according to the Globally Harmonized System



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

Version Revision Date: SDS Number: Date of last issue: 04.04.2023 30.09.2023 7567911-00009 Date of first issue: 20.11.2020 2.6

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Product name Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Manufacturer or supplier's details

MSD Company

Address Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

Telephone +1-908-740-4000

Emergency telephone number: +1-908-423-6000

EHSDATASTEWARD@msd.com E-mail address

Recommended use of the chemical and restrictions on use

Recommended use Veterinary product Restrictions on use Not applicable

#### 2. HAZARDS IDENTIFICATION

### Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

#### Classification

Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

**GHS Classification** 

Skin sensitisation Category 1

Reproductive toxicity Category 1B

repeated exposure (Oral)

Specific target organ toxicity - : Category 2 (Central nervous system, Lungs, Liver, Stomach)

Short-term (acute) aquatic

hazard

Category 1

Long-term (chronic) aquatic

hazard

Category 1

**GHS** label elements

Hazard pictograms







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Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.

H360D May damage the unborn child.

H373 May cause damage to organs (Central nervous system, Lungs, Liver, Stomach) through prolonged or repeated expo-

sure if swallowed.

H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : Prevention:

P203 Obtain, read and follow all safety instructions before use. P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray. P272 Contaminated work clothing should not be allowed out of

the workplace.

P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water. P318 IF exposed or concerned, get medical advice.

P333 + P317 If skin irritation or rash occurs: Get medical help. P362 + P364 Take off contaminated clothing and wash it before

reuse.

P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

### Other hazards which do not result in classification

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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

## Components

Chemical name	CAS-No.	Concentration (%	
		w/w)	
Starch	9005-25-8	>= 30 - < 50	
Lufenuron (ISO)	103055-07-8	>= 5 - < 10	
Savorysel Bacon Flavor	Not Assigned	>= 5 - < 10	
Sucrose	57-50-1	>= 5 - < 10	
praziquantel	55268-74-1	>= 2.5 - < 5	
Sodium chloride	7647-14-5	>= 1 - < 5	
Milbemycin Oxime	129496-10-2	>= 0.25 - < 1	

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4. FIRST AID MEASURES

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

vice immediately.

When symptoms persist or in all cases of doubt seek medical

advice.

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.

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

Get medical attention if irritation develops and persists.

If swallowed If swallowed, DO NOT induce vomiting.

Get medical attention.

Rinse mouth thoroughly with water. May cause an allergic skin reaction.

and effects, both acute and May damage the unborn child.

delayed May cause damage to organs through prolonged or repeated

exposure if swallowed.

Contact with dust can cause mechanical irritation or drying of

the skin.

Dust contact with the eyes can lead to mechanical irritation. 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).

Treat symptomatically and supportively. Notes to physician

5. FIREFIGHTING MEASURES

Protection of first-aiders

Most important symptoms

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical None known.

Unsuitable extinguishing

media

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Nitrogen oxides (NOx)

Metal oxides

Chlorine compounds

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.

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

Evacuate area.

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Special protective equipment:

for firefighters

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

Use personal protective equipment.

#### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

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

tective equipment recommendations (see section 8).

Environmental precautions : Avoid release to the environment.

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

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Sweep up or vacuum up spillage and collect in suitable con-

tainer for disposal.

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

with compressed air).

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

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 7. HANDLING AND STORAGE

Technical measures : Static electricity may accumulate and ignite suspended dust

causing an explosion.

Provide adequate precautions, such as electrical grounding

and bonding, or inert atmospheres.

Local/Total ventilation : If sufficient ventilation is unavailable, use with local exhaust

ventilation.

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

Do not breathe dust, fume, gas, mist, vapours or spray.

Do not swallow.

Avoid contact with eyes.

Wash skin thoroughly after handling.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure as-

sessment

Keep container tightly closed.

Minimize dust generation and accumulation. Keep container closed when not in use. Keep away from heat and sources of ignition.

Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product.

Take care to prevent spills, waste and minimize release to the

according to the Globally Harmonized System



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environment.

Conditions for safe storage : Keep in properly labelled containers.

Store locked up. Keep tightly closed.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	TWA	10 mg/m3	ACGIH
Lufenuron (ISO)	103055-07-8	TWA	OEB 3 (>= 10 < 100 μg/m3)	Internal
Sucrose	57-50-1	TWA	10 mg/m3	ACGIH
Savorysel Bacon Flavor	Not Assigned	Wipe limit	OEB 2 (>= 100 < 1000 μg/m3)	Internal
praziquantel	55268-74-1	TWA	0.5 mg/m3 (OEB 2)	Internal
Milbemycin Oxime	129496-10-2	TWA	0.1 mg/m3 (OEB2)	Internal

**Engineering measures** : 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 contain-

ment devices).

Minimize open handling.

Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and organic vapour type

Filter type
Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving.

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

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

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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.

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

flushing systems and safety showers close to the working

place.

When using do not eat, drink or smoke.

Contaminated work clothing should not be allowed out of the

workplace.

Wash contaminated clothing before re-use.

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

use of administrative controls.

#### 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid

Colour : brown

Odour : characteristic

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, han-

dling or other means.

Flammability (liquids) : Not applicable

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapour pressure : Not applicable

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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.

Molecular weight : No data available

Particle size : No data available

#### 10. STABILITY AND REACTIVITY

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

Possibility of hazardous reac-

tions

May form explosive dust-air mixture during processing, han-

dling or other means.

Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.

Avoid dust formation.

Incompatible materials

Hazardous decomposition

products

Oxidizing agents

No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Information on likely routes of:

exposure

: Inhalation Skin contact

> Ingestion Eye contact

#### **Acute toxicity**

Not classified based on available information.

### **Product:**

according to the Globally Harmonized System



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Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg

Method: Calculation method

**Components:** 

Starch:

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

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

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.

Sucrose:

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

praziquantel:

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

LD50 (Mouse): 2,454 mg/kg

LD50 (Dog): > 200 mg/kg

LD50 (Rabbit): 1,050 mg/kg

Sodium chloride:

Acute oral toxicity : LD50 (Rat): 3,550 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 42 mg/l

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Exposure time: 1 h

Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 5,000 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/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

Sodium chloride:

Species : Rabbit

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.

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**Components:** 

Starch:

Species : Rabbit

Result : No eye irritation

Lufenuron (ISO):

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

Savorysel Bacon Flavor:

Remarks : Based on data from similar materials

May irritate eyes.

praziquantel:

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

Sodium chloride:

Species : Rabbit

Result : No 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:** 

Starch:

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

Lufenuron (ISO):

Test Type : Maximisation Test

Species : Guinea pig

Assessment : May cause sensitisation by skin contact.

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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.

Sodium chloride:

Test Type : Local lymph node assay (LLNA)

Exposure routes : Skin contact
Species : Mouse
Result : negative

Milbemycin Oxime:

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

Germ cell mutagenicity

Not classified based on available information.

**Components:** 

Starch:

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

Result: negative

Lufenuron (ISO):

Genotoxicity in vitro : Test Type: Ames test

Result: negative

Test Type: Mouse Lymphoma Test system: Chinese hamster cells

Result: negative

Test Type: Cytogenetic assay

Test system: Chinese hamster ovary cells

Result: negative

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

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

Result: negative

Test system: Human lymphocytes

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Result: negative

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

cytogenetic assay) Species: Mouse Result: negative

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

lar cells Species: Rat Result: negative

Germ cell mutagenicity -

Assessment

Weight of evidence does not support classification as a germ

cell mutagen.

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.

Sucrose:

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

Result: negative

praziquantel:

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

Result: negative

Test Type: Chromosomal aberration Test system: Chinese hamster cells

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat Result: negative

Sodium chloride:

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

Result: positive

Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Saccharomyces cerevisiae, gene mutation assay

(in vitro) Result: positive

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

thesis in mammalian cells (in vitro)

Result: positive

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Test Type: Chromosome aberration test in vitro

Result: positive

Test Type: Chromosome aberration test in vitro

Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test

Species: Mouse

Application Route: Intraperitoneal injection

Result: negative

Test Type: Mutagenicity (in vivo mammalian bone-marrow

cytogenetic test, chromosomal analysis)

Species: Rat

Application Route: Intraperitoneal injection

Result: positive

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

### Carcinogenicity

Not classified based on available information.

#### Components:

### Lufenuron (ISO):

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

Carcinogenicity - Assess-

ment

Weight of evidence does not support classification as a car-

cinogen

praziquantel:

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

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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

Sodium chloride:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
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 develop-

ment

Test Type: Development

Species: Rat

Application Route: Oral

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

Symptoms: No adverse effects

Remarks: No significant adverse effects were reported

Test Type: Fertility/early embryonic development

Species: Rat

**Application Route: Ingestion** 

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

Embryo-foetal toxicity: 8.3 mg/kg body weight

Result: foetal abnormalities

Reproductive toxicity - As-

sessment

Clear evidence of adverse effects on development, based on

animal experiments.

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Savorysel Bacon Flavor:

Effects on fertility : Remarks: No data available

Effects on foetal develop-

ment

: Remarks: No data available

praziquantel:

Effects on fertility : Test Type: Fertility

Species: Rat

Remarks: No significant adverse effects were reported

Test Type: Fertility Species: Mouse

Remarks: No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

Remarks: No significant adverse effects were reported

Test Type: Development

Species: Mouse

Remarks: No significant adverse effects were reported

Milbemycin Oxime:

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

Species: Dog

Application Route: Ingestion

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Ingestion

Result: negative

Test Type: Embryo-foetal development

Species: Rabbit

Application Route: Ingestion

Result: negative

Test Type: Embryo-foetal development

Species: Dog

Application Route: Ingestion

Result: negative

### 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.

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#### STOT - repeated exposure

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

### **Components:**

Lufenuron (ISO):

Exposure routes : Oral

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

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

centrations of 10 mg/kg bw or less.

Milbemycin Oxime:

Exposure routes : Ingestion

Target Organs : Central nervous system

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

centrations of 10 mg/kg bw or less.

#### Repeated dose toxicity

## **Components:**

Starch:

Species : Rat

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

Method : OECD Test Guideline 410

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

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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

Sodium chloride:

Species : Rat

LOAEL : 2,533 mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Milbemycin Oxime:

Species : Rat

NOAEL : 3 mg/kg

LOAEL : 15 mg/kg

Application Route : Ingestion

Exposure time : 90 Days

Symptoms : Liver disorders, Blood disorders

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

**Aspiration toxicity** 

Not classified based on available information.

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### **Experience with human exposure**

**Components:** 

Lufenuron (ISO):

General Information : Remarks: May be harmful if swallowed.

May cause neurotoxic effects.

Savorysel Bacon Flavor:

General Information : Remarks: Based on data from similar materials

May irritate skin. May irritate eyes.

praziquantel:

Inhalation : Symptoms: Headache, Tiredness, Dizziness, Gastrointestinal

discomfort, decrease body temperature, Allergic reactions

Milbemycin Oxime:

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

Vomiting, Tremors, Coma

Remarks: Based on Animal Evidence

**Further information** 

Components:

Savorysel Bacon Flavor:

Remarks : No toxicology information is available.

#### 12. ECOLOGICAL INFORMATION

### **Ecotoxicity**

### 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

according to the Globally Harmonized System



# Milbemycin Oxime / Lufenuron / Praziquantel Formulation

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Toxicity to algae/aquatic

plants

EC50 (Raphidocelis subcapitata (freshwater green alga)):

209 µg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 ( Scenedesmus subspicatus): 17 μg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

M-Factor (Acute aquatic tox-

icity)

10,000

Toxicity to fish (Chronic tox-

icity)

NOEC: 80 µg/l

Exposure time: 33 d

Species: Oncorhynchus mykiss (rainbow trout)

Method: OECD Test Guideline 210

NOEC: 20 µg/l Exposure time: 359 d

Species: Oncorhynchus mykiss (rainbow trout)

Method: OECD Test Guideline 229

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 8.38 μg/l Exposure time: 21 d

Exposure time: 21 a

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

praziguantel:

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

according to the Globally Harmonized System



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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

Sodium chloride:

Toxicity to fish LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 4,136 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

EC50: > 2,000 mg/lExposure time: 96 h

Toxicity to microorganisms EC10: > 1,000 mg/l

Toxicity to fish (Chronic tox-

icity)

NOEC: 252 mg/l

Exposure time: 33 d

Species: Pimephales promelas (fathead minnow)

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 314 mg/l Exposure time: 21 d

Species: Daphnia pulex (Water flea)

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

Toxicity to algae/aquatic

plants

Exposure time: 48 h

EC50:  $> 87 \mu g/l$ 

M-Factor (Acute aquatic tox-

icity)

Exposure time: 72 h

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

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

M-Factor (Chronic aquatic

toxicity)

10,000

10,000

### Persistence and degradability

No data available

according to the Globally Harmonized System



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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

Sucrose:

Partition coefficient: n-

octanol/water

: Pow: < 1

praziquantel:

Partition coefficient: n-

octanol/water

log Pow: 2.012

pH: 7

Milbemycin Oxime:

Bioaccumulation : Bioconcentration factor (BCF): 440

Partition coefficient: n-

octanol/water

log Pow: 7

Mobility in soil

**Components:** 

Lufenuron (ISO):

Distribution among environ-

mental compartments

log Koc: 5.38

Method: OECD Test Guideline 106

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

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

dling site for recycling or disposal.

If not otherwise specified: Dispose of as unused product.

14. TRANSPORT INFORMATION

**International Regulations** 

according to the Globally Harmonized System



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**UNRTDG** 

**UN** number **UN 3077** 

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

(Milbemycin Oxime, Lufenuron (ISO))

Class 9 Packing group Ш Labels 9 Environmentally hazardous yes

**IATA-DGR** 

UN/ID No. **UN 3077** 

Proper shipping name Environmentally hazardous substance, solid, n.o.s.

(Milbernycin Oxime, Lufenuron (ISO))

9 Class Ш Packing group

Miscellaneous Labels

Packing instruction (cargo

aircraft)

956 Packing instruction (passen-

ger aircraft)

Environmentally hazardous yes

**IMDG-Code** 

UN 3077 **UN** number

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, Proper shipping name

N.O.S.

956

(Milbemycin Oxime, Lufenuron (ISO))

Class Ш Packing group Labels **EmS Code** F-A, S-F Marine pollutant yes

#### Transport in bulk according to IMO instruments

Not applicable for product as supplied.

#### 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.

#### 15. REGULATORY INFORMATION

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

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

**AICS** not determined

DSL not determined

according to the Globally Harmonized System



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IECSC : not determined

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

Revision Date : 30.09.2023

**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 Agentus http://cehn.com/cenns/search/se

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA : 8-hour, time-weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response: ERG - Emergency Response Guide: GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States): UN - United Nations: UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods: vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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

according to the Globally Harmonized System



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considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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