

Pyrantel Pamoate / Moxidectin Formulation

Version Revision Date: SDS Number: Date of last issue: 04/09/2022
3.5 10/01/2022 4892850-00009 Date of first issue: 09/17/2019

SECTION 1. IDENTIFICATION

Product name : Pyrantel Pamoate / Moxidectin Formulation
Other means of identification : No data available

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 126 E. Lincoln Avenue
 : Rahway, New Jersey U.S.A. 07065
Telephone : 908-740-4000
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.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 in accordance with the Hazardous Products Regulations**

Reproductive toxicity : Category 2

Specific target organ toxicity : Category 1 (Central nervous system)
- repeated exposure

GHS label elements

Hazard pictograms : 

Signal Word : Danger

Hazard Statements : H361d Suspected of damaging the unborn child.
 : H372 Causes damage to organs (Central nervous system)
 : through prolonged or repeated exposure.

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 or spray.
 : P264 Wash skin thoroughly after handling.
 : P270 Do not eat, drink or smoke when using this product.
 : P280 Wear protective gloves, protective clothing, eye protection
 : and face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical attention.

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Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

| Chemical name | Common Name/Synonym | CAS-No. | Concentration (% w/w) |
|---|---------------------|-------------|-----------------------|
| 4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1) | No data available | 22204-24-6 | 38.3 |
| Propylene glycol | 1,2-Propanediol | 57-55-6 | 15 |
| Glycerine | 1,2,3-Propanetriol | 56-81-5 | 10 |
| Moxidectin | No data available | 113507-06-5 | 1 |
| Ethanol# | Ethyl alcohol | 64-17-5 | 0.1 |

Voluntarily-disclosed substance

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 : Flush eyes with water as a precaution.
 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 : Suspected of damaging the unborn child.

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and effects, both acute and delayed
 Protection of first-aiders : Causes damage to organs through prolonged or repeated exposure.
 : 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)
 Sulfur oxides

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 for fire-fighters : In the event of fire, wear self-contained breathing apparatus.
 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 : Soak up with inert absorbent material.
 For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.
 Clean up remaining materials from spill with suitable absorbent.
 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.

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SECTION 7. HANDLING AND STORAGE

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust, fume, gas, mist, vapors or spray.
 Do not swallow.
 Avoid contact with eyes.
 Avoid prolonged or repeated contact with skin.
 Wash skin thoroughly after handling.
 Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment
 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.
 Store in accordance with the particular national regulations.
- Materials to avoid : 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 |
|---|-------------|-------------------------------|--|-----------|
| 4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1) | 22204-24-6 | TWA | 250 µg/m ³ (OEB 2) | Internal |
| Propylene glycol | 57-55-6 | TWA (Vapour and aerosols) | 50 ppm 155 mg/m ³ | CA ON OEL |
| | | TWA (aerosol) | 10 mg/m ³ | CA ON OEL |
| Glycerine | 56-81-5 | TWA (Mist) | 10 mg/m ³ | CA AB OEL |
| | | TWA (Mist) | 10 mg/m ³ | CA BC OEL |
| | | TWA (Respirable mist) | 3 mg/m ³ | CA BC OEL |
| | | TWAEV (Mist) | 10 mg/m ³ | CA QC OEL |
| Moxidectin | 113507-06-5 | TWA | 10 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 100 µg/100 cm ² | Internal |
| Ethanol | 64-17-5 | TWA | 1,000 ppm 1,880 mg/m ³ | CA AB OEL |

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|--|--|------|-----------|-----------|
| | | STEL | 1,000 ppm | CA BC OEL |
| | | STEV | 1,000 ppm | CA QC OEL |
| | | STEL | 1,000 ppm | ACGIH |

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.

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. 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 : paste

Color : yellow

Odor : No data available

Odor Threshold : No data available

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|--|---|--|
| 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) | : | Not applicable |
| Flammability (liquids) | : | No data available |
| Upper explosion limit / Upper flammability limit | : | No data available |
| 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 | : | No data available |
| 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 | : | Not applicable |

SECTION 10. STABILITY AND REACTIVITY

| | | |
|------------|---|--|
| Reactivity | : | Not classified as a reactivity hazard. |
|------------|---|--|

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| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | Can react with strong oxidizing agents. |
| Conditions to avoid | : | None known. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product:

| | | |
|---------------------------|---|---|
| Acute oral toxicity | : | Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method |
| Acute inhalation toxicity | : | Acute toxicity estimate: > 5 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method |
| Acute dermal toxicity | : | Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method |

Components:**4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):**

| | | |
|---------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 24,000 mg/kg LD50 (Mouse): > 24,000 mg/kg LD50 (Dog): 2,000 mg/kg |
|---------------------|---|---|

Propylene glycol:

| | | |
|---------------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat): 22,000 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): > 44.9 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rabbit): > 2,000 mg/kg Assessment: The substance or mixture has no acute dermal toxicity |

Glycerine:

| | | |
|---------------------|---|---------------------------|
| Acute oral toxicity | : | LD50 (Rat): > 5,000 mg/kg |
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Acute dermal toxicity : LD50 (Guinea pig): > 5,000 mg/kg

Moxidectin:

Acute oral toxicity : LD50 (Rat): 106 mg/kg
LD50 (Mouse): 42 - 84 mg/kg

Acute inhalation toxicity : LC50 (Rat): 3.28 mg/l
Exposure time: 5 h
Test atmosphere: dust/mist

LC50 (Rat): 2.87 - 4.06 mg/l
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: No significant adverse effects were reported

Acute toxicity (other routes of administration) : LD50 (Rat): 394 mg/kg
Application Route: Intraperitoneal

LD50 (Mouse): 84 mg/kg
Application Route: Intraperitoneal

LD50 (Rat): > 640 mg/kg
Application Route: Subcutaneous

LD50 (Mouse): 263 mg/kg
Application Route: Subcutaneous

Ethanol:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 124.7 mg/l
Exposure time: 4 h
Test atmosphere: vapor

Skin corrosion/irritation

Not classified based on available information.

Components:**Propylene glycol:**

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

Glycerine:

Species : Rabbit
Result : No skin irritation

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Moxidectin:

Species : Rabbit
Result : Mild skin irritation

Ethanol:

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

Serious eye damage/eye irritation

Not classified based on available information.

Components:**Propylene glycol:**

Species : Rabbit
Result : No eye irritation
Method : OECD Test Guideline 405

Glycerine:

Species : Rabbit
Result : No eye irritation

Moxidectin:

Species : Rabbit
Result : Moderate eye irritation

Ethanol:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Method : OECD Test Guideline 405

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Components:**Propylene glycol:**

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

Moxidectin:

Test Type : Buehler Test
Routes of exposure : Dermal

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Species : Guinea pig
 Result : Not a skin sensitizer.

Ethanol:

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

Germ cell mutagenicity

Not classified based on available information.

Components:

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

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

Propylene glycol:

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

Test Type: Chromosome aberration test in vitro
 Method: OECD Test Guideline 473
 Result: negative

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

Glycerine:

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

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

Moxidectin:

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

Test Type: In vitro mammalian cell gene mutation test

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Test system: Chinese hamster ovary cells
Result: negative

Test Type: in vitro test
Test system: Escherichia coli
Result: negative

Genotoxicity in vivo : Test Type: Chromosomal aberration
Species: Rat
Cell type: Bone marrow
Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo
Species: Rat
Cell type: Liver cells
Result: negative

Ethanol:

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

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

Genotoxicity in vivo : Test Type: Rodent dominant lethal test (germ cell) (in vivo)
Species: Mouse
Application Route: Ingestion
Result: equivocal

Carcinogenicity

Not classified based on available information.

Components:

Propylene glycol:

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

Glycerine:

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

Moxidectin:

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
NOAEL : 4.5 mg/kg body weight

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Result : negative

Species : Rat

Application Route : Oral

Exposure time : 2 Years

NOAEL : 4.5 mg/kg body weight

Result : negative

Species : Dog

Application Route : Oral

Exposure time : 1 Years

NOAEL : 0.5 mg/kg body weight

Result : negative

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Effects on fetal development : Test Type: Embryo-fetal development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 3,000 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Test Type: Embryo-fetal development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 1,000 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Propylene glycol:

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

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

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

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Species: Rat
 Application Route: Ingestion
 Result: negative

Moxidectin:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
 Species: Rat
 Application Route: Oral
 General Toxicity F1: LOAEL: 0.8 mg/kg body weight
 Symptoms: Reduced fetal weight., Fetal mortality.
 Result: No effects on fertility., Some evidence of adverse effects on development, based on animal experiments.

Test Type: Three-generation reproduction toxicity study
 Species: Rat
 Application Route: Oral
 General Toxicity F1: LOAEL: 0.8 mg/kg body weight
 Symptoms: Reduced fetal weight., Fetal mortality.
 Result: No effects on fertility., Some evidence of adverse effects on development, based on animal experiments.

Effects on fetal development : Test Type: Embryo-fetal development
 Species: Rat
 Application Route: Oral
 General Toxicity Maternal: LOAEL: 10 mg/kg body weight
 Embryo-fetal toxicity.: LOAEL: 10 mg/kg body weight
 Result: Skeletal malformations.
 Remarks: The effects were seen only at maternally toxic doses.

Test Type: Embryo-fetal development
 Species: Rabbit
 Application Route: Oral
 General Toxicity Maternal: LOAEL: 5 mg/kg body weight
 Developmental Toxicity: NOAEL: 10 mg/kg body weight
 Result: No teratogenic effects., No embryotoxic effects.

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

Ethanol:

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

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Causes damage to organs (Central nervous system) through prolonged or repeated exposure.

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Components:

Moxidectin:

| | | |
|---------------|---|---|
| Target Organs | : | Central nervous system |
| Assessment | : | Causes damage to organs through prolonged or repeated exposure. |

Repeated dose toxicity

Components:

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

| | | |
|-------------------|---|--|
| Species | : | Dog |
| NOAEL | : | 10 mg/kg |
| LOAEL | : | 30 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 3 d |
| Remarks | : | No significant adverse effects were reported |

| | | |
|-------------------|---|--|
| Species | : | Dog |
| NOAEL | : | 600 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 19 d |
| Remarks | : | No significant adverse effects were reported |

| | | |
|-------------------|---|--|
| Species | : | Dog |
| NOAEL | : | 600 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 30 d |
| Remarks | : | No significant adverse effects were reported |

| | | |
|-------------------|---|--|
| Species | : | Dog |
| NOAEL | : | 600 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 90 d |
| Remarks | : | No significant adverse effects were reported |

Propylene glycol:

| | | |
|-------------------|---|----------------|
| Species | : | Rat, male |
| NOAEL | : | >= 1,700 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 2 y |

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 |

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Application Route : Ingestion
Exposure time : 2 y

Species : Rabbit
NOAEL : 5,040 mg/kg
Application Route : Skin contact
Exposure time : 45 Weeks

Moxidectin:

Species : Mouse
NOAEL : 3.9 mg/kg
LOAEL : 15.4 mg/kg
Application Route : Oral
Exposure time : 4 Weeks
Symptoms : Tremors

Species : Rat
NOAEL : 3.9 mg/kg
LOAEL : 7.9 mg/kg
Application Route : Oral
Exposure time : 13 Weeks
Target Organs : Central nervous system
Symptoms : Tremors, Salivation

Species : Dog
NOAEL : 0.3 mg/kg
LOAEL : 0.9 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Central nervous system
Symptoms : Tremors, Lachrymation, Salivation

Species : Dog
NOAEL : 0.3 mg/kg
LOAEL : 0.87 mg/kg
Application Route : Oral
Exposure time : 52 Weeks
Target Organs : Central nervous system
Symptoms : Tremors, Lachrymation

Ethanol:

Species : Rat
NOAEL : 1,280 mg/kg
LOAEL : 3,156 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Aspiration toxicity

Not classified based on available information.

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Experience with human exposure

Components:

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Ingestion : Symptoms: Abdominal pain, Nausea, Vomiting, Diarrhea, Headache, Dizziness, Fever

Moxidectin:

Inhalation : Remarks: No human information is available.
 Skin contact : Remarks: No human information is available.
 Eye contact : Remarks: No human information is available.
 Ingestion : Remarks: No human information is available.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

4,4'-Methylenebis[3-hydroxy-2-naphthoic] acid, compound with (E)-1,4,5,6-tetrahydro-1-methyl-2-[2-(2-thienyl)vinyl]pyrimidine (1:1):

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

Propylene glycol:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l
 Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l
 Exposure time: 72 h
 Method: OECD Test Guideline 201

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l
 Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l
 Exposure time: 18 h

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

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Exposure time: 16 h
Method: DIN 38 412 Part 8

Moxidectin:

Toxicity to fish : LC50 (*Lepomis macrochirus* (Bluegill sunfish)): 0.0006 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

LC50 (*Oncorhynchus mykiss* (rainbow trout)): 0.0002 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): 0.00003 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (*Pseudokirchneriella subcapitata* (green algae)): 0.087 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Ethanol:

Toxicity to fish : LC50 (*Pimephales promelas* (fathead minnow)): > 1,000 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Ceriodaphnia* (water flea)): > 1,000 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (*Chlorella vulgaris* (Fresh water algae)): 275 mg/l
Exposure time: 72 h

EC10 (*Chlorella vulgaris* (Fresh water algae)): 11.5 mg/l
Exposure time: 72 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (*Daphnia magna* (Water flea)): 9.6 mg/l
Exposure time: 9 d

Toxicity to microorganisms : EC50 (*Pseudomonas putida*): 6,500 mg/l
Exposure time: 16 h

Persistence and degradability

Components:

Propylene glycol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

Glycerine:

Biodegradability : Result: Readily biodegradable.

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

Ethanol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 84 %
Exposure time: 20 d

Bioaccumulative potential**Components:****Propylene glycol:**

Partition coefficient: n-octanol/water : log Pow: -1.07
Method: Regulation (EC) No. 440/2008, Annex, A.8

Glycerine:

Partition coefficient: n-octanol/water : log Pow: -1.75

Moxidectin:

Partition coefficient: n-octanol/water : log Pow: 4.7

Ethanol:

Partition coefficient: n-octanol/water : log Pow: -0.35

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : 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.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Moxidectin)
Class : 9

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Packing group : III
Labels : 9

IATA-DGR

UN/ID No. : UN 3077
Proper shipping name : Environmentally hazardous substance, solid, n.o.s.
(Moxidectin)
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.
(Moxidectin)
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.

Domestic regulation

TDG

UN number : UN 3077
Proper shipping name : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,
N.O.S.
(Moxidectin)
Class : 9
Packing group : III
Labels : 9
ERG Code : 171
Marine pollutant : yes(Moxidectin)

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

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

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

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SECTION 16. OTHER INFORMATION

Full text of other abbreviations

| | | |
|-------------------|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| CA AB OEL | : | Canada. Alberta, Occupational Health and Safety Code (table 2: OEL) |
| CA BC OEL | : | Canada. British Columbia OEL |
| CA ON OEL | : | Ontario Table of Occupational Exposure Limits made under the Occupational Health and Safety Act. |
| CA QC OEL | : | Québec. Regulation respecting occupational health and safety, Schedule 1, Part 1: Permissible exposure values for airborne contaminants |
| ACGIH / STEL | : | Short-term exposure limit |
| CA AB OEL / TWA | : | 8-hour Occupational exposure limit |
| CA BC OEL / TWA | : | 8-hour time weighted average |
| CA BC OEL / STEL | : | short-term exposure limit |
| CA ON OEL / TWA | : | Time-Weighted Average Limit (TWA) |
| CA QC OEL / TWAEV | : | Time-weighted average exposure value |
| CA QC OEL / STEV | : | Short-term exposure value |

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

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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/>

Revision Date : 10/01/2022
Date format : mm/dd/yyyy

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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