SAFETY DATA SHEET

Fluralaner / Diethyltoluamide Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: -
1.0	07.12.2020	7663876-00001	Date of first issue: 07.12.2020

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product name : Fluralaner / Diethyltoluamide Liquid Formulation

Manufacturer or supplier's details

Company : Merck & Co., Inc

Address : 126 E. Lincoln Avenue
Rahway, New Jersey U.S.A. 07065

Telephone : +1-908-740-4000

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

E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

2. HAZARDS IDENTIFICATION

GHS Classification

Flammable liquids : Category 2

Acute toxicity (Inhalation) : Category 5

Reproductive toxicity : Category 1B

Aspiration hazard : Category 2

Long-term (chronic) aquatic hazard : Category 1

GHS-Labelling

Hazard pictograms :

Signal word : Danger

Hazard statements : H225 Highly flammable liquid and vapour.
H305 May be harmful if swallowed and enters airways.
H333 May be harmful if inhaled.
H360D May damage the unborn child.
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.

P210 Keep away from heat/ sparks/ open flames/ hot surfaces. No smoking.
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P391 Collect spillage.

Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 17,4 %

Other hazards which do not result in classification

Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Pure substance/mixture : Mixture

Components

Chemical name	CAS-No.	Classification	MAC value mg/m3 / TSEL value	Concentration (% w/w)
N,N-Dimethylacetamide	127-19-5	Flam. Liq.4; H227 Acute Tox.5; H303 Acute Tox.4; H332 Acute Tox.4; H312 Eye Irrit.2A; H319 Repr.1B; H360D	MPC-TWA: 1 mg/m3 Class 3 - Moderately dangerous, Substances which require special skin and eye protection Data Source: RU OEL MPC-STEL: 3 mg/m3 Class 3 - Moderately dangerous, Substances which require special skin and eye protection Data Source: RU OEL	>= 30 - < 50
Fluralaner	864731-61-3	Repr.2; H361d Aquatic Chronic1; H410	No data available	>= 25 - < 30

N,N-Diethyl-m-toluamide	134-62-3	Acute Tox.4; H302 Acute Tox.5; H333 Acute Tox.5; H313 Skin Irrit.2; H315 Eye Irrit.2A; H319 Aquatic Acute3; H402 Aquatic Chronic3; H412	MPC-STEL: 5 mg/m3 Class 3 - Moderately dangerous, Substances which require special skin and eye protection Data Source: RU OEL	>= 10 - < 20
Acetone	67-64-1	Flam. Liq.2; H225 Eye Irrit.2A; H319 STOT SE3; H336 Asp. Tox.2; H305	MPC-TWA: 200 mg/m3 Class 4 - Low hazard Data Source: RU OEL MPC-STEL: 800 mg/m3 Class 4 - Low hazard Data Source: RU OEL	>= 10 - < 20

For explanation of abbreviations see section 16.

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 centre 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 be harmful if swallowed and enters airways. May be harmful if inhaled. 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.

5. FIREFIGHTING MEASURES

Flammable properties

Flash point	:	7 °C
Ignition temperature	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Flammability (solid, gas)	:	Not applicable
Flammability (liquids)	:	Not applicable
Suitable extinguishing media	:	Water spray Alcohol-resistant foam Carbon dioxide (CO2) 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. 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 (NOx)
Specific extinguishing methods	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for firefighters	:	In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	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).
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.
Methods and materials for containment and 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. 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.

7. HANDLING AND STORAGE

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 vapours or spray mist. Do not swallow. Avoid contact with eyes. 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. Take care to prevent spills, waste and minimize release to the environment. See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
Conditions for safe storage	:	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.
Materials to avoid	:	Do not store with the following product types: Strong oxidizing agents 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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Data Source
N,N-Dimethylacetamide	127-19-5	STEL	20 ppm 72 mg/m3	2000/39/EC
		TWA	10 ppm 36 mg/m3	2000/39/EC
		MPC-TWA (vapour and/or gas)	1 mg/m3	RU OEL
	Further information: Class 3 - Moderately dangerous, Substances which require special skin and eye protection			
		MPC-STEL (vapour and/or gas)	3 mg/m3	RU OEL
	Further information: Class 3 - Moderately dangerous, Substances which require special skin and eye protection			
Fluralaner	864731-61-3	TWA	100 µg/m3 (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 µg/100 cm²	Internal
N,N-Diethyl-m-toluamide	134-62-3	MPC-STEL (mixture of vapour and aerosol)	5 mg/m3	RU OEL
	Further information: Class 3 - Moderately dangerous, Substances which require special skin and eye protection			
Acetone	67-64-1	TWA	500 ppm 1.210 mg/m3	2000/39/EC
		MPC-TWA (vapour	200 mg/m3	RU OEL

		and/or gas)		
	Further information: Class 4 - Low hazard			
		MPC-STEL (vapour and/or gas)	800 mg/m3	RU OEL
	Further information: Class 4 - Low hazard			

Engineering measures : Use explosion-proof electrical, ventilating and lighting equipment.

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.

Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Self-contained breathing apparatus

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : 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	:	103 °C
Flash point	:	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
Vapour pressure	:	67 hPa (20 °C)
Relative vapour 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
Auto-ignition 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

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 vapour. Vapours 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.

11. TOXICOLOGICAL INFORMATION

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

Acute toxicity

May be harmful if inhaled.

Product:

Acute oral toxicity	:	LD50 (Rat): > 2.000 mg/kg Remarks: No mortality observed at this dose.
Acute inhalation toxicity	:	Acute toxicity estimate: 5,95 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	LD50 (Rat): > 2.000 mg/kg Symptoms: Erythema

Components:

N,N-Dimethylacetamide:

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 harmonised classification in EU regulation 1272/2008, Annex VI

Fluralaner:

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

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: vapour

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

N,N-Diethyl-m-toluamide:

Species : Rabbit
Result : 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

N,N-Diethyl-m-toluamide:

Species : Rabbit
Result : Irritation to eyes, reversing within 21 days

Acetone:

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

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

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

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.

Acetone:

Test Type	:	Maximisation Test
Exposure routes	:	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

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 (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

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. 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

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 (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
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

Aspiration toxicity

May be harmful if swallowed and enters airways.

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.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

N,N-Dimethylacetamide:

Toxicity to fish	:	LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l Exposure time: 96 h
Toxicity to daphnia and other	:	EC50 (Daphnia magna (Water flea)): > 500 mg/l

aquatic invertebrates		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
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 (Zebrafish): >= 0,049 mg/l Exposure time: 21 d Method: OECD Test Guideline 204 Remarks: No toxicity at the limit of solubility
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): 0,000047 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
M-Factor (Chronic aquatic toxicity)	:	1.000

N,N-Diethyl-m-toluamide:

Toxicity to fish	:	LC50 (Pimephales promelas (fathead minnow)): 110 mg/l Exposure time: 96 h
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 75 mg/l Exposure time: 48 h

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 daphnia and other aquatic invertebrates (Chronic toxicity)	:	NOEC (Daphnia magna (Water flea)): >= 79 mg/l Exposure time: 21 d Method: OECD Test Guideline 211
Toxicity to microorganisms	:	EC50: 61.150 mg/l Exposure time: 30 min Method: ISO 8192

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.

N,N-Diethyl-m-toluamide:

Biodegradability	:	Result: Not readily biodegradable.

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

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: 3,4

Other adverse effects

Components:

Fluralaner:

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

Hygienic standards:

(Allowable concentration in air, water, including fishery waters, soil)

Components	Air	Water	Soil	Data Source
N,N-Dimethylacetamide 127-19-5	MPC maximum value: 0,2 mg/m3 Limiting health hazard indicator: Reflectory-resorptive Class 2 - highly dangerous MPC average value: 0,006 mg/m3 Limiting health hazard indicator: Reflectory-resorptive Class 2 - highly dangerous	Maximum Permissible Concentration 1,2 Milligrams per cubed decimeter Limiting health hazard indicator: sanitary - violation of environmental conditions: changing trophic water bodies fishery; hydrochemical parameters: oxygen, nitrogen, phosphorus, pH, impaired self-purification of water bodies of water fishery: BOD5 (biochemical oxygen demand for 5 days), the number of saprophytic microflora Hazard class: 4 Maximum Allowable Concentration: 0,4 mg/l Limiting health hazard indicator: sanitary-toxicological Hazard class: Class		List 1 List 4 List 5

		2 - highly dangerous		
Acetone 67-64-1	MPC maximum value: 0,35 mg/m3 Limiting health hazard indicator: reflectory Class 4 - low hazard	Maximum Allowable Concentration: 2,2 mg/l Limiting health hazard indicator: general sanitary Hazard class: Class 3 - moderately dangerous Maximum Permissible Concentration 0,05 Milligrams per cubed decimeter Limiting health hazard indicator: toxic Hazard class: 3		List 1 List 4 List 5

List 1: GN 2.1.6.3492-17 Maximum permissible concentrations (MPC) of pollutants in the atmospheric air of urban and rural settlements

List 4: GN 2.1.5.1315-03 Maximum Allowable Concentrations (MAC) of Chemical Substances Contained in Water of Water Bodies for Economic-Potable and Social-Domestic Water Use

List 5: Order of the Russian Federal Fisheries Agency "Standards of maximum permissible concentrations of harmful substances in fishery water bodies"

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues	:	Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste handling site for recycling or disposal. 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.

14. TRANSPORT INFORMATION

ADR

UN number	:	UN 1090
Proper shipping name	:	ACETONE, SOLUTION
Class	:	3
Packing group	:	II
Labels	:	3
Hazard Identification Number	:	33
Tunnel restriction code	:	(D/E)
Environmentally hazardous	:	yes

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.

Special precautions for user

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

15. REGULATORY INFORMATION

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

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

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

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.

H227	Combustible liquid.
H302	Harmful if swallowed.
H303	May be harmful if swallowed.
H305	May be harmful if swallowed and enters airways.
H312	Harmful in contact with skin.
H313	May be harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H333	May be harmful if inhaled.
H336	May cause drowsiness or dizziness.
H360D	May damage the unborn child.
H361d	Suspected of damaging the unborn child.
H402	Harmful to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
H412	Harmful 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
Asp. Tox.	:	Aspiration hazard
Eye Irrit.	:	Eye irritation
Flam. Liq.	:	Flammable liquids
Repr.	:	Reproductive toxicity
Skin Irrit.	:	Skin irritation
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
RU OEL	:	Hygienic standard GN 2.2.5.3532-18 "Maximum allowed concentration (MAC) of harmful substances in the air of the working zone"
2000/39/EC / TWA	:	Limit Value - eight hours
2000/39/EC / STEL	:	Short term exposure limit
RU OEL / MPC-STEL	:	Maximum Permissible Concentration - Short Term Exposure
RU OEL / MPC-TWA	:	Maximum Permissible Concentration - Time Weighted Average

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European 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; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; 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 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; TCSI - Taiwan Chemical Substance 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/

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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