according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



# Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.07.2024 13.0 28.09.2024 462542-00029 Date of first issue: 15.01.2016

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Fluralaner / Diethyltoluamide Liquid Formulation

Other means of identification : BRAVECTO SPOT-ON (A011261)

BRAVECTO 1000 MG FLURALANER SPOT-ON SOLUTION

FOR LARGE DOGS (82794)

BRAVECTO 112.5 MG FLURALANER SPOT-ON SOLUTION

FOR SMALL CATS (82807)

BRAVECTO 112.5 MG FLURALANER SPOT-ON SOLUTION

FOR VERY SMALL DOGS (82798)

BRAVECTO 1400 MG FLURALANER SPOT-ON SOLUTION

FOR VERY LARGE DOGS (82795)

BRAVECTO 250 MG FLURALANER SPOT-ON SOLUTION

FOR MEDIUM CATS (82806)

BRAVECTO 250 MG FLURALANER SPOT-ON SOLUTION

FOR SMALL DOGS (82797)

BRAVECTO 500 MG FLURALANER SPOT-ON SOLUTION

FOR LARGE CATS (82804)

BRAVECTO 500 MG FLURALANER SPOT-ON SOLUTION

FOR MEDIUM DOGS (82796)

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

Use of the Sub- : Veterinary product

stance/Mixture

Recommended restrictions

on use

Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD

Kilsheelan

Clonmel Tipperary, IE

Telephone : 353-51-601000

E-mail address of person

responsible for the SDS

: EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

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#### **SECTION 2: Hazards identification**

### 2.1 Classification of the substance or mixture

## Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 2 Reproductive toxicity, Category 1B Long-term (chronic) aquatic hazard, Cat-

egory 1

H225: Highly flammable liquid and vapour. H360D: May damage the unborn child.

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.

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, hot surfaces, sparks, open

flames and other ignition sources. No smoking. P273 Avoid release to the environment.

P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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

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.

Ecological information: 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.

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Toxicological information: 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.

Vapours may form explosive mixture with air.

# **SECTION 3: Composition/information on ingredients**

## 3.2 Mixtures

### Components

Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
N,N-Dimethylacetamide	127-19-5	Acute Tox. 4; H332	>= 30 - < 50
	204-826-4	Acute Tox. 4; H312	
	616-011-00-4	Eye Irrit. 2; H319	
		Repr. 1B; H360D	
		Acute toxicity esti-	
		mate	
		Acute inhalation	
		toxicity (dust/mist):	
		2,2 mg/l	
		Acute dermal toxici-	
		ty: 1.100 mg/kg	
Fluralaner	864731-61-3	Repr. 2; H361d	>= 25 - < 30
		Aquatic Chronic 1;	
		H410	
		M-Factor (Chronic	
		aquatic toxicity):	
		1.000	
Poly(oxy-1,2-ethanediyl), .alpha	31692-85-0	Eye Irrit. 2; H319	>= 10 - < 20
[(tetrahydro-2-furanyl)methyl]-			
.omegahydroxy-			
N,N-Diethyl-m-toluamide	134-62-3	Acute Tox. 4; H302	>= 10 - < 20
	205-149-7	Skin Irrit. 2; H315	
	616-018-00-2	Eye Irrit. 2; H319	
		Acute toxicity esti-	
		mate	
		Acute oral toxicity:	
		1.892 mg/kg	
Acetone	67-64-1	Flam. Liq. 2; H225	>= 10 - < 20
	200-662-2	Eye Irrit. 2; H319	
	606-001-00-8	STOT SE 3; H336	

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EUH066

For explanation of abbreviations see section 16.

## **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 ad-

vice 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 : Flush eyes with water as a precaution.

Get medical attention if irritation develops and persists.

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 : May damage the unborn child.

## 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

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Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

High volume water jet

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 prod: :

ucts

Carbon oxides

Chlorine compounds Fluorine compounds Nitrogen oxides (NOx)

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 meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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 pro-

tective 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.

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## 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. Clean up remaining materials from spill with suitable absor-

bent.

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 deter-

mine 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 equip-

ment.

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 as-

sessment

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.

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 contami-

nated 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,

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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:

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-	127-19-5	TWA	10 ppm	FOR-2011-	
Dimethylacetamide			36 mg/m3	12-06-1358	
	Further inform	ation: Substances c	onsidered to be reprotoxic, C	hemicals that	
	can be absorb	can be absorbed through the skin.			
		STEL	20 ppm	FOR-2011-	
			72 mg/m3	12-06-1358	
	Further information: Substances considered to be reprotoxic, Chemicals that				
	can be absorbed through the skin.				
		TWA	10 ppm	2000/39/EC	
			36 mg/m3		
	Further information: Identifies the possibility of significant uptake through the				
	skin, Indicative				
		STEL	20 ppm	2000/39/EC	
			72 mg/m3		
	Further information: Identifies the possibility of significant uptake through the skin, Indicative				

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I		TWA	10 ppm	2004/37/EC	
			36 mg/m3		
	Further inform	Further information: Skin, Carcinogens or mutagens			
	STEL 20 p		20 ppm	2004/37/EC	
			72 mg/m3		
	Further inform	Further information: Skin, Carcinogens or mutagens			
Fluralaner	864731-61-	TWA	100 μg/m3 (OEB 2)	Internal	
	3				
	Further inform	Further information: Skin			
		Wipe limit	1000 μg/100 cm <sup>2</sup>	Internal	
Acetone	67-64-1	TWA	125 ppm	FOR-2011-	
			295 mg/m3	12-06-1358	
		TWA	500 ppm	2000/39/EC	
			1.210 mg/m3		
	Further inform	Further information: Indicative			

## 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/m3
	Workers	Inhalation	Acute systemic effects	36 mg/m3
	Workers	Skin contact	Acute systemic effects	13,6 mg/kg bw/day
	Consumers	Inhalation	Long-term local ef- fects	7 mg/m3
	Consumers	Skin contact	Long-term systemic effects	2,7 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	1 mg/kg bw/day
Acetone	Workers	Inhalation	Long-term systemic effects	1210 mg/m3
	Workers	Inhalation	Acute local effects	2420 mg/m3
	Workers	Skin contact	Long-term systemic effects	186 mg/kg bw/day
	Consumers	Inhalation	Long-term systemic effects	200 mg/m3
	Consumers	Skin contact	Long-term systemic effects	62 mg/kg bw/day
	Consumers	Ingestion	Long-term systemic effects	62 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
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

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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.)

## 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.

Laboratory operations do not require special containment.

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 : Take note that the product is flammable, which may impact

the selection of hand protection.

Skin and body protection : Work uniform or laboratory coat.

Respiratory protection : If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Equipment should conform to NS EN 137

Filter type : Self-contained breathing apparatus

## **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : yellow

Odour : No data available

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Odour Threshold : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

103 °C

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

Flash point : 7 °C

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Vapour pressure : 67 hPa (20 °C)

Relative density : No data available

Density : 1,059 g/cm<sup>3</sup>

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not explosive

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

Evaporation rate : No data available

Molecular weight : No data available

## **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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of: Inhalation Skin contact exposure

> Inaestion Eye contact

## **Acute toxicity**

Not classified based on available information.

**Product:** 

Acute oral toxicity LD50 (Rat): > 2.000 mg/kg

Remarks: No mortality observed at this dose.

Acute inhalation toxicity Acute toxicity estimate: > 5 mg/l

Exposure time: 4 h

Test atmosphere: dust/mist Method: Calculation method

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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 national or regional regulation.

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

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

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## 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), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-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 : Skin irritation

Remarks : Based on national or regional regulation.

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

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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

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

## 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

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Species : Guinea pig

Result : Not a skin sensitizer.

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

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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

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 - Assess-

ment

: No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 develop-

ment

Test Type: Embryo-foetal development

Species: Rat

Application Route: Inhalation

Result: positive

Reproductive toxicity - As-

sessment

: 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 develop-

ment were detected.

Remarks: No significant adverse effects were reported

Effects on foetal develop-

ment

Test Type: Development

Species: Rat

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 - As-

sessment

Suspected of damaging the unborn child.

N,N-Diethyl-m-toluamide:

Effects on foetal develop-

ment

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 develop-

ment

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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## Repeated dose toxicity

## **Components:**

## N,N-Dimethylacetamide:

**Species** : Rat NOAEL 90 mg/m3 : 360 mg/m3 : inhalation (vapour) LOAEL

Application Route

: 24 Months Exposure time

#### Fluralaner:

Species Dog NOAEL 1 mg/kg Application Route Exposure time Oral 52 Weeks Target Organs Liver

No significant adverse effects were reported Remarks

Species Juvenile dog 56 - 280 mg/kg LOAEL

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 Exposure time Dermal 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## **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.

#### 11.2 Information on other hazards

### **Endocrine disrupting properties**

#### **Product:**

Assessment : The substance/mixture does not contain components consid-

ered 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.

## **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**

## 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 : EC50 (Desmodesmus subspicatus (green algae)): > 500 mg/l

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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plants 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 tox-

icity)

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 (Chron-

ic toxicity)

NOEC: 0,0736 µg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

M-Factor (Chronic aquatic : 1.000

toxicity)

## 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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 : aquatic invertebrates (Chron-

ic toxicity)

NOEC: 3,7 mg/l 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 (Chron-

ic toxicity)

NOEC: >= 79 mg/l Exposure time: 21 d

Species: Daphnia magna (Water flea) Method: OECD Test Guideline 211

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## 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:

Biodegradability Result: Readily biodegradable.

Biodegradation: 91 % Exposure time: 28 d

### 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-: loa Pow: < 4

octanol/water 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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## 12.4 Mobility in soil

## **Components:**

#### Fluralaner:

Distribution among environ- : log Koc: 4,1

mental compartments

#### 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 Endocrine disrupting properties

### **Product:**

Assessment The substance/mixture does not contain components consid-

ered 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.

#### 12.7 Other adverse effects

No data available

## **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 han-

dling 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.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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## **SECTION 14: Transport information**

## 14.1 UN number or ID number

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

## 14.2 UN proper shipping name

ADN : ACETONE, SOLUTION

ADR : ACETONE, SOLUTION

RID : ACETONE, SOLUTION

IMDG : ACETONE, SOLUTION

(Fluralaner)

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

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Labels : 3

**IMDG** 

Packing group : II
Labels : 3
EmS Code : F-E, S-D

IATA (Cargo)

Packing instruction (cargo : 364

aircraft)

Packing instruction (LQ) : Y341
Packing group : II

Labels : Flammable Liquids

IATA (Passenger)

Packing instruction (passen: 353

ger aircraft)

Packing instruction (LQ) : Y341
Packing group : II

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 Maritime transport in bulk according to IMO instruments

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

Number on list 30: N,N-Dimethylacetamide

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) Number on list 72: N,N-Dimethylacetamide

Number on list 75: If you intend to use this product as tattoo ink, please contact your vendor.

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

not

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).

REACH - List of substances subject to authorisation

(Annex XIV)

Regulation (EC) on substances that deplete the ozone

layer

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

N,N-Dimethylacetamide

Not applicable

Not applicable

Not applicable

Not applicable

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors

This product is regulated by Regulation (EU) 2019/1148: all suspi- Acetone (ANNEX II) cious transactions, and significant disappearances and thefts should be reported to the relevant national contact point.

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

P5c	FLAMMABLE LIQUIDS	Quantity 1	Quantity 2
E1		5.000 t	50.000 t
E1	ENVIRONMENTAL HAZARDS	100 t	200 t

### Other regulations:

Note the Working Environment Act § 4-1 and § 4-2 on requirements for the employer to protect pregnant employees against discomfort and injury as a result of the work situation and the working environment.

Note the regulation on organization, leadership and participation, chapter 12 on the work of children and young people.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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.

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. H360D : May damage the unborn child.

H361d : May damage the unborn child.

Suspected of damaging the unborn child.

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

EUH066 : Repeated exposure may cause skin dryness or cracking.

## Full text of other abbreviations

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic 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

2004/37/EC : Europe. Directive 2004/37/EC on the protection of workers

from the risks related to exposure to carcinogens or mutagens

at work

FOR-2011-12-06-1358 : Norway. 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 FOR-2011-12-06-1358 / : Long term exposure limit

TWA

FOR-2011-12-06-1358 / : Short term exposure limit

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STEL

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 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

eChem Portal search results and European Chemicals Agen-Sheet cy, http://echa.europa.eu/

Classification of the mixture: Classification procedure:

Flam. Liq. 2 H225 Based on product data or assessment

Internal technical data, data from raw material SDSs, OECD

Repr. 1B H360D Calculation method Aquatic Chronic 1 H410 Calculation method

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

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

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



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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.

NO / EN