# SAFETY DATA SHEETS

## This SDS packet was issued with item:

078927999

**The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).**

078927998 078928000 078928001 078928002 078928003 078928004

**The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).**

078928005

# SAFETY DATA SHEET

# Fluralaner / Diethyltoluamide Liquid Formulation

| Version | Revision Date: | SDS Number: | Date of last issue: 10/01/2022 |
|---|---|---|---|
| 11.5 | 04/04/2023 | 412190-00021 | Date of first issue: 01/15/2016 |

## SECTION 1. IDENTIFICATION

Product name : Fluralaner / Diethyltoluamide Liquid Formulation

**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 OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Flammable liquids : Category 2

Reproductive toxicity : Category 1B

**GHS label elements**

Hazard pictograms :

Signal Word : Danger

Hazard Statements : H225 Highly flammable liquid and vapor.
H360D May damage the unborn child.

Precautionary Statements :

**Prevention:**

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P210 Keep away from heat, sparks, open flame and hot surfaces. No smoking.
P233 Keep container tightly closed.
P241 Use explosion-proof electrical, ventilating and lighting equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P280 Wear protective gloves, protective clothing, eye protection and face protection.

**Response:**

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P308 + P313 IF exposed or concerned: Get medical attention.

**Storage:**

P403 + P235 Store in a well-ventilated place. Keep cool.
P405 Store locked up.

**Disposal:**

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

**Other hazards**

Vapors may form explosive mixture with air.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

**Components**

| Chemical name | CAS-No. | Concentration (% w/w) |
|---|---|---|
| N,N-Dimethylacetamide | 127-19-5 | >= 30 - < 50 |
| Fluralaner | 864731-61-3 | >= 20 - < 30 |
| Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy- | 31692-85-0 | >= 10 - < 20 |
| N,N-Diethyl-m-toluamide | 134-62-3 | >= 10 - < 20 |
| Acetone | 67-64-1 | >= 10 - < 20 |

Actual concentration is withheld as a trade secret

## 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.
If vomiting occurs have person lean forward.
Call a physician or poison control center immediately.
Rinse mouth thoroughly with water.

Never give anything by mouth to an unconscious person.

| | | |
|---|---|---|
| Most important symptoms and effects, both acute and delayed | : | May damage the unborn child. |
| Protection of first-aiders | : | First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8). |
| Notes to physician | : | Treat symptomatically and supportively. |

## SECTION 5. FIRE-FIGHTING MEASURES

| | | |
|---|---|---|
| Suitable extinguishing media | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical |
| Unsuitable extinguishing media | : | High volume water jet |
| Specific hazards during fire fighting | : | Do not use a solid water stream as it may scatter and spread fire.<br>Flash back possible over considerable distance.<br>Vapors may form explosive mixtures with air.<br>Exposure to combustion products may be a hazard to health. |
| Hazardous combustion products | : | Carbon oxides<br>Chlorine compounds<br>Fluorine compounds<br>Nitrogen oxides (NOx) |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do so.<br>Evacuate area. |
| Special protective equipment for fire-fighters | : | In the event of fire, wear self-contained breathing apparatus.<br>Use personal protective equipment. |

## SECTION 6. ACCIDENTAL RELEASE MEASURES

| | | |
|---|---|---|
| Personal precautions, protective equipment and emergency procedures | : | Remove all sources of ignition.<br>Ventilate the area.<br>Use personal protective equipment.<br>Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8). |
| Environmental precautions | : | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Prevent spreading over a wide area (e.g., by containment or oil barriers).<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages cannot be contained. |
| Methods and materials for | : | Non-sparking tools should be used. |

| | |
|---|---|
| containment and cleaning up | Soak up with inert absorbent material.<br>Suppress (knock down) gases/vapors/mists with a water spray jet.<br>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.<br>Clean up remaining materials from spill with suitable absorbent.<br>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.<br>Sections 13 and 15 of this SDS provide information regarding certain local or national requirements. |

## SECTION 7. HANDLING AND STORAGE

| | | |
|---|---|---|
| Technical measures | : | See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section. |
| Local/Total ventilation | : | If sufficient ventilation is unavailable, use with local exhaust ventilation.<br>Use explosion-proof electrical, ventilating and lighting equipment. |
| Advice on safe handling | : | Do not get on skin or clothing.<br>Do not breathe vapors or spray mist.<br>Do not swallow.<br>Avoid contact with eyes.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Non-sparking tools should be used.<br>Keep container tightly closed.<br>Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.<br>Take precautionary measures against static discharges.<br>Take care to prevent spills, waste and minimize release to the environment. |
| Conditions for safe storage | : | Keep in properly labeled containers.<br>Store locked up.<br>Keep tightly closed.<br>Keep in a cool, well-ventilated place.<br>Store in accordance with the particular national regulations.<br>Keep away from heat and sources of ignition. |
| Materials to avoid | : | Do not store with the following product types:<br>Strong oxidizing agents<br>Self-reactive substances and mixtures<br>Organic peroxides<br>Flammable solids<br>Pyrophoric liquids<br>Pyrophoric solids<br>Self-heating substances and mixtures<br>Substances and mixtures which in contact with water emit |

flammable gases
Explosives
Gases
Very acutely toxic substances and mixtures

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Ingredients with workplace control parameters**

| Components | CAS-No. | Value type (Form of exposure) | Control parameters / Permissible concentration | Basis |
|---|---|---|---|---|
| N,N-Dimethylacetamide | 127-19-5 | TWA | 10 ppm | ACGIH |
| | | TWA | 10 ppm<br>35 mg/m³ | NIOSH REL |
| | | TWA | 10 ppm<br>35 mg/m³ | OSHA Z-1 |
| Fluralaner | 864731-61-3 | TWA | 100 µg/m3 (OEB 2) | Internal |
| | Further information: Skin | | | |
| | | Wipe limit | 1000 µg/100 cm² | Internal |
| Acetone | 67-64-1 | TWA | 250 ppm | ACGIH |
| | | STEL | 500 ppm | ACGIH |
| | | TWA | 250 ppm<br>590 mg/m³ | NIOSH REL |
| | | TWA | 1,000 ppm<br>2,400 mg/m³ | OSHA Z-1 |

**Biological occupational exposure limits**

| Components | CAS-No. | Control parameters | Biological specimen | Sampling time | Permissible concentration | Basis |
|---|---|---|---|---|---|---|
| N,N-Dimethylacetamide | 127-19-5 | N-Methylacetamide | Urine | End of shift at end of work-week | 30 mg/g Creatinine | ACGIH BEI |
| Acetone | 67-64-1 | Acetone | Urine | End of shift (As soon as possible after exposure ceases) | 25 mg/l | ACGIH BEI |

**Engineering measures** : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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.
Laboratory operations do not require special containment.

Use explosion-proof electrical, ventilating and lighting equipment.

**Personal protective equipment**

Respiratory protection : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection

Material : Chemical-resistant gloves

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

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.

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 | : | liquid |
| Color | : | yellow |
| Odor | : | No data available |
| Odor Threshold | : | No data available |
| pH | : | No data available |
| Melting point/freezing point | : | No data available |

| | | |
|---|---|---|
| Initial boiling point and boiling range | : | 217 °F / 103 °C |
| Flash point | : | 45 °F / 7 °C |
| 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 |
| Vapor pressure | : | 67 hPa (68 °F / 20 °C) |
| Relative vapor density | : | No data available |
| Relative density | : | No data available |
| Density | : | 1.059 g/cm³ |
| 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 | : | No data available |
| 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. |
| Chemical stability | : | Stable under normal conditions. |
| Possibility of hazardous reactions | : | Highly flammable liquid and vapor.<br>Vapors may form explosive mixture with air. |

Can react with strong oxidizing agents.

| | | |
|---|---|---|
| Conditions to avoid | : | Heat, flames and sparks. |
| Incompatible materials | : | Oxidizing agents |
| Hazardous decomposition products | : | No hazardous decomposition products are known. |

## SECTION 11. TOXICOLOGICAL INFORMATION

**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

**Acute toxicity**

Not classified based on available information.

**Product:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Remarks: No mortality observed at this dose. |
| Acute inhalation toxicity | : | Acute toxicity estimate: 5.95 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist<br>Method: Calculation method |
| Acute dermal toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Symptoms: Erythema |

**Components:**

**N,N-Dimethylacetamide:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): 4,800 mg/kg |
| Acute inhalation toxicity | : | LC50 (Rat): 2.2 mg/l<br>Exposure time: 4 h<br>Test atmosphere: dust/mist |
| Acute dermal toxicity | : | Acute toxicity estimate: 1,100 mg/kg<br>Method: Expert judgment<br>Remarks: Based on national or regional regulation. |

**Fluralaner:**

| | | |
|---|---|---|
| Acute oral toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Remarks: No mortality observed at this dose.<br>No significant adverse effects were reported |
| Acute dermal toxicity | : | LD50 (Rat): > 2,000 mg/kg<br>Remarks: No significant adverse effects were reported |

**Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-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): 1,950 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: vapor

Acute dermal toxicity : LD50 (Rabbit): 7,426 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Product:**

Species : Rabbit
Result : No skin irritation

**Components:**

**N,N-Dimethylacetamide:**

Species : Rabbit
Result : No skin irritation

**Fluralaner:**

Species : Rabbit
Result : No skin irritation

**Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-:**

Species : reconstructed human epidermis (RhE)
Method : OECD Test Guideline 439
Remarks : Based on data from similar materials

Result : No skin irritation

**N,N-Diethyl-m-toluamide:**

Species : Rabbit
Result : No skin irritation

**Acetone:**

Assessment : Repeated exposure may cause skin dryness or cracking.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Product:**

Species : Rabbit
Result : Mild eye irritation

**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), α-[(tetrahydro-2-furanyl)methyl]-ω-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

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
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.

**Product:**

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

**Components:**

**N,N-Dimethylacetamide:**

| | | |
|---|---|---|
| Routes of exposure | : | Skin contact |
| Species | : | Guinea pig |
| Result | : | negative |

**Fluralaner:**

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

**Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-:**

| | | |
|---|---|---|
| Test Type | : | KeratinoSens assay |
| 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 | : | Maximization Test |
| Routes of exposure | : | Skin contact |
| Species | : | Guinea pig |
| 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
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), α-[(tetrahydro-2-furanyl)methyl]-ω-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

**Carcinogenicity**

Not classified based on available information.

**Components:**

**N,N-Dimethylacetamide:**

| | | |
|---|---|---|
| Species | : | Rat |
| Application Route | : | inhalation (vapor) |
| 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 |

**IARC** Group 2B: Possibly carcinogenic to humans
N,N-Dimethylacetamide 127-19-5

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

May damage the unborn child.

**Components:**

**N,N-Dimethylacetamide:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Inhalation<br>Result: negative |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: Inhalation<br>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<br>Species: Rat<br>Application Route: Oral<br>General Toxicity Parent: NOAEL: 50 mg/kg body weight<br>General Toxicity F1: LOAEL: 100 mg/kg body weight<br>Result: No effects on fertility., Postimplantation loss., Adverse neonatal effects.<br><br>Test Type: One-generation reproduction toxicity study<br>Species: Dog<br>Application Route: Oral<br>Fertility: NOAEL: 75 mg/kg body weight<br>Result: No effects on fertility and early embryonic development were detected.<br>Remarks: No significant adverse effects were reported |
| Effects on fetal development | : | Test Type: Development<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 100 mg/kg body weight<br>Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects.<br><br>Test Type: Development<br>Species: Rabbit<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 10 mg/kg body weight<br>Result: Skeletal malformations., Visceral malformations.<br>Remarks: Maternal toxicity observed.<br><br>Test Type: Development<br>Species: Rabbit<br>Application Route: Dermal<br>Developmental Toxicity: NOAEL: 100 mg/kg body weight<br>Result: Skeletal malformations. |
| Reproductive toxicity - Assessment | : | Suspected of damaging the unborn child. |

**N,N-Diethyl-m-toluamide:**

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

**Acetone:**

| | | |
|---|---|---|
| Effects on fertility | : | Test Type: One-generation reproduction toxicity study<br>Species: Rat<br>Application Route: Ingestion<br>Result: negative |
| Effects on fetal development | : | Test Type: Embryo-fetal development<br>Species: Rat<br>Application Route: inhalation (vapor)<br>Result: negative |

**STOT-single exposure**

Not classified based on available information.

**Components:**

**Acetone:**

| | | |
|---|---|---|
| Assessment | : | May cause drowsiness or dizziness. |

**STOT-repeated exposure**

Not classified based on available information.

**Repeated dose toxicity**

**Components:**

**N,N-Dimethylacetamide:**

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 90 mg/m³ |
| LOAEL | : | 360 mg/m³ |
| Application Route | : | inhalation (vapor) |
| 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 | : | Diarrhea |
| | | |
| 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 |
| LOAEL | : | 1,700 mg/kg |
| Application Route | : | Ingestion |
| Exposure time | : | 90 Days |

| | | |
|---|---|---|
| Species | : | Rat |
| NOAEL | : | 45 mg/l |
| Application Route | : | inhalation (vapor) |
| Exposure time | : | 8 Weeks |

**Aspiration toxicity**

Not classified based on available information.

**Components:**

**Fluralaner:**

Not applicable

**Acetone:**

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

**Experience with human exposure**

**Product:**

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

**Components:**

**Fluralaner:**

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

## SECTION 12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**N,N-Dimethylacetamide:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l<br>Exposure time: 96 h |

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 500 mg/l<br>Exposure time: 48 h<br>Method: Directive 67/548/EEC, Annex V, C.2. |
| Toxicity to algae/aquatic plants | : | EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l<br>Exposure time: 72 h<br><br>EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l<br>Exposure time: 72 h |
| Toxicity to microorganisms | : | EC10: > 1,995 mg/l<br>Exposure time: 30 min |

**Fluralaner:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): > 0.0488 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 0.015 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to algae/aquatic plants | : | NOEC (Pseudokirchneriella subcapitata (green algae)): >= 0.08 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to fish (Chronic toxicity) | : | NOEC (Zebrafish): >= 0.049 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 204<br>Remarks: No toxicity at the limit of solubility. |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 0.0736 µg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211 |

**Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy-:**

| | | |
|---|---|---|
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 100 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202<br>Remarks: Based on data from similar materials |
| Toxicity to algae/aquatic plants | : | EC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: Based on data from similar materials<br><br>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<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203 |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 75 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br><br>NOEC (Selenastrum capricornutum (green algae)): 7.6 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): 3.7 mg/l<br>Exposure time: 21 d |

**Acetone:**

| | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Oncorhynchus mykiss (rainbow trout)): 5,540 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia pulex (Water flea)): 8,800 mg/l<br>Exposure time: 48 h |
| Toxicity to algae/aquatic plants | : | NOEC (Pseudokirchneriella subcapitata (green algae)): 7,000 mg/l<br>Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC (Daphnia magna (Water flea)): >= 79 mg/l<br>Exposure time: 21 d<br>Method: OECD Test Guideline 211 |
| Toxicity to microorganisms | : | EC50: 61,150 mg/l<br>Exposure time: 30 min<br>Method: ISO 8192 |

**Persistence and degradability**

**Components:**

**N,N-Dimethylacetamide:**

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

**Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-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:**

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

**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), α-[(tetrahydro-2-furanyl)methyl]-ω-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

**Mobility in soil**

**Components:**

**Fluralaner:**

Distribution among environmental compartments : log Koc: 4.1

**Other adverse effects**

**Components:**

**Fluralaner:**

| | | |
|---|---|---|
| Results of PBT and vPvB assessment | : | This substance is not considered to be persistent, bioaccumulating and toxic (PBT). |

## SECTION 13. DISPOSAL CONSIDERATIONS

**Disposal methods**

| | | |
|---|---|---|
| Waste from residues | : | Dispose of in accordance with local regulations.<br>Do not dispose of waste into sewer. |
| Contaminated packaging | : | Empty containers should be taken to an approved waste handling site for recycling or disposal.<br>Empty containers retain residue and can be dangerous.<br>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.<br>If not otherwise specified: Dispose of as unused product. |

## SECTION 14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**

| | | |
|---|---|---|
| UN number | : | UN 1090 |
| Proper shipping name | : | ACETONE SOLUTION |
| Class | : | 3 |
| Packing group | : | II |
| Labels | : | 3 |

**IATA-DGR**

| | | |
|---|---|---|
| UN/ID No. | : | UN 1090 |
| Proper shipping name | : | Acetone solution |
| Class | : | 3 |
| Packing group | : | II |
| Labels | : | Flammable Liquids |
| Packing instruction (cargo aircraft) | : | 364 |
| Packing instruction (passenger aircraft) | : | 353 |

**IMDG-Code**

| | | |
|---|---|---|
| UN number | : | UN 1090 |
| Proper shipping name | : | ACETONE SOLUTION (Fluralaner) |
| Class | : | 3 |
| Packing group | : | II |
| Labels | : | 3 |
| EmS Code | : | F-E, S-D |
| 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**

**49 CFR**

| | | |
|---|---|---|
| UN/ID/NA number | : | UN 1090 |
| Proper shipping name | : | Acetone SOLUTION |
| Class | : | 3 |
| Packing group | : | II |
| Labels | : | FLAMMABLE LIQUID |
| ERG Code | : | 127 |
| Marine pollutant | : | yes(Fluralaner) |

**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

**CERCLA Reportable Quantity**

| Components | CAS-No. | Component RQ (lbs) | Calculated product RQ (lbs) |
|---|---|---|---|
| Acetone | 67-64-1 | 5000 | 46728 |

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Flammable (gases, aerosols, liquids, or solids)
Reproductive toxicity

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**US State Regulations**

**Pennsylvania Right To Know**

| | |
|---|---|
| N,N-Dimethylacetamide | 127-19-5 |
| Fluralaner | 864731-61-3 |
| Poly(oxy-1,2-ethanediyl), α-[(tetrahydro-2-furanyl)methyl]-ω-hydroxy- | 31692-85-0 |
| N,N-Diethyl-m-toluamide | 134-62-3 |
| Acetone | 67-64-1 |

**California Prop. 65**

WARNING: This product can expose you to chemicals including N,N-Dimethylacetamide, which is/are known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

**California List of Hazardous Substances**

| | |
|---|---|
| N,N-Dimethylacetamide | 127-19-5 |
| Acetone | 67-64-1 |

**California Permissible Exposure Limits for Chemical Contaminants**

| | |
|---|---|
| N,N-Dimethylacetamide | 127-19-5 |
| Acetone | 67-64-1 |

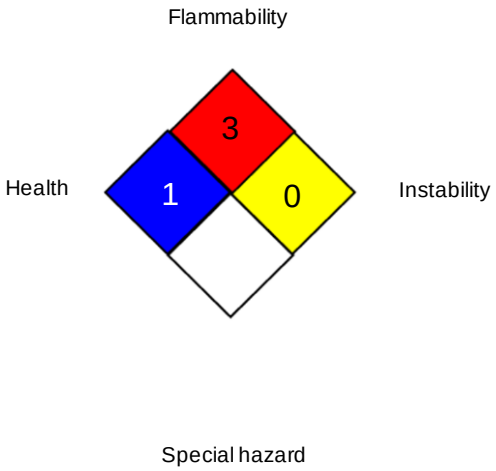
**The ingredients of this product are reported in the following inventories:**

| | | |
|---|---|---|
| AICS | : | not determined |
| DSL | : | not determined |
| IECSC | : | not determined |

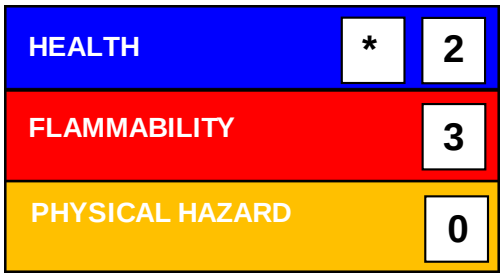
## SECTION 16. OTHER INFORMATION

**Further information**

**NFPA 704:**




**HMIS® IV:**




HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

| | | |
|---|---|---|
| ACGIH | : | USA. ACGIH Threshold Limit Values (TLV) |
| ACGIH BEI | : | ACGIH - Biological Exposure Indices (BEI) |
| NIOSH REL | : | USA. NIOSH Recommended Exposure Limits |
| OSHA Z-1 | : | USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants |
| ACGIH / TWA | : | 8-hour, time-weighted average |
| ACGIH / STEL | : | Short-term exposure limit |
| NIOSH REL / TWA | : | Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek |
| OSHA Z-1 / TWA | : | 8-hour time weighted average |

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; 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

| | | |
|---|---|---|
| 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 | : | 04/04/2023 |

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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