

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: 04.04.2023
3.1	30.09.2023	7602788-00009	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
Kilsheelan
Clonmel Tipperary, IE

Telephone : 353-51-601000

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)


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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

- 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

SAFETY DATA SHEET

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



Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Version 3.1 Revision Date: 30.09.2023 SDS Number: 7602788-00009 Date of last issue: 04.04.2023
Date of first issue: 20.11.2020

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 (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	>= 2,5 - < 10
Savorysel Bacon Flavor	Not Assigned		>= 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 aquatic toxicity): 10.000 Acute toxicity esti- mate Acute oral toxicity: 532 mg/kg Acute inhalation toxicity (dust/mist): 1,2 mg/l	>= 0,25 - < 1

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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.
- 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.

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
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 products : Carbon oxides
Nitrogen oxides (NO_x)
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 con-

SAFETY DATA SHEET

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Commission Regulation (EU) 2020/878



Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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.
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.
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 assessment
Keep container tightly closed.
Minimize dust generation and accumulation.
Keep container closed when not in use.
Keep away from heat and sources of ignition.
Take precautionary measures against static discharges.
Do not eat, drink or smoke when using this product.
Take care to prevent spills, waste and minimize release to the environment. |
| 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 |

SAFETY DATA SHEET

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



Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Version 3.1 Revision Date: 30.09.2023 SDS Number: 7602788-00009 Date of last issue: 04.04.2023
Date of first issue: 20.11.2020

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	OEB 3 ($\geq 10 < 100 \mu\text{g}/\text{m}^3$)	Internal
Savorysel Bacon Flavor	Not Assigned	Wipe limit	OEB 2 ($\geq 100 < 1000 \mu\text{g}/\text{m}^3$)	Internal
praziquantel	55268-74-1	TWA	0.5 mg/m ³ (OEB 2)	Internal
Milbemycin Oxime	129496-10-2	TWA	0.1 mg/m ³ (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 ³
	Workers	Inhalation	Acute systemic effects	2068,62 mg/m ³
	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 effects	443,28 mg/m ³
	Consumers	Inhalation	Acute systemic effects	443,28 mg/m ³
	Consumers	Skin contact	Long-term systemic	126,65 mg/kg

SAFETY DATA SHEET

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



Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Version 3.1 Revision Date: 30.09.2023 SDS Number: 7602788-00009 Date of last issue: 04.04.2023
Date of first issue: 20.11.2020

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

Hand protection

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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 exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to NS 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

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

Viscosity
Viscosity, kinematic : Not applicable

Solubility(ies)
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

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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/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

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

LD50 (Mouse): 722 - 946 mg/kg

Acute inhalation toxicity : LC50 (Rat): 1.200 mg/m³
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

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

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:

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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

Savorysel Bacon Flavor:

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

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

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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.

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

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: 04.04.2023
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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
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.

SAFETY DATA SHEET

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Commission Regulation (EU) 2020/878



Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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.

Savorysel Bacon Flavor:

Effects on fertility : Remarks: No data available

Effects on foetal development : 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 development : Test Type: Development
Species: Rat
Remarks: No significant adverse effects were reported

Test Type: Development
Species: Mouse
Remarks: No significant adverse effects were reported

Milbemycin Oxime:

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

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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.

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

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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

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

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

Symptoms : Tremors

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

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.

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):

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

- 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
- 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)
Method: OECD Test Guideline 211

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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
Method: OECD Test Guideline 305

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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 environ-
mental 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.

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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

ADN Packing group	:	III
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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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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

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

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : 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:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

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

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIC - 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

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: 04.04.2023
3.1	30.09.2023	7602788-00009	Date of first issue: 20.11.2020

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; 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 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 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.

NO / EN