

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".



## Fluralaner Solid Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 13.09.2019  |
| 2.3     | 23.03.2020     | 2365938-00007 | Date of first issue: 10.01.2018 |

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

#### 1.1 Product identifier

Trade name : Fluralaner Solid Formulation

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

Use of the Sub-stance/Mixture : Veterinary product

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
Balıkhisar Mah. Köyiçi Küme Evleri No: 765/A  
Çubuk Yolu 2. Km  
Akyurt / Ankara / TÜRKİYE

Telephone : +90 312 840 53 00

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

#### 1.4 Emergency telephone number

National Poison Control Center (UZEM): 114  
Emergency: 1-908-423-6000

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification T.R. SEA No 28848

Reproductive toxicity, Category 2  
Long-term (chronic) aquatic hazard, Category 1

H361d: Suspected of damaging the unborn child.  
H410: Very toxic to aquatic life with long lasting effects.

#### 2.2 Label elements

##### Labelling T.R. SEA No 28848

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.  
H410 Very toxic to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**

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P201 Obtain special instructions before use.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

### Response:

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

### Storage:

P405 Store locked up.

Hazardous components which must be listed on the label:  
Fluralaner

### 2.3 Other hazards

None known.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name            | CAS-No.<br>EC-No.<br>Index-No.<br>Registration number | Classification                                                                                  | Concentration<br>(% w/w) |
|--------------------------|-------------------------------------------------------|-------------------------------------------------------------------------------------------------|--------------------------|
| Fluralaner               | 864731-61-3                                           | Repr.2; H361d<br>Aquatic Chronic1;<br>H410<br><br>M-Factor (Chronic aquatic toxicity):<br>1.000 | $\geq 5 - < 20$          |
| Sodium n-dodecyl sulfate | 151-21-3<br>205-788-1                                 | Acute Tox.4; H302<br>Skin Irrit.2; H315<br>Eye Dam.1; H318<br>Aquatic Chronic3;<br>H412         | $\geq 1 - \leq 5$        |

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 advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

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- |                            |   |                                                                                                                                                                                                              |
|----------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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.<br>Get medical attention.                                                                                                                                                   |
| In case of skin contact    | : | In case of contact, immediately flush skin with plenty of water.<br>Remove contaminated clothing and shoes.<br>Get medical attention.<br>Wash clothing before reuse.<br>Thoroughly clean shoes before reuse. |
| In case of eye contact     | : | Flush eyes with water as a precaution.<br>Get medical attention if irritation develops and persists.                                                                                                         |
| If swallowed               | : | If swallowed, DO NOT induce vomiting.<br>Get medical attention.<br>Rinse mouth thoroughly with water.                                                                                                        |

### 4.2 Most important symptoms and effects, both acute and delayed

- |       |   |                                         |
|-------|---|-----------------------------------------|
| Risks | : | Suspected of damaging 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<br>Alcohol-resistant foam<br>Carbon dioxide (CO <sub>2</sub> )<br>Dry chemical |
| Unsuitable extinguishing media | : | None known.                                                                                |

### 5.2 Special hazards arising from the substance or mixture

- |                                       |   |                                                                                             |
|---------------------------------------|---|---------------------------------------------------------------------------------------------|
| Specific hazards during fire-fighting | : | Exposure to combustion products may be a hazard to health.                                  |
| Hazardous combustion products         | : | Carbon oxides<br>Chlorine compounds<br>Fluorine compounds<br>Sulphur oxides<br>Metal oxides |

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### 5.3 Advice for firefighters

- Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.
- Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

### 6.2 Environmental precautions

- Environmental precautions : Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

### 6.4 Reference to other sections

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

## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- Technical measures : See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not get on skin or clothing. Do not swallow. Avoid contact with eyes. Handle in accordance with good industrial hygiene and safety

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practice, based on the results of the workplace exposure assessment  
Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.

Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents

### 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    |
|---------------------------|-------------|-------------------------------|-------------------------------|----------|
| Fluralaner                | 864731-61-3 | TWA                           | 100 µg/m <sup>3</sup> (OEB 2) | Internal |
| Further information: Skin |             |                               |                               |          |
|                           |             | Wipe limit                    | 1000 µg/100 cm <sup>2</sup>   | Internal |

#### Derived No Effect Level (DNEL) :

| Substance name           | End Use   | Exposure routes | Potential health effects   | Value                 |
|--------------------------|-----------|-----------------|----------------------------|-----------------------|
| Sodium n-dodecyl sulfate | Workers   | Inhalation      | Long-term systemic effects | 285 mg/m <sup>3</sup> |
|                          | Workers   | Skin contact    | Long-term systemic effects | 4060 mg/kg bw/day     |
|                          | Consumers | Inhalation      | Long-term systemic effects | 85 mg/m <sup>3</sup>  |
|                          | Consumers | Skin contact    | Long-term systemic effects | 2440 mg/kg bw/day     |
|                          | Consumers | Ingestion       | Long-term systemic effects | 24 mg/kg bw/day       |

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|           |           |            |                            |                  |
|-----------|-----------|------------|----------------------------|------------------|
| Glycerine | Workers   | Inhalation | Long-term local effects    | 56 mg/m3         |
|           | Consumers | Ingestion  | Long-term systemic effects | 229 mg/kg bw/day |
|           | Consumers | Inhalation | Long-term local effects    | 33 mg/m3         |

### Predicted No Effect Concentration (PNEC) :

| Substance name           | Environmental Compartment | Value                         |
|--------------------------|---------------------------|-------------------------------|
| Sodium n-dodecyl sulfate | Fresh water               | 0,176 mg/l                    |
|                          | Marine water              | 0,018 mg/l                    |
|                          | Sewage treatment plant    | 1,35 mg/l                     |
|                          | Fresh water sediment      | 6,97 mg/kg dry weight (d.w.)  |
|                          | Marine sediment           | 0,697 mg/kg dry weight (d.w.) |
| Glycerine                | Soil                      | 1,29 mg/kg dry weight (d.w.)  |
|                          | Fresh water               | 0,885 mg/l                    |
|                          | Marine water              | 0,0885 mg/l                   |
|                          | Intermittent use/release  | 8,85 mg/l                     |
|                          | Sewage treatment plant    | 1000 mg/l                     |
|                          | Fresh water sediment      | 3,3 mg/kg dry weight (d.w.)   |
|                          | Marine sediment           | 0,33 mg/kg dry weight (d.w.)  |
|                          | Soil                      | 0,141 mg/kg dry weight (d.w.) |

## 8.2 Exposure controls

### Engineering measures

Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

### Personal protective equipment

- 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.
- Hand protection  
Material : Chemical-resistant gloves
- Skin and body protection : Work uniform or laboratory coat.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to TS EN 14387
- Filter type : Combined particulates and organic vapour type (A-P)

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic physical and chemical properties

|                                                  |   |                                                          |
|--------------------------------------------------|---|----------------------------------------------------------|
| Appearance                                       | : | Pasty solid                                              |
| Colour                                           | : | light brown                                              |
| Odour                                            | : | No data available                                        |
| Odour Threshold                                  | : | No data available                                        |
| pH                                               | : | No data available                                        |
| Melting point/freezing point                     | : | No data available                                        |
| Initial boiling point and boiling range          | : | No data available                                        |
| Flash point                                      | : | Not applicable                                           |
| Evaporation rate                                 | : | No data available                                        |
| Flammability (solid, gas)                        | : | Not classified as a flammability hazard                  |
| Upper explosion limit / Upper flammability limit | : | No data available                                        |
| Lower explosion limit / Lower flammability limit | : | No data available                                        |
| Vapour pressure                                  | : | No data available                                        |
| Relative vapour density                          | : | No data available                                        |
| Relative density                                 | : | No data available                                        |
| Density                                          | : | No data available                                        |
| 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. |

#### 9.2 Other information

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Flammability (liquids) : No data available

Particle size : 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 : Can react with strong oxidizing agents.

#### 10.4 Conditions to avoid

Conditions to avoid : None known.

#### 10.5 Incompatible materials

Materials to avoid : Oxidizing agents

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

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

##### Acute toxicity

Not classified based on available information.

##### Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg  
Method: Calculation method

##### Components:

##### 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

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### Sodium n-dodecyl sulfate:

|                       |   |                                                                                                               |
|-----------------------|---|---------------------------------------------------------------------------------------------------------------|
| Acute oral toxicity   | : | LD50 (Rat): 1.200 mg/kg<br>Method: OECD Test Guideline 401                                                    |
| Acute dermal toxicity | : | LD50 (Rat): > 2.000 mg/kg<br>Method: OECD Test Guideline 402<br>Remarks: Based on data from similar materials |

### Skin corrosion/irritation

Not classified based on available information.

### Components:

#### Fluralaner:

|         |   |                    |
|---------|---|--------------------|
| Species | : | Rabbit             |
| Result  | : | No skin irritation |

#### Sodium n-dodecyl sulfate:

|         |   |                 |
|---------|---|-----------------|
| Species | : | Rabbit          |
| Result  | : | Skin irritation |

### Serious eye damage/eye irritation

Not classified based on available information.

### Components:

#### Fluralaner:

|         |   |                     |
|---------|---|---------------------|
| Species | : | Rabbit              |
| Result  | : | Mild eye irritation |

#### Sodium n-dodecyl sulfate:

|         |   |                                 |
|---------|---|---------------------------------|
| Species | : | Rabbit                          |
| Method  | : | OECD Test Guideline 405         |
| Result  | : | Irreversible effects on the eye |

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified based on available information.

#### Respiratory sensitisation

Not classified based on available information.

### Components:

#### Fluralaner:

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

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### Sodium n-dodecyl sulfate:

|                 |                                        |
|-----------------|----------------------------------------|
| Test Type       | : Maximisation Test                    |
| Exposure routes | : Skin contact                         |
| Species         | : Guinea pig                           |
| Result          | : negative                             |
| Remarks         | : Based on data from similar materials |

### Germ cell mutagenicity

Not classified based on available information.

### Components:

#### Fluralaner:

|                       |                                                                          |
|-----------------------|--------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Result: negative |
|-----------------------|--------------------------------------------------------------------------|

|                                               |
|-----------------------------------------------|
| Test Type: Mouse Lymphoma<br>Result: negative |
|-----------------------------------------------|

|                                                       |
|-------------------------------------------------------|
| Test Type: Chromosomal aberration<br>Result: negative |
|-------------------------------------------------------|

|                      |                                                                                                                           |
|----------------------|---------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vivo | : Test Type: Micronucleus test<br>Species: Mouse<br>Cell type: Bone marrow<br>Application Route: Oral<br>Result: negative |
|----------------------|---------------------------------------------------------------------------------------------------------------------------|

### Sodium n-dodecyl sulfate:

|                       |                                                                                                             |
|-----------------------|-------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES)<br>Method: OECD Test Guideline 471<br>Result: negative |
|-----------------------|-------------------------------------------------------------------------------------------------------------|

|                                                                           |
|---------------------------------------------------------------------------|
| Test Type: In vitro mammalian cell gene mutation test<br>Result: negative |
|---------------------------------------------------------------------------|

|                      |                                                                                                                                      |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------|
| Genotoxicity in vivo | : Test Type: Rodent dominant lethal test (germ cell) (in vivo)<br>Species: Mouse<br>Application Route: Ingestion<br>Result: negative |
|----------------------|--------------------------------------------------------------------------------------------------------------------------------------|

### Carcinogenicity

Not classified based on available information.

### Components:

#### Fluralaner:

|                           |                     |
|---------------------------|---------------------|
| Carcinogenicity - Assess- | : No data available |
|---------------------------|---------------------|

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### Sodium n-dodecyl sulfate:

|                   |   |                                      |
|-------------------|---|--------------------------------------|
| Species           | : | Rat                                  |
| Application Route | : | Ingestion                            |
| Exposure time     | : | 2 Years                              |
| Method            | : | OECD Test Guideline 453              |
| Result            | : | negative                             |
| Remarks           | : | Based on data from similar materials |

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### Fluralaner:

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

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<br>Species: Rat<br>Application Route: Oral<br>Developmental Toxicity: NOAEL: 100 mg/kg body weight<br>Result: Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, No teratogenic effects |
|-------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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

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Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

### **Sodium n-dodecyl sulfate:**

Effects on fertility : Test Type: Two-generation reproduction toxicity study  
Species: Rat  
Application Route: Ingestion  
Method: OECD Test Guideline 416  
Result: negative  
Remarks: Based on data from similar materials

Effects on foetal development : Test Type: Embryo-foetal development  
Species: Rat  
Application Route: Ingestion  
Result: negative  
Remarks: Based on data from similar materials

### **STOT - single exposure**

Not classified based on available information.

### **STOT - repeated exposure**

Not classified based on available information.

### **Repeated dose toxicity**

#### **Product:**

Species : Dog  
LOAEL : 25 mg/kg  
Application Route : Oral  
Exposure time : 168 d  
Symptoms : Vomiting  
Remarks : No significant adverse effects were reported

#### **Components:**

##### **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

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|                   |   |                                              |
|-------------------|---|----------------------------------------------|
| 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 |

### Sodium n-dodecyl sulfate:

|                   |   |                                      |
|-------------------|---|--------------------------------------|
| Species           | : | Rat                                  |
| NOAEL             | : | 488 mg/kg                            |
| Application Route | : | Ingestion                            |
| Exposure time     | : | 90 Days                              |
| Remarks           | : | Based on data from similar materials |

### Aspiration toxicity

Not classified based on available information.

### Components:

#### Fluralaner:

Not applicable

### Experience with human exposure

### Components:

#### Fluralaner:

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

## SECTION 12: Ecological information

### 12.1 Toxicity

### Components:

#### Fluralaner:

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

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|                                                                        |   |                                                                                                                                                                                     |
|------------------------------------------------------------------------|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Toxicity to algae/aquatic plants                                       | : | NOEC (Pseudokirchneriella subcapitata (green algae)): $\geq$ 0,08 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201<br>Remarks: No toxicity at the limit of solubility |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC: $\geq$ 0,049 mg/l<br>Exposure time: 21 d<br>Species: Zebrafish<br>Method: OECD Test Guideline 204<br>Remarks: No toxicity at the limit of solubility                          |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0,000047 mg/l<br>Exposure time: 21 d<br>Species: Daphnia magna (Water flea)<br>Method: OECD Test Guideline 211                                                                |
| M-Factor (Chronic aquatic toxicity)                                    | : | 1.000                                                                                                                                                                               |
| <b>Sodium n-dodecyl sulfate:</b>                                       |   |                                                                                                                                                                                     |
| Toxicity to fish                                                       | : | LC50 (Pimephales promelas (fathead minnow)): 29 mg/l<br>Exposure time: 96 h                                                                                                         |
| Toxicity to daphnia and other aquatic invertebrates                    | : | EC50 (Ceriodaphnia dubia (water flea)): 5,55 mg/l<br>Exposure time: 48 h                                                                                                            |
| Toxicity to algae/aquatic plants                                       | : | ErC50 (Desmodesmus subspicatus (green algae)): $>$ 120 mg/l<br>Exposure time: 72 h<br><br>NOEC (Desmodesmus subspicatus (green algae)): 30 mg/l<br>Exposure time: 72 h              |
| Toxicity to microorganisms                                             | : | EC50 : 135 mg/l<br>Exposure time: 3 h                                                                                                                                               |
| Toxicity to fish (Chronic toxicity)                                    | : | NOEC: $\geq$ 1,357 mg/l<br>Exposure time: 42 d<br>Species: Pimephales promelas (fathead minnow)                                                                                     |
| Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) | : | NOEC: 0,88 mg/l<br>Exposure time: 7 d<br>Species: Ceriodaphnia dubia (water flea)                                                                                                   |

### 12.2 Persistence and degradability

#### Components:

##### **Sodium n-dodecyl sulfate:**

|                  |   |                                                        |
|------------------|---|--------------------------------------------------------|
| Biodegradability | : | Result: Readily biodegradable.<br>Biodegradation: 95 % |
|------------------|---|--------------------------------------------------------|

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Exposure time: 28 d  
Method: OECD Test Guideline 301B

### 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

##### **Sodium n-dodecyl sulfate:**

Partition coefficient: n-octanol/water : log Pow: 0,83

### 12.4 Mobility in soil

#### Components:

##### **Fluralaner:**

Distribution among environmental compartments : log Koc: 3,4

### 12.5 Results of PBT and vPvB assessment

#### Components:

##### **Fluralaner:**

Assessment : This substance is not considered to be persistent, bioaccumulating and toxic (PBT)..

### 12.6 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. |
| Contaminated packaging | : Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.                                                                                                              |

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### SECTION 14: Transport information

#### 14.1 UN number

|      |   |         |
|------|---|---------|
| ADN  | : | UN 3077 |
| ADR  | : | UN 3077 |
| RID  | : | UN 3077 |
| IMDG | : | UN 3077 |
| IATA | : | UN 3077 |

#### 14.2 UN proper shipping name

|      |   |                                                                    |
|------|---|--------------------------------------------------------------------|
| ADN  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(Fluralaner) |
| ADR  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(Fluralaner) |
| RID  | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(Fluralaner) |
| IMDG | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.<br>(Fluralaner) |
| IATA | : | Environmentally hazardous substance, solid, n.o.s.<br>(Fluralaner) |

#### 14.3 Transport hazard class(es)

|      |   |   |
|------|---|---|
| ADN  | : | 9 |
| ADR  | : | 9 |
| RID  | : | 9 |
| IMDG | : | 9 |
| IATA | : | 9 |

#### 14.4 Packing group

|                              |   |               |
|------------------------------|---|---------------|
| ADN                          |   |               |
| Packing group                | : | III           |
| Classification Code          | : | M7            |
| Hazard Identification Number | : | 90            |
| Labels                       | : | 9 (ENVIRONM.) |
| ADR                          |   |               |
| Packing group                | : | III           |
| Classification Code          | : | M7            |
| Hazard Identification Number | : | 90            |
| Labels                       | : | 9 (ENVIRONM.) |

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Tunnel restriction code : (-)

### RID

Packing group : III  
Classification Code : M7  
Hazard Identification Number : 90  
Labels : 9 (ENVIRONM.)

### IMDG

Packing group : III  
Labels : 9 (ENVIRONM.)  
EmS Code : F-A, S-F

### IATA (Cargo)

Packing instruction (cargo aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous,

### IATA (Passenger)

Packing instruction (passenger aircraft) : 956  
Packing instruction (LQ) : Y956  
Packing group : III  
Labels : Miscellaneous,

## 14.5 Environmental hazards

### ADN

Environmentally hazardous : yes

### ADR

Environmentally hazardous : yes

### RID

Environmentally hazardous : yes

### IMDG

Marine pollutant : yes

### IATA (Passenger)

Environmentally hazardous : yes

### IATA (Cargo)

Environmentally hazardous : yes

## 14.6 Special precautions for user

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

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

Remarks : Not applicable for product as supplied.

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### SECTION 15: Regulatory information

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, : Not applicable  
placing on the market and use of certain dangerous  
substances, mixtures and articles (Annex 17)

Regulation on Persistent Organic Pollutants (Number : Not applicable  
30595)

Regulation on prevention of major industrial accidents. Reg number 30702

|    |                          |                     |                     |
|----|--------------------------|---------------------|---------------------|
| E1 | ENVIRONMENTAL<br>HAZARDS | Quantity 1<br>100 t | Quantity 2<br>200 t |
|----|--------------------------|---------------------|---------------------|

#### Other regulations:

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures; Part I".

Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.

Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 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

|       |                                                         |
|-------|---------------------------------------------------------|
| H302  | : Harmful if swallowed.                                 |
| H315  | : Causes skin irritation.                               |
| H318  | : Causes serious eye damage.                            |
| H361d | : Suspected of damaging the unborn child.               |
| H410  | : Very toxic to aquatic life with long lasting effects. |
| H412  | : Harmful to aquatic life with long lasting effects.    |

The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.

#### Full text of other abbreviations

|                 |                                      |
|-----------------|--------------------------------------|
| Acute Tox.      | : Acute toxicity                     |
| Aquatic Chronic | : Long-term (chronic) aquatic hazard |

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|             |                         |
|-------------|-------------------------|
| Eye Dam.    | : Serious eye damage    |
| Repr.       | : Reproductive toxicity |
| Skin Irrit. | : Skin irritation       |

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; AICS - Australian Inventory of Chemical Substances; 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

### Further information

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

### Classification of the mixture:

|                   |       |
|-------------------|-------|
| Repr. 2           | H361d |
| Aquatic Chronic 1 | H410  |

### Classification procedure:

|                    |
|--------------------|
| Calculation method |
| Calculation method |

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be

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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.

TR / EN