)	: 956
Packing instruction (LQ)	: Y956
Packing group	: III
Labels	: Miscellaneous

### 14.5 Environmental hazards

<b>ADN</b>	
Environmentally hazardous	: yes

<b>ADR</b>	
Environmentally hazardous	: yes

<b>RID</b>	
Environmentally hazardous	: yes

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

### 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 concern (SVHC) for Authorisation : Not applicable

The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain) : Not applicable

Regulation (EU) No 2024/590 on substances that deplete the ozone layer : Not applicable

UK REACH List of substances subject to authorisation (Annex XIV) : Not applicable

GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation : Not applicable

Control of Major Accident Hazards Regulations 2015 (COMAH)

		Quantity 1	Quantity 2
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

### 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.

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

AICS : not determined

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

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.

#### 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 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;

# SAFETY DATA SHEET

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



## Milbemycin Oxime / Lufenuron Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
6.1	09.05.2025	9374592-00010	Date of first issue: 27.08.2021

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 Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Skin Sens. 1	H317
Repr. 1B	H360D
STOT RE 1	H372
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 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