

Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Version 2.6 Revision Date: 30.09.2023 SDS Number: 7567881-00009 Date of last issue: 04.04.2023
Date of first issue: 20.11.2020

SECTION 1. IDENTIFICATION

Product name : Milbemycin Oxime / Lufenuron / Praziquantel Formulation

Manufacturer or supplier's details

Company : MSD

Address : Talcahuano 750, 6th floor, Ciudad Autonoma
Buenos Aires, Argentina C1013AAP

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

Skin sensitization : Category 1

Reproductive toxicity : Category 1B

Specific target organ toxicity - repeated exposure (Oral) : 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 :



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,

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Lungs, Liver, Stomach) through prolonged or repeated exposure if swallowed.
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.
 P202 Do not handle until all safety precautions have been read and understood.
 P260 Do not breathe dust/ fume/ gas/ mist/ vapors/ 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 protection/ face protection.

Response:

P302 + P352 IF ON SKIN: Wash with plenty of water.
 P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
 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.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Starch	9005-25-8	>= 30 -< 50
Glycerine	56-81-5	>= 10 -< 20
Lufenuron (ISO)	103055-07-8	>= 5 -< 10
Sucrose	57-50-1	>= 5 -< 10
Savorysel Bacon Flavor	Not Assigned	>= 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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SECTION 4. 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.
- 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.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
May damage the unborn child.
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.
- 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).
- Notes to physician : Treat symptomatically and supportively.

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- 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
- 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.
- Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

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for fire-fighters

Use personal protective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective 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 container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

SECTION 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, vapors 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.
- Conditions for safe storage : Keep in properly labeled containers.

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Materials to avoid : Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.
: Do not store with the following product types:
Strong oxidizing agents
Self-reactive substances and mixtures
Organic peroxides
Explosives
Gases

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Starch	9005-25-8	CMP	10 mg/m ³	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		TWA	10 mg/m ³	ACGIH
Glycerine	56-81-5	CMP (Mist)	10 mg/m ³	AR OEL
Lufenuron (ISO)	103055-07-8	TWA	OEB 3 (>= 10 < 100 µg/m ³)	Internal
Sucrose	57-50-1	CMP	10 mg/m ³	AR OEL
	Further information: A4 - Not classifiable as a human carcinogen			
		TWA	10 mg/m ³	ACGIH
Savorysel Bacon Flavor	Not Assigned	Wipe limit	OEB 2 (>= 100 < 1000 µg/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

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

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Filter type : Combined particulates and organic vapor type
Hand protection :
Material : Chemical-resistant gloves
Remarks : Consider double gloving.

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- 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.
- 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : solid
- Color : brown
- Odor : characteristic
- Odor 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, handling or other means.
- Flammability (liquids) : Not applicable
- Upper explosion limit / Upper flammability limit : No data available

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Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	Not applicable
Relative vapor density	:	Not applicable
Relative density	:	No data available
Density	:	No data available
Solubility(ies)	:	
Water solubility	:	soluble
Partition coefficient: n-octanol/water	:	Not applicable
Autoignition 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

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.
Conditions to avoid	:	Heat, flames and sparks. Avoid dust formation.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

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

Not classified based on available information.

Product:

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

Glycerine:

Acute oral toxicity : LD50 (Rat): > 5.000 mg/kg

Acute dermal toxicity : LD50 (Guinea pig): > 5.000 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

Sucrose:

Acute oral toxicity : LD50 (Rat): 29.700 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

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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
Exposure time: 1 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 5.000 mg/kg

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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:

Glycerine:

Species : Rabbit
Result : No skin irritation

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

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Result : No skin irritation

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Starch:**

Species : Rabbit
Result : No eye irritation

Glycerine:

Species : Rabbit
Result : No eye irritation

Lufenuron (ISO):

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

Savorysel Bacon Flavor:

Remarks : Based on data from similar materials
May irritate eyes.

Praziquantel:

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

Sodium chloride:

Species : Rabbit
Result : No eye irritation

Milbemycin Oxime:

Species : Rabbit
Result : No eye irritation

Respiratory or skin sensitization**Skin sensitization**

May cause an allergic skin reaction.

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Respiratory sensitization

Not classified based on available information.

Components:**Starch:**

Test Type : Maximization Test
Routes of exposure : Skin contact
Species : Guinea pig
Result : negative

Lufenuron (ISO):

Test Type : Maximization Test
Species : Guinea pig
Assessment : May cause sensitization by skin contact.
Result : Sensitizer

Savorysel Bacon Flavor:

Remarks : Not classified due to lack of data.

Praziquantel:

Test Type : Maximization Test
Routes of exposure : Dermal
Species : Guinea pig
Result : Not a skin sensitizer.

Sodium chloride:

Test Type : Local lymph node assay (LLNA)
Routes of exposure : Skin contact
Species : Mouse
Result : negative

Milbemycin Oxime:

Routes of exposure : 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

Glycerine:

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

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

Test Type: Chromosome aberration test in vitro
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
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 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.

Sucrose:

Genotoxicity in vitro

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

Savorysel Bacon Flavor:

Genotoxicity in vitro

: Remarks: Not classified due to lack of data.

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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

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 synthesis in mammalian cells (in vitro)
Result: positive

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.

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

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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:

Glycerine:

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

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

Sodium chloride:

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

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Reproductive toxicity

May damage the unborn child.

Components:

Glycerine:

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

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

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 fetal 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-fetal toxicity.: 8,3 mg/kg body weight
Result: Fetal 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 fetal development : Remarks: No data available

Praziquantel:

Effects on fertility : Test Type: Fertility
Species: Rat
Remarks: No significant adverse effects were reported

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

Effects on fetal 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 fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Ingestion
Result: negative

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

Test Type: Embryo-fetal 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 (Central nervous system, Lungs, Liver, Stomach) through prolonged or repeated exposure if swallowed.

Components:

Lufenuron (ISO):

Routes of exposure : Oral
Target Organs : Central nervous system, Lungs, Liver, Stomach

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

Milbemycin Oxime:

Routes of exposure : 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:

Starch:

Species : Rat
 NOAEL : >= 2.000 mg/kg
 Application Route : Skin contact
 Exposure time : 28 Days
 Method : OECD Test Guideline 410

Glycerine:

Species : Rat
 NOAEL : 0,167 mg/l
 LOAEL : 0,622 mg/l
 Application Route : inhalation (dust/mist/fume)
 Exposure time : 13 Weeks

Species : Rat
 NOAEL : 8.000 - 10.000 mg/kg
 Application Route : Ingestion
 Exposure time : 2 y

Species : Rabbit
 NOAEL : 5.040 mg/kg
 Application Route : Skin contact
 Exposure time : 45 Weeks

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 y
 Symptoms : central nervous system effects, Convulsions

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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 y
 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 y

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

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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.

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, Diarrhea, 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

Ecotoxicity

Components:

Glycerine:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 54.000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 1.955 mg/l
Exposure time: 48 h

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 10.000 mg/l
Exposure time: 16 h
Method: DIN 38 412 Part 8

Lufenuron (ISO):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 73.100 µg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

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		LC50 (Oncorhynchus mykiss (rainbow trout)): > 29.000 µg/l Exposure time: 96 h Method: OECD Test Guideline 203
		LC50 (Oncorhynchus mykiss (rainbow trout)): 370 µg/l Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Americamysis): 0,042 µg/l Exposure time: 96 h Method: US-EPA OPPTS 850.1035
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 (Oncorhynchus mykiss (rainbow trout)): 80 µg/l Exposure time: 33 d Method: OECD Test Guideline 210
		NOEC (Oncorhynchus mykiss (rainbow trout)): 20 µg/l Exposure time: 359 d Method: OECD Test Guideline 229
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 8,38 µg/l Exposure time: 21 d Method: OECD Test Guideline 211
		NOEC (Daphnia magna (Water flea)): 90 µg/l Exposure time: 21 d Method: OECD Test Guideline 211
		NOEC (Chironomus riparius (harlequin fly)): 2 µg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	10
Praziquantel:		
Toxicity to fish	:	LC50 (Carassius auratus (goldfish)): 29,2 mg/l Exposure time: 96 hrs Method: OECD Test Guideline 203
		LC50 (Danio rerio (zebra fish)): 31,6 mg/l Exposure time: 96 hrs

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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

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/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
Exposure time: 33 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia pulex (Water flea)): 314 mg/l
Exposure time: 21 d

Toxicity to microorganisms : EC10: > 1.000 mg/l

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 (Daphnia magna (Water flea)): 0,01 µg/l

M-Factor (Chronic aquatic toxicity) : 10.000

Persistence and degradability

Components:

Glycerine:

Biodegradability : Result: Readily biodegradable.

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Biodegradation: 92 %
Exposure time: 30 d
Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

Glycerine:

Partition coefficient: n-octanol/water : log Pow: -1,75

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 environmental compartments : log Koc: 5,38
Method: OECD Test Guideline 106

Other adverse effects

No data available

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

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SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime, Lufenuron (ISO))
Class	:	9
Packing group	:	III
Labels	:	9
Environmentally hazardous	:	yes

IATA-DGR

UN/ID No.	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Milbemycin Oxime, Lufenuron (ISO))
Class	:	9
Packing group	:	III
Labels	:	Miscellaneous
Packing instruction (cargo aircraft)	:	956
Packing instruction (passenger aircraft)	:	956
Environmentally hazardous	:	yes

IMDG-Code

UN number	:	UN 3077
Proper shipping name	:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Milbemycin Oxime, Lufenuron (ISO))
Class	:	9
Packing group	:	III
Labels	:	9
EmS Code	:	F-A, S-F
Marine pollutant	:	yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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.

SECTION 15. REGULATORY INFORMATION

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

Argentina. Carcinogenic Substances and Agents Registry.	:	Not applicable
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Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

SECTION 16. OTHER INFORMATION

Revision Date	: 30.09.2023
Date format	: dd.mm.yyyy

Further information

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Full text of other abbreviations

ACGIH	: USA. ACGIH Threshold Limit Values (TLV)
AR OEL	: Argentina. Occupational Exposure Limits
ACGIH / TWA	: 8-hour, time-weighted average
AR OEL / CMP	: TLV (Threshold Limit Value)

AICC - 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

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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 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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