according to the Globally Harmonized System



Fluralaner / Diethyltoluamide Liquid Formulation

Version Revision Date: SDS Number: Date of last issue: 06.04.2024 9.0 06.07.2024 462539-00026 Date of first issue: 15.01.2016

1. PRODUCT AND COMPANY IDENTIFICATION

Product 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)

Manufacturer or supplier's details

Company : MSD

Address : Briahnager - Off Pune Nagar Road

Wagholi - Pune - India 412 207

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 Restrictions on use : Not applicable

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification

Very highly flammable liquids

GHS Classification

Flammable liquids : Category 2

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Acute toxicity (Inhalation) : Category 5

Reproductive toxicity : Category 1B

Aspiration hazard : Category 2

Long-term (chronic) aquatic

hazard

Category 1

GHS label elements

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:**

P203 Obtain, read and follow all safety 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:

P301 + P316 IF SWALLOWED: Get emergency medical help

immediately.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse affected areas with water.

P304 + P317 IF INHALED: Get medical help.

P318 IF exposed or concerned, get medical advice.

P331 Do NOT induce vomiting.

P391 Collect spillage.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

Other hazards which do not result in classification

Vapours may form explosive mixture with air.

3. COMPOSITION/INFORMATION ON INGREDIENTS

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Substance / Mixture Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
N,N-Dimethylacetamide	127-19-5	>= 30 - < 50
Fluralaner	864731-61-3	>= 25 - < 30
Poly(oxy-1,2-ethanediyl), .alpha[(tetrahydro-2-	31692-85-0	>= 10 - < 20
furanyl)methyl]omegahydroxy-		
N,N-Diethyl-m-toluamide	134-62-3	>= 10 - < 20
Acetone	67-64-1	>= 10 - < 20

4. FIRST AID MEASURES

In the case of accident or if you feel unwell, seek medical ad-General advice

vice 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

Remove contaminated clothing and shoes.

Get medical attention. Wash clothing before reuse.

Thoroughly clean shoes before reuse. : Flush eyes with water as a precaution.

In case of eye contact

Get medical attention if irritation develops and persists.

If swallowed, DO NOT induce vomiting. If swallowed

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

delayed

May damage the unborn child.

First Aid responders should pay attention to self-protection, Protection of first-aiders

and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Treat symptomatically and supportively. Notes to physician

5. FIREFIGHTING MEASURES

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

Flash back possible over considerable distance. Vapours may form explosive mixtures with air.

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Exposure to combustion products may be a hazard to health.

Hazardous combustion prod-

ucts

Carbon oxides

Chlorine compounds Fluorine compounds Nitrogen oxides (NOx)

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.

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, protec: :

tive equipment and emer-

gency procedures

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).

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 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.

7. HANDLING AND STORAGE

Technical measures : See Engineering measures under EXPOSURE

according to the Globally Harmonized System



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CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation If sufficient ventilation is unavailable, use with local exhaust

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-

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.

Keep in properly labelled containers. Conditions for safe storage

> 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. Do not store with the following product types:

Self-reactive substances and mixtures

Organic peroxides Oxidizing agents Flammable gases Pyrophoric liquids Pyrophoric solids

Self-heating substances and mixtures

Poisonous gases

Explosives

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Materials to avoid

Components 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
Fluralaner	864731-61-3	TWA	100 μg/m3 (OEB 2)	Internal
	Further information: Skin			
		Wipe limit	1000 μg/100 cm ²	Internal
Acetone	67-64-1	TWA	750 ppm 1,780 mg/m3	IN OEL
		STEL	1,000 ppm 2,375 mg/m3	IN OEL

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U	TWA	250 ppm	ACGIH
	STEL	500 ppm	ACGIH

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sam- pling time	Permissible concentration	Basis
N,N-Dimethylacetamide	127-19-5	N- Methyla- cetamide	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., 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 equip-

ment.

Personal protective equipment

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

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type Hand protection Self-contained breathing apparatus

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.

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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

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No data available Auto-ignition temperature

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 characteristics

Particle size Not applicable

10. STABILITY AND REACTIVITY

Reactivity Not classified as a reactivity hazard. Chemical stability Stable under normal conditions.

Possibility of hazardous reac-

tions

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:

LD50(Rat): > 2,000 mg/kgAcute oral toxicity

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

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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

Skin corrosion/irritation

Not classified based on available information.

Product:

Species : Rabbit

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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 : 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), .alpha.-[(tetrahydro-2-furanyl)methyl]-.omega.-hydroxy-:

Species : Tissue Culture

Method : OECD Test Guideline 492

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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 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

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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

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-:

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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- : No data available

ment

N,N-Diethyl-m-toluamide:

Species : Rat
Application Route : Ingestion
Exposure time : 104 weeks
Result : negative

Acetone:

Species : Mouse
Application Route : Skin contact

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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

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

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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.

Repeated dose toxicity

Components:

N,N-Dimethylacetamide:

Species : Rat

NOAEL : 90 mg/m3

LOAEL : 360 mg/m3

Application Route : inhalation (vapour)

Application Route . Illialation (vapou

Exposure time : 24 Months

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

Remarks : No significant adverse effects were reported

: Juvenile dog **Species** : 56 - 280 mg/kg

Application Route
Exposure time
Symptoms : Oral 24 Weeks Symptoms : Diarrhoea

: Rat Species

: 400 mg/kg LOAEL Application Route Exposure time Target Organs : Oral : 90 Days

Target Organs : Liver, thymus gland

: Rat Species NOAEL : 500 mg/kg Application Route
Exposure time : Dermal : 90 Days : Liver Target Organs

Remarks : No significant adverse effects were reported

Acetone:

Species Rat NOAEL : 900 mg/kg LOAEL : 1,700 mg/kg Application Route : Ingestion : 90 Days Exposure time

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.

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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

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): > 500 mg/l

Exposure time: 48 h

Method: Directive 67/548/EEC, Annex V, C.2.

Toxicity to algae/aquatic

plants

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

Exposure time: 72 h

EC10 (Desmodesmus subspicatus (green algae)): > 500 mg/l

Exposure time: 72 h

EC10: > 1,995 mg/lToxicity to microorganisms

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

according to the Globally Harmonized System



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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

toxicity)

1,000

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

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 100 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Remarks: Based on data from similar materials

Toxicity to algae/aquatic

plants

EC50 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

EC10 (Pseudokirchneriella subcapitata (green algae)): > 100

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Remarks: Based on data from similar materials

N,N-Diethyl-m-toluamide:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 97 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): 75 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Selenastrum capricornutum (green algae)): 7.6 mg/l

ErC50 (Selenastrum capricornutum (green algae)): 41 mg/l

Exposure time: 72 h

Exposure time: 21 d

Method: OECD Test Guideline 201

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC: 3.7 mg/l

Species: Daphnia magna (Water flea)

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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

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

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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: nlog Pow: < 4

octanol/water Remarks: Calculation

N,N-Diethyl-m-toluamide:

Partition coefficient: n-: log Pow: 2.02

octanol/water

Acetone:

Partition coefficient: n-: log Pow: -0.27 - -0.23

octanol/water

Mobility in soil

Components:

Fluralaner:

Distribution among environ: log Koc: 4.1

mental compartments

Other adverse effects

Components:

Fluralaner:

Results of PBT and vPvB

assessment

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

13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Empty containers should be taken to an approved waste han-Contaminated packaging

dling site for recycling or disposal.

Empty containers retain residue and can be dangerous.

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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

International Regulations

UNRTDG

UN number : UN 1090

Proper shipping name : ACETONE SOLUTION

Class : 3
Packing group : II
Labels : 3
Environmentally hazardous : no

IATA-DGR

UN/ID No. : UN 1090

Proper shipping name : Acetone solution

Class : 3 Packing group : II

Labels : Flammable Liquids

Packing instruction (cargo

aircraft)

Packing instruction (passen: 353

ger aircraft)

IMDG-Code

UN number : UN 1090

Proper shipping name : ACETONE SOLUTION

(Fluralaner)

364

Class : 3
Packing group : II
Labels : 3
EmS Code : F-E, S-D
Marine pollutant : yes

Transport in bulk according to IMO instruments

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

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DSL : not determined

IECSC : not determined

16. OTHER INFORMATION

Revision Date : 06.07.2024

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 Agen-

cy, http://echa.europa.eu/

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

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
ACGIH BEI : ACGIH - Biological Exposure Indices (BEI)

IN OEL : India. Permissible levels of certain chemical substances in

work environment.

ACGIH / TWA : 8-hour, time-weighted average ACGIH / STEL : Short-term exposure limit

IN OEL / TWA : Time-Weighted Average Concentration (TWA) (8 hrs.)

IN OEL / STEL : Short-term exposure Limit STEL (15 min)

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR -Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No

according to the Globally Harmonized System



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1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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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