

Fluralaner / Moxidectin Liquid Formulation

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|---------|----------------|--------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 14.11.2024 |
| 13.1 | 14.04.2025 | 656891-00026 | Date of first issue: 02.05.2016 |

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier**

Trade name : Fluralaner / Moxidectin Liquid Formulation

Other means of identification : Bravecto Plus (A011446)
BRAVECTO PLUS FLEA, TICK AND WORM 112.5 MG
FLURALANER AND 5.6 MG MOXIDECTIN SPOT-ON
SOLUTION FOR KITTENS AND SMALL CATS (85418)
BRAVECTO PLUS FLEA, TICK AND WORM 250 MG
FLURALANER AND 12.5 MG MOXIDECTIN SPOT-ON
SOLUTION FOR MEDIUM CATS (85416)
BRAVECTO PLUS FLEA, TICK AND WORM 500 MG
FLURALANER AND 25 MG MOXIDECTIN SPOT-ON
SOLUTION FOR LARGE CATS (85413)

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-
stance/Mixture : Veterinary product

Recommended restrictions
on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person
responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification (REGULATION (EC) No 1272/2008)**

| | |
|--|--|
| Flammable liquids, Category 2 | H225: Highly flammable liquid and vapour. |
| Eye irritation, Category 2 | H319: Causes serious eye irritation. |
| Reproductive toxicity, Category 1B | H360D: May damage the unborn child. |
| Specific target organ toxicity - repeated exposure, Category 2 | H373: May cause damage to organs through prolonged or repeated exposure. |
| Short-term (acute) aquatic hazard, Category 1 | H400: Very toxic to aquatic life. |

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Long-term (chronic) aquatic hazard, Category 1

H410: Very toxic to aquatic life with long lasting effects.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements :
 H225 Highly flammable liquid and vapour.
 H319 Causes serious eye irritation.
 H360D May damage the unborn child.
 H373 May cause damage to organs through prolonged or repeated exposure.
 H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.
 P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
 P273 Avoid release to the environment.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.
 P391 Collect spillage.

Hazardous components which must be listed on the label:

N,N-Dimethylacetamide
 Moxidectin

Additional Labelling

Restricted to professional users.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Vapours may form explosive mixture with air.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. | Classification | Concentration (% w/w) |
|---------------|-------------------|----------------|--------------------------|
|---------------|-------------------|----------------|--------------------------|

SAFETY DATA SHEET



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| | Index-No. Registration number | | |
|---|---------------------------------------|--|-----------------|
| N,N-Dimethylacetamide | 127-19-5 204-826-4 616-011-00-4 | Acute Tox. 4; H332 Acute Tox. 4; H312 Eye Irrit. 2; H319 Repr. 1B; H360D | >= 30 - < 50 |
| Fluralaner | 864731-61-3 | Repr. 2; H361d Aquatic Chronic 1; H410 M-Factor (Chronic aquatic toxicity): 1.000 | >= 25 - < 30 |
| Poly(oxy-1,2-ethanediyl), .alpha.- [(tetrahydro-2-furanyl)methyl]- .omega.-hydroxy- | 31692-85-0 | Eye Irrit. 2; H319 | >= 20 - < 30 |
| N,N-Diethyl-m-toluamide | 134-62-3 205-149-7 616-018-00-2 | Acute Tox. 4; H302 Skin Irrit. 2; H315 Eye Irrit. 2; H319 | >= 10 - < 20 |
| Acetone | 67-64-1 200-662-2 606-001-00-8 | Flam. Liq. 2; H225 Eye Irrit. 2; H319 STOT SE 3; H336 | >= 10 - < 20 |
| Moxidectin | 113507-06-5 | Acute Tox. 3; H301 Acute Tox. 4; H332 Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 1; H372 (Central nervous system) Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 10.000 M-Factor (Chronic aquatic toxicity): 10.000 | >= 1 - < 2,5 |
| 2,6-Di-tert-butyl-p-cresol | 128-37-0 204-881-4 | Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1 | >= 0,1 - < 0,25 |

For explanation of abbreviations see section 16.

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SECTION 4: First aid measures**4.1 Description of first aid measures**

- | | | |
|----------------------------|---|---|
| General advice | : | In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice. |
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| If inhaled | : | If inhaled, remove to fresh air. Get medical attention. |
| In case of skin contact | : | In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. |
| In case of eye contact | : | In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention. |
| If swallowed | : | If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. |

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|--|
| Risks | : | Causes serious eye irritation. May damage the unborn child. May cause damage to organs through prolonged or repeated exposure. |
|-------|---|--|

4.3 Indication of any immediate medical attention and special treatment needed

- | | | |
|-----------|---|---|
| Treatment | : | Treat symptomatically and supportively. |
|-----------|---|---|
-

SECTION 5: Firefighting measures**5.1 Extinguishing media**

- | | | |
|------------------------------|---|--|
| Suitable extinguishing media | : | Water spray Alcohol-resistant foam Carbon dioxide (CO ₂) Dry chemical |
| Unsuitable extinguishing | : | High volume water jet |
-

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media

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : Do not use a solid water stream as it may scatter and spread fire.
Flash back possible over considerable distance.
Vapours may form explosive mixtures with air.
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides
Chlorine compounds
Fluorine compounds
Nitrogen oxides (NO_x)

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Use water spray to cool unopened containers.
Remove undamaged containers from fire area if it is safe to do so.
Evacuate area.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Remove all sources of ignition.
Ventilate the area.
Use personal protective equipment.
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.
Prevent further leakage or spillage if safe to do so.
Prevent spreading over a wide area (e.g. by containment or oil barriers).
Retain and dispose of contaminated wash water.
Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Non-sparking tools should be used.
Soak up with inert absorbent material.
Suppress (knock down) gases/vapours/mists with a water spray jet.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.

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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.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

- | | | |
|-------------------------|---|--|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation. Use explosion-proof electrical, ventilating and lighting equipment. |
| Advice on safe handling | : | Do not get on skin or clothing. Do not breathe mist or vapours. Do not swallow. Do not get in 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 Non-sparking tools should be used. Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharges. Do not eat, drink or smoke when using this product. Take care to prevent spills, waste and minimize release to the environment. |
| Hygiene measures | : | If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls. |

7.2 Conditions for safe storage, including any incompatibilities

- | | | |
|---|---|---|
| Requirements for storage areas and containers | : | Keep in properly labelled containers. Store locked up. Keep tightly closed. Keep in a cool, well-ventilated place. Store in accordance with the particular national regulations. Keep away from heat and sources of ignition. |
| Advice on common storage | : | Do not store with the following product types: |

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Strong oxidizing agents
 Self-reactive substances and mixtures
 Organic peroxides
 Flammable solids
 Pyrophoric liquids
 Pyrophoric solids
 Self-heating substances and mixtures
 Substances and mixtures, which in contact with water, emit flammable gases
 Explosives
 Gases
 Very acutely toxic substances and mixtures

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|-----------------------|---|-------------------------------|------------------------------------|------------|
| N,N-Dimethylacetamide | 127-19-5 | OEL-RL | 20 ppm | ZA OEL |
| | Further information: danger of cutaneous absorption, Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | |
| | | TWA | 10 ppm 36 mg/m ³ | 2000/39/EC |
| | | STEL | 20 ppm 72 mg/m ³ | 2000/39/EC |
| | | TWA | 10 ppm 36 mg/m ³ | 2004/37/EC |
| | | STEL | 20 ppm 72 mg/m ³ | 2004/37/EC |
| Fluralaner | 864731-61-3 | TWA | 100 µg/m ³ (OEB 2) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 1000 µg/100 cm ² | Internal |
| Acetone | 67-64-1 | OEL- RL STEL/C | 1.000 ppm | ZA OEL |
| | Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | |
| | | OEL-RL | 500 ppm | ZA OEL |
| | Further information: Occupational Exposure Limits - Restricted Limits For Hazardous Chemical Agents | | | |
| | | TWA | 500 ppm 1.210 mg/m ³ | 2000/39/EC |
| Moxidectin | 113507-06-5 | TWA | 10 µg/m ³ (OEB 3) | Internal |
| | | Wipe limit | 100 µg/100 cm ² | Internal |

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Biological occupational exposure limits

| Substance name | CAS-No. | Control parameters | Sampling time | Basis |
|-----------------------|----------|---|------------------------------------|--------|
| N,N-Dimethylacetamide | 127-19-5 | N-Methylacetamide: 30 mg/g creatinine (Urine) | End of shift at end of workweek | ZA BEI |
| Acetone | 67-64-1 | Acetone: 25 mg/l (Urine) | End of shift | ZA BEI |

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|----------------------------|-----------|-----------------|----------------------------|------------------------|
| N,N-Dimethylacetamide | Workers | Inhalation | Long-term systemic effects | 36 mg/m ³ |
| | Workers | Inhalation | Acute systemic effects | 36 mg/m ³ |
| | Workers | Skin contact | Acute systemic effects | 13,6 mg/kg bw/day |
| | Consumers | Inhalation | Long-term local effects | 7 mg/m ³ |
| | Consumers | Skin contact | Long-term systemic effects | 2,7 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 1 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 1 mg/kg bw/day |
| Acetone | Workers | Inhalation | Long-term systemic effects | 1210 mg/m ³ |
| | Workers | Inhalation | Acute local effects | 2420 mg/m ³ |
| | Workers | Skin contact | Long-term systemic effects | 186 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 200 mg/m ³ |
| | Consumers | Skin contact | Long-term systemic effects | 62 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 62 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 62 mg/kg bw/day |
| 2,6-Di-tert-butyl-p-cresol | Workers | Inhalation | Long-term systemic effects | 3,5 mg/m ³ |
| | Workers | Dermal | Long-term systemic effects | 0,5 mg/kg bw/day |
| | Consumers | Inhalation | Long-term systemic effects | 0,86 mg/m ³ |
| | Consumers | Dermal | Long-term systemic effects | 0,25 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0,25 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0,25 mg/kg bw/day |
| | Consumers | Ingestion | Long-term systemic effects | 0,25 mg/kg bw/day |

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

| Substance name | Environmental Compartment | Value |
|-----------------------|---------------------------|-------------|
| Fluralaner | Water | 7 ng/l |
| Moxidectin | Water | 0,3 ng/l |
| N,N-Dimethylacetamide | Fresh water | 0,5 mg/l |
| | Marine water | 0,0966 mg/l |
| | Intermittent use/release | 5 mg/l |
| | Sewage treatment plant | 485 mg/l |
| | Sewage treatment plant | 485 mg/l |

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| | Fresh water sediment | 2,27 mg/kg |
| | Soil | 0,15 mg/kg |
| Acetone | Fresh water | 10,6 mg/l |
| | Marine water | 1,06 mg/l |
| | Intermittent use/release | 21 mg/l |
| | Sewage treatment plant | 100 mg/l |
| | Fresh water sediment | 30,4 mg/kg dry weight (d.w.) |
| | Marine sediment | 3,04 mg/kg dry weight (d.w.) |
| | Soil | 29,5 mg/kg dry weight (d.w.) |
| 2,6-Di-tert-butyl-p-cresol | Fresh water | 0,199 µg/l |
| | Intermittent use/release | 0,02 µg/l |
| | Marine water | 0,02 µg/l |
| | Sewage treatment plant | 0,17 mg/l |
| | Fresh water sediment | 0,0996 mg/kg dry weight (d.w.) |
| | Marine sediment | 0,00996 mg/kg dry weight (d.w.) |
| | Soil | 0,04769 mg/kg dry weight (d.w.) |
| | Oral (Secondary Poisoning) | 8,33 mg/kg food |

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

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.

Use explosion-proof electrical, ventilating and lighting equipment.

Personal protective equipment

Eye/face protection : Wear safety glasses with side shields or goggles.
 If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
 Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection

Material : Chemical-resistant gloves

Remarks : Consider double gloving. Take note that the product is flammable, which may impact the selection of hand protection.

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

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| Respiratory protection | : | contaminated clothing. If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. |
| Filter type | : | Self-contained breathing apparatus |

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

| | | |
|--|---|----------------------------|
| Appearance | : | liquid |
| Colour | : | Colorless to pale yellow |
| Odour | : | No data available |
| 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 | : | 2 °C Method: closed cup |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| Flammability (liquids) | : | Not applicable |
| Upper explosion limit / Upper flammability limit | : | No data available |
| Lower explosion limit / Lower flammability limit | : | No data available |
| Vapour pressure | : | No data available |
| Relative vapour density | : | No data available |
| Relative density | : | 1,06 |
| Density | : | 1,08 g/cm ³ |
| Solubility(ies) | : | |
| Water solubility | : | No data available |
| Partition coefficient: n-octanol/water | : | Not applicable |
| Auto-ignition temperature | : | No data available |
| Decomposition temperature | : | No data available |
| Viscosity | : | |
| Viscosity, kinematic | : | 7,5 mm ² /s |

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Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information

Particle size : Not applicable

SECTION 10: Stability and reactivity**10.1 Reactivity**

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : Highly flammable liquid and vapour.
Vapours may form explosive mixture with air.
Can react with strong oxidizing agents.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products

No hazardous decomposition products are known.

SECTION 11: Toxicological information**11.1 Information on toxicological effects**

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

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : LD50 (Rat, female): > 2.000 mg/kg
Method: OECD Test Guideline 423

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Acute dermal toxicity : LD50 (Rat, male and female): > 2.000 mg/kg

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Method: OECD Test Guideline 402

Components:**N,N-Dimethylacetamide:**

| | | |
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| Acute oral toxicity | : | LD50 (Rat): 4.800 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): 2,2 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
| Acute dermal toxicity | : | Acute toxicity estimate: 1.100 mg/kg Method: Expert judgement Remarks: Based on national or regional regulation. |

Fluralaner:

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| Acute oral toxicity | : | LD50 (Rat): > 2.000 mg/kg Remarks: No mortality observed at this dose. No significant adverse effects were reported |
| Acute dermal toxicity | : | LD50 (Rat): > 2.000 mg/kg Remarks: No significant adverse effects were reported |

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

| | | |
|---------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat, female): > 2.000 mg/kg Method: OECD Test Guideline 423 Remarks: Based on data from similar materials |
|---------------------|---|---|

N,N-Diethyl-m-toluamide:

| | | |
|---------------------------|---|---|
| Acute oral toxicity | : | LD50 (Rat): 1.892 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): 5,95 mg/l Exposure time: 4 h Test atmosphere: dust/mist |
| Acute dermal toxicity | : | LD50 (Rat): 5.000 mg/kg |

Acetone:

| | | |
|---------------------------|---|--|
| Acute oral toxicity | : | LD50 (Rat): 5.800 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): 76 mg/l Exposure time: 4 h Test atmosphere: vapour |
| Acute dermal toxicity | : | LD50 (Rabbit): 7.426 mg/kg |

Moxidectin:

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

2,6-Di-tert-butyl-p-cresol:

Acute oral toxicity : LD50 (Rat): > 6.000 mg/kg
Method: OECD Test Guideline 401

Acute dermal toxicity : LD50 (Rat): > 2.000 mg/kg
Method: OECD Test Guideline 402
Assessment: The substance or mixture has no acute dermal toxicity

Skin corrosion/irritation

Not classified based on available information.

Product:

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

Components:**N,N-Dimethylacetamide:**

Species : Rabbit
Result : No skin irritation

Fluralaner:

Species : Rabbit
Result : No skin irritation

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439

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Remarks : Based on data from similar materials

Result : No skin irritation

N,N-Diethyl-m-toluamide:

Species : Rabbit

Result : Skin irritation

Remarks : Based on national or regional regulation.

Acetone:

Assessment : Repeated exposure may cause skin dryness or cracking.

Moxidectin:

Species : Rabbit

Result : Mild skin irritation

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Remarks : Based on data from similar materials

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Components:**N,N-Dimethylacetamide:**

Species : Rabbit

Result : Irritation to eyes, reversing within 21 days

Fluralaner:

Species : Rabbit

Result : Mild eye irritation

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Species : Tissue Culture

Method : OECD Test Guideline 492

Remarks : Based on data from similar materials

Species : Bovine cornea

Method : OECD Test Guideline 437

Remarks : Based on data from similar materials

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Result : Irritation to eyes, reversing within 21 days

N,N-Diethyl-m-toluamide:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days
Remarks : Based on national or regional regulation.

Acetone:

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

Moxidectin:

Species : Rabbit
Result : Moderate eye irritation

2,6-Di-tert-butyl-p-cresol:

Species : Rabbit
Method : OECD Test Guideline 405
Result : No eye irritation
Remarks : Based on data from similar materials

Respiratory or skin sensitisation**Skin sensitisation**

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

Test Type : Local lymph node assay (LLNA)
Method : OECD Test Guideline 429
Result : negative

Components:**N,N-Dimethylacetamide:**

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

Fluralaner:

Test Type : Maximisation Test
Exposure routes : Dermal
Species : Guinea pig
Result : Not a skin sensitizer.

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Test Type : KeratinoSens assay

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| | | |
|-----------|---|--|
| Method | : | OECD Test Guideline 442D |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |
| Test Type | : | Direct Peptide Reactivity Assay (DPRA) |
| Method | : | OECD Test Guideline 442C |
| Result | : | positive |
| Remarks | : | Based on data from similar materials |
| Test Type | : | Dendritic cell activation test |
| Method | : | OECD Test Guideline 442E |
| Result | : | negative |
| Remarks | : | Based on data from similar materials |

Acetone:

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

Moxidectin:

| | | |
|-----------------|---|------------------------|
| Test Type | : | Buehler Test |
| Exposure routes | : | Dermal |
| Species | : | Guinea pig |
| Result | : | Not a skin sensitizer. |

2,6-Di-tert-butyl-p-cresol:

| | | |
|-----------------|---|--|
| Test Type | : | Human repeat insult patch test (HRIPT) |
| Exposure routes | : | Skin contact |
| Species | : | Humans |
| Result | : | negative |

Germ cell mutagenicity

Not classified based on available information.

Components:**N,N-Dimethylacetamide:**

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| Genotoxicity in vivo | : | Test Type: Rodent dominant lethal test (germ cell) (in vivo) Species: Rat Application Route: Inhalation Method: OECD Test Guideline 478 Result: negative |

Fluralaner:

| | | |
|-----------------------|---|--|
| Genotoxicity in vitro | : | Test Type: Bacterial reverse mutation assay (AMES) Result: negative |
| | : | Test Type: Mouse Lymphoma |

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Result: negative

Test Type: Chromosomal aberration

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse
Cell type: Bone marrow
Application Route: Oral
Result: negative

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:

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

Acetone:

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

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

Moxidectin:

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

Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster ovary cells
Result: negative

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

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

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Result: negative

Test Type: Unscheduled DNA synthesis (UDS) test with mammalian liver cells in vivo

Species: Rat

Cell type: Liver cells

Result: negative

2,6-Di-tert-butyl-p-cresol:Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Result: negativeTest Type: In vitro mammalian cell gene mutation test
Result: negativeTest Type: Chromosome aberration test in vitro
Result: negativeGenotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative**Carcinogenicity**

Not classified based on available information.

Components:**N,N-Dimethylacetamide:**Species : Rat
Application Route : inhalation (vapour)
Exposure time : 18 month(s)
Result : negative**Fluralaner:**

Carcinogenicity - Assessment : No data available

N,N-Diethyl-m-toluamide:Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative**Acetone:**Species : Mouse
Application Route : Skin contact
Exposure time : 424 days
Result : negative

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Moxidectin:

| | |
|-------------------|-------------------------|
| Species | : Mouse |
| Application Route | : Oral |
| Exposure time | : 2 Years |
| NOAEL | : 4,5 mg/kg body weight |
| 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 |

2,6-Di-tert-butyl-p-cresol:

| | |
|-------------------|-------------|
| Species | : Rat |
| Application Route | : Ingestion |
| Exposure time | : 22 Months |
| Result | : negative |

Reproductive toxicity

May damage the unborn child.

Components:**N,N-Dimethylacetamide:**

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

| | |
|-------------------------------|---|
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Rat Application Route: Inhalation Result: positive |
|-------------------------------|---|

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

Fluralaner:

| | |
|----------------------|---|
| Effects on fertility | : Test Type: Two-generation study Species: Rat Application Route: Oral General Toxicity - Parent: NOAEL: 50 mg/kg body weight General Toxicity F1: LOAEL: 100 mg/kg body weight Result: No effects on fertility, Postimplantation loss., Adverse neonatal effects. |
|----------------------|---|

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-
- Test Type: One-generation reproduction toxicity study
Species: Dog
Application Route: Oral
Fertility: NOAEL: 75 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.
Remarks: No significant adverse effects were reported
- Effects on foetal development : Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects
- Test Type: Development
Species: Rabbit
Application Route: Oral
Developmental Toxicity: NOAEL: 10 mg/kg body weight
Result: Skeletal malformations, Visceral malformations
Remarks: Maternal toxicity observed.
- Test Type: Development
Species: Rabbit
Application Route: Dermal
Developmental Toxicity: NOAEL: 100 mg/kg body weight
Result: Skeletal malformations
- Reproductive toxicity - Assessment : Suspected of damaging the unborn child.
- N,N-Diethyl-m-toluamide:**
- Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative
- Acetone:**
- Effects on fertility : Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative
- Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: inhalation (vapour)
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

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Symptoms: Reduced foetal weight, foetal 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 foetal weight, foetal mortality
Result: No effects on fertility, Some evidence of adverse effects on development, based on animal experiments.

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

Test Type: Embryo-foetal 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.

2,6-Di-tert-butyl-p-cresol:

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

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

STOT - single exposure

Not classified based on available information.

Components:**Acetone:**

Assessment : May cause drowsiness or dizziness.

STOT - repeated exposure

May cause damage to organs 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. |

2,6-Di-tert-butyl-p-cresol:

| | | |
|------------|---|--|
| Assessment | : | No significant health effects observed in animals at concentrations of 100 mg/kg bw or less. |
|------------|---|--|

Repeated dose toxicity**Components:****N,N-Dimethylacetamide:**

| | | |
|-------------------|---|-----------------------|
| Species | : | Rat |
| NOAEL | : | 90 mg/m ³ |
| LOAEL | : | 360 mg/m ³ |
| Application Route | : | inhalation (vapour) |
| Exposure time | : | 24 Months |

Fluralaner:

| | | |
|-------------------|---|--|
| Species | : | Dog |
| NOAEL | : | 1 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 52 Weeks |
| Target Organs | : | Liver |
| Remarks | : | No significant adverse effects were reported |

| | | |
|-------------------|---|----------------|
| Species | : | Juvenile dog |
| LOAEL | : | 56 - 280 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 24 Weeks |
| Symptoms | : | Diarrhoea |

| | | |
|-------------------|---|---------------------|
| Species | : | Rat |
| LOAEL | : | 400 mg/kg |
| Application Route | : | Oral |
| Exposure time | : | 90 Days |
| Target Organs | : | Liver, thymus gland |

| | | |
|-------------------|---|--|
| Species | : | Rat |
| NOAEL | : | 500 mg/kg |
| Application Route | : | Dermal |
| Exposure time | : | 90 Days |
| Target Organs | : | Liver |
| Remarks | : | No significant adverse effects were reported |

Acetone:

| | | |
|---------|---|-----------|
| Species | : | Rat |
| NOAEL | : | 900 mg/kg |

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LOAEL : 1.700 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

Species : Rat
NOAEL : 45 mg/l
Application Route : inhalation (vapour)
Exposure time : 8 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 : 1,15 mg/kg
Application Route : Oral
Exposure time : 52 Weeks
Target Organs : Central nervous system
Symptoms : Tremors, Lachrymation

2,6-Di-tert-butyl-p-cresol:

Species : Rat
NOAEL : 25 mg/kg
Application Route : Ingestion
Exposure time : 22 Months

Aspiration toxicity

Not classified based on available information.

Components:**Fluralaner:**

Not applicable

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Acetone:

The substance or mixture causes concern owing to the assumption that it causes a human aspiration toxicity hazard.

Experience with human exposure**Components:****Fluralaner:**

| | | |
|--------------|---|------------------------------------|
| Skin contact | : | Remarks: May irritate skin. |
| Eye contact | : | Remarks: May cause eye irritation. |

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**12.1 Toxicity****Components:****N,N-Dimethylacetamide:**

| | | |
|---|---|--|
| Toxicity to fish | : | LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 500 mg/l Exposure time: 48 h Method: Directive 67/548/EEC, Annex V, C.2. |
| Toxicity to algae/aquatic plants | : | EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l Exposure time: 72 h EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l Exposure time: 72 h |
| Toxicity to microorganisms | : | EC10 : > 1.995 mg/l Exposure time: 30 min |

Fluralaner:

| | | |
|---|---|--|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 0,0488 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: No toxicity at the limit of solubility |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 0,015 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: No toxicity at the limit of solubility |

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Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0,08 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: No toxicity at the limit of solubility

Toxicity to fish (Chronic toxicity) : NOEC: >= 0,049 mg/l
Exposure time: 21 d
Species: Zebrafish
Method: OECD Test Guideline 204
Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,0736 µg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1.000

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

Toxicity to algae/aquatic plants : EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 97 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 75 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 7,6 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to daphnia and other : NOEC: 3,7 mg/l

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aquatic invertebrates (Chronic toxicity)

Exposure time: 21 d
Species: Daphnia magna (Water flea)

Acetone:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 5.540 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia pulex (Water flea)): 8.800 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : NOEC (Pseudokirchneriella subcapitata (green algae)): 7.000 mg/l
Exposure time: 96 h

Toxicity to microorganisms : EC50 : 61.150 mg/l
Exposure time: 30 min
Method: ISO 8192

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: \geq 79 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

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

M-Factor (Acute aquatic toxicity) : 10.000

M-Factor (Chronic aquatic toxicity) : 10.000

2,6-Di-tert-butyl-p-cresol:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 0,57 mg/l
Exposure time: 96 h
Method: Directive 67/548/EEC, Annex V, C.1.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0,48 mg/l
Exposure time: 48 h

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Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 0,24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,24 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to microorganisms : EC50 : > 10.000 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 0,053 mg/l
Exposure time: 30 d
Species: Oryzias latipes (Japanese medaka)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,316 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)

M-Factor (Chronic aquatic toxicity) : 1

12.2 Persistence and degradability

Components:

N,N-Dimethylacetamide:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 70 %
Exposure time: 28 d
Remarks: The 10 day time window criterion is not fulfilled.

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Biodegradability : Result: Not readily biodegradable.
Method: OECD Test Guideline 301F
Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 83,8 %
Exposure time: 28 d
Method: OECD Test Guideline 301B

Acetone:

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Biodegradability : Result: Readily biodegradable.
Biodegradation: 91 %
Exposure time: 28 d

2,6-Di-tert-butyl-p-cresol:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 4,5 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

12.3 Bioaccumulative potential**Components:****Fluralaner:**

Bioaccumulation : Species: Zebrafish
Bioconcentration factor (BCF): 79,4
Method: OECD Test Guideline 305

Partition coefficient: n-octanol/water : log Pow: 4,5

Poly(oxy-1,2-ethanediyl), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Partition coefficient: n-octanol/water : log Pow: < 4
Remarks: Calculation

N,N-Diethyl-m-toluamide:

Partition coefficient: n-octanol/water : log Pow: 2,02

Acetone:

Partition coefficient: n-octanol/water : log Pow: -0,27 - -0,23

Moxidectin:

Partition coefficient: n-octanol/water : log Pow: 4,7

2,6-Di-tert-butyl-p-cresol:

Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 330 - 1.800

Partition coefficient: n-octanol/water : log Pow: 5,1

12.4 Mobility in soil**Components:****Fluralaner:**

Distribution among environmental compartments : log Koc: 4,1

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12.5 Results of PBT and vPvB assessment**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Components:**Fluralaner:**

Assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).

12.6 Other adverse effects**Product:**

Endocrine disrupting potential : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

| | |
|------------------------|--|
| Product | : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal. Empty containers retain residue and can be dangerous. Do not pressurize, cut, weld, braze, solder, drill, grind, or expose such containers to heat, flame, sparks, or other sources of ignition. They may explode and cause injury and/or death. If not otherwise specified: Dispose of as unused product. |

SECTION 14: Transport information**14.1 UN number**

| | |
|------|-----------|
| ADN | : UN 1090 |
| ADR | : UN 1090 |
| RID | : UN 1090 |
| IMDG | : UN 1090 |
| IATA | : UN 1090 |

14.2 UN proper shipping name

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| | | |
|-------------|---|---|
| ADN | : | ACETONE, SOLUTION |
| ADR | : | ACETONE, SOLUTION |
| RID | : | ACETONE, SOLUTION |
| IMDG | : | ACETONE, SOLUTION (Fluralaner, Moxidectin) |
| IATA | : | Acetone, solution |

14.3 Transport hazard class(es)

| | Class | Subsidiary risks |
|-------------|-------|------------------|
| ADN | : 3 | |
| ADR | : 3 | |
| RID | : 3 | |
| IMDG | : 3 | |
| IATA | : 3 | |

14.4 Packing group

| | |
|--|---------------------|
| ADN | |
| Packing group | : II |
| Classification Code | : F1 |
| Hazard Identification Number | : 33 |
| Labels | : 3 |
| ADR | |
| Packing group | : II |
| Classification Code | : F1 |
| Hazard Identification Number | : 33 |
| Labels | : 3 |
| Tunnel restriction code | : (D/E) |
| RID | |
| Packing group | : II |
| Classification Code | : F1 |
| Hazard Identification Number | : 33 |
| Labels | : 3 |
| IMDG | |
| Packing group | : II |
| Labels | : 3 |
| EmS Code | : F-E, S-D |
| IATA (Cargo) | |
| Packing instruction (cargo aircraft) | : 364 |
| Packing instruction (LQ) | : Y341 |
| Packing group | : II |
| Labels | : Flammable Liquids |
| IATA (Passenger) | |
| Packing instruction (passenger aircraft) | : 353 |
| Packing instruction (LQ) | : Y341 |
| Packing group | : II |

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Labels : Flammable Liquids

14.5 Environmental hazards**ADN**

Environmentally hazardous : yes

ADR

Environmentally hazardous : yes

RID

Environmentally hazardous : yes

IMDG

Marine pollutant : yes

14.6 Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

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

AICS : not determined

DSL : not determined

IECSC : not determined

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-Statements

H225 : Highly flammable liquid and vapour.

H301 : Toxic if swallowed.

H302 : Harmful if swallowed.

H312 : Harmful in contact with skin.

H315 : Causes skin irritation.

H319 : Causes serious eye irritation.

H332 : Harmful if inhaled.

H336 : May cause drowsiness or dizziness.

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| | | |
|-------|---|---|
| H360D | : | May damage the unborn child. |
| H361d | : | Suspected of damaging the unborn child. |
| H372 | : | Causes damage to organs through prolonged or repeated exposure. |
| H400 | : | Very toxic to aquatic life. |
| H410 | : | Very toxic to aquatic life with long lasting effects. |

Full text of other abbreviations

| | | |
|-------------------------|---|--|
| Acute Tox. | : | Acute toxicity |
| Aquatic Acute | : | Short-term (acute) aquatic hazard |
| Aquatic Chronic | : | Long-term (chronic) aquatic hazard |
| Eye Irrit. | : | Eye irritation |
| Flam. Liq. | : | Flammable liquids |
| Repr. | : | Reproductive toxicity |
| Skin Irrit. | : | Skin irritation |
| STOT RE | : | Specific target organ toxicity - repeated exposure |
| STOT SE | : | Specific target organ toxicity - single exposure |
| 2000/39/EC | : | Europe. Commission Directive 2000/39/EC establishing a first list of indicative occupational exposure limit values |
| 2004/37/EC | : | Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens, mutagens or reprotoxic substances at work - Annex III |
| ZA BEI | : | South Africa. The Regulations for Hazardous Chemical Agents, Biological Exposure Indices |
| ZA OEL | : | South Africa. The Regulations for Hazardous Chemical Agents, Occupational Exposure Limits |
| 2000/39/EC / TWA | : | Limit Value - eight hours |
| 2000/39/EC / STEL | : | Short term exposure limit |
| 2004/37/EC / STEL | : | Short term exposure limit |
| 2004/37/EC / TWA | : | Long term exposure limit |
| ZA OEL / OEL-RL | : | Occupational Exposure Limit Restricted limit - 8- hour exposure or equivalent (12 hour shifts) |
| ZA OEL / OEL- RL STEL/C | : | Occupational Exposure Limit Restricted limit - Short term occupational exposure limits / ceiling limits |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of

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Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

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

Classification of the mixture:

| | |
|-------------------|-------|
| Flam. Liq. 2 | H225 |
| Eye Irrit. 2 | H319 |
| Repr. 1B | H360D |
| STOT RE 2 | H373 |
| Aquatic Acute 1 | H400 |
| Aquatic Chronic 1 | H410 |

Classification procedure:

| |
|-------------------------------------|
| Based on product data or assessment |
| Based on product data or assessment |
| Calculation method |
| Calculation method |
| Calculation method |
| Calculation method |

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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