

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".



Orbifloxacin Liquid Formulation

| | | | |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number: | Date of last issue: 13.09.2019 |
| 2.3 | 23.03.2020 | 2569672-00006 | Date of first issue: 27.02.2018 |

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

1.1 Product identifier

Trade name : Orbifloxacin Liquid Formulation

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

Use of the Substance/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
Specific target organ toxicity - repeated exposure, Category 2, Eye

H361d: Suspected of damaging the unborn child.
H373: May cause damage to organs through prolonged or repeated exposure if swallowed.

2.2 Label elements

Labelling T.R. SEA No 28848

Hazard pictograms :



Signal word : Warning

Hazard statements : H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

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Precautionary statements : **Prevention:**
P201 Obtain special instructions before use.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:
P405 Store locked up.

Hazardous components which must be listed on the label:
Orbifloxacin

2.3 Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

| Chemical name | CAS-No. EC-No. Index-No. Registration number | Classification | Concentration (% w/w) |
|------------------|---|---|--------------------------|
| Orbifloxacin | 113617-63-3 | Repr.2; H361d | $\geq 3 - < 10$ |
| Lactic acid | 50-21-5 200-018-0 | Skin Irrit.2; H315 Eye Dam.1; H318 | $\geq 1 - < 3$ |
| Sodium hydroxide | 1310-73-2 215-185-5 011-002-00-6 | Met. Corr.1; H290 Skin Corr.1A; H314 Eye Dam.1; H318 | $\geq 1 - < 2$ |

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.

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).

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

4.2 Most important symptoms and effects, both acute and delayed

- | | | |
|-------|---|--|
| Risks | : | Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed. |
|-------|---|--|

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 Carbon dioxide (CO2) 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 Metal oxides |

5.3 Advice for firefighters

- | | | |
|---|---|--|
| Special protective equipment for firefighters | : | In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment. |
|---|---|--|

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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.
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.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container.
Clean up remaining materials from spill with suitable absorbent.
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

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 : Avoid inhalation of vapour or mist.
Do not swallow.

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Avoid contact with eyes.
Avoid prolonged or repeated contact with skin.
Handle in accordance with good industrial hygiene and safety 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 |
|--------------|-------------|-------------------------------|--------------------|----------|
| Orbifloxacin | 113617-63-3 | TWA | 0.2 mg/m3 (OEB 2) | Internal |

Derived No Effect Level (DNEL) :

| Substance name | End Use | Exposure routes | Potential health effects | Value |
|------------------|-----------|-----------------|----------------------------|-----------|
| Propylene glycol | Workers | Inhalation | Long-term local effects | 10 mg/m3 |
| | Workers | Inhalation | Long-term systemic effects | 168 mg/m3 |
| | Consumers | Inhalation | Long-term local effects | 10 mg/m3 |
| | Consumers | Inhalation | Long-term systemic effects | 50 mg/m3 |
| Silicon dioxide | Workers | Inhalation | Long-term systemic | 4 mg/m3 |

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| | | | effects | |
|------------------|-----------|------------|-------------------------|-----------|
| Lactic acid | Workers | Inhalation | Long-term local effects | 592 mg/m3 |
| | Workers | Inhalation | Acute local effects | 592 mg/m3 |
| | Consumers | Inhalation | Acute local effects | 296 mg/m3 |
| Sodium hydroxide | Consumers | Inhalation | Long-term local effects | 1 mg/m3 |
| | Workers | Inhalation | Long-term local effects | 1 mg/m3 |

Predicted No Effect Concentration (PNEC) :

| Substance name | Environmental Compartment | Value |
|------------------|---------------------------|------------|
| Propylene glycol | Fresh water | 260 mg/l |
| | Marine water | 26 mg/l |
| | Intermittent use/release | 183 mg/l |
| | Sewage treatment plant | 20000 mg/l |
| | Fresh water sediment | 572 mg/kg |
| | Marine sediment | 57,2 mg/kg |
| | Soil | 50 mg/kg |

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.

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)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Appearance : suspension
Colour : light brown
Odour : odourless

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| | | |
|--|---|--|
| 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 | : | No data available |
| Evaporation rate | : | No data available |
| Flammability (solid, gas) | : | Not applicable |
| 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 | : | No data available |
| 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

| | | |
|------------------------|---|-------------------|
| Flammability (liquids) | : | No data available |
| Molecular weight | : | No data available |
| Particle size | : | No data available |

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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 : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Orbifloxacin:

Acute oral toxicity : LD50 (Rat): > 3.000 mg/kg
Remarks: No mortality observed at this dose.

LD50 (Mouse): > 2.000 mg/kg
Remarks: No mortality observed at this dose.

LD50 (Dog): > 600 mg/kg
Symptoms: Vomiting
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of : LD50 (Rat): > 200 mg/kg

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administration) Application Route: Intramuscular

LD50 (Mouse): 500 mg/kg
Application Route: Intramuscular

LD50 (Rat): 233 mg/kg
Application Route: Intravenous

LD50 (Mouse): 250 mg/kg
Application Route: Intravenous

Lactic acid:

Acute oral toxicity : LD50 (Rat): > 2.000 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2.000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Sodium hydroxide:

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation

Not classified based on available information.

Product:

Species : Rabbit
Result : No skin irritation

Components:

Orbifloxacin:

Species : Rabbit
Method : Draize Test
Result : No skin irritation

Lactic acid:

Species : Rabbit
Result : Skin irritation
Remarks : Based on data from similar materials

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Sodium hydroxide:

Result : Corrosive after 3 minutes or less of exposure

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Species : Rabbit
Result : Mild eye irritation

Components:

Orbifloxacin:

Species : Rabbit
Method : Draize Test
Result : Mild eye irritation

Lactic acid:

Species : Chicken eye
Result : Irreversible effects on the eye
Remarks : Based on data from similar materials

Sodium hydroxide:

Result : Irreversible effects on the eye
Remarks : Based on skin corrosivity.

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

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

Components:

Orbifloxacin:

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

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Lactic acid:

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

Sodium hydroxide:

| | |
|-----------------|--|
| Test Type | : Human repeat insult patch test (HRIPT) |
| Exposure routes | : Skin contact |
| Result | : negative |

Germ cell mutagenicity

Not classified based on available information.

Components:

Orbifloxacin:

| | |
|-----------------------|---|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Result: equivocal |
|-----------------------|---|

Test Type: Mouse Lymphoma
Result: positive

Test Type: Chromosomal aberration
Test system: Human lymphocytes
Result: positive

| | |
|----------------------|--|
| Genotoxicity in vivo | : Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Intraperitoneal injection Result: negative |
|----------------------|--|

Test Type: unscheduled DNA synthesis assay
Species: Rat
Cell type: Liver cells
Application Route: Oral
Result: negative

| | |
|------------------------------------|--|
| Germ cell mutagenicity- Assessment | : Weight of evidence does not support classification as a germ cell mutagen. |
|------------------------------------|--|

Lactic acid:

| | |
|-----------------------|--|
| Genotoxicity in vitro | : Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials |
|-----------------------|--|

Test Type: In vitro mammalian cell gene mutation test

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Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Method: OECD Test Guideline 473
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity

Not classified based on available information.

Components:

Orbifloxacin:

| | |
|-------------------|-------------------------|
| Species | : Rat |
| Application Route | : Oral |
| Exposure time | : 2 Years |
| NOAEL | : 200 mg/kg body weight |
| Result | : negative |

| | |
|-------------------|-------------------------|
| Species | : Mouse |
| Application Route | : Oral |
| Exposure time | : 2 Years |
| NOAEL | : 200 mg/kg body weight |
| Result | : negative |

Lactic acid:

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

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Orbifloxacin:

| | |
|----------------------|--|
| Effects on fertility | : Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity - Parent: NOAEL: 50 mg/kg body weight Early Embryonic Development: NOAEL: 50 mg/kg body weight Result: No adverse effects |
|----------------------|--|

| | |
|-------------------------------|---|
| Effects on foetal development | : Test Type: Embryo-foetal development Species: Rat Application Route: Oral |
|-------------------------------|---|

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Embryo-foetal toxicity: LOAEL: 333 mg/kg body weight
Result: No teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses

Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
General Toxicity Maternal: NOAEL: 20 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 60 mg/kg body weight
Result: No effects on early embryonic development, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced maternal body weight gain

Test Type: Development
Species: Dog
Application Route: Oral
Developmental Toxicity: LOAEL: 2,5 mg/kg body weight
Result: Effects on postnatal development, Skeletal malformations

Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

Lactic acid:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.

Product:

Target Organs : Eye
Assessment : May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Product:

Species : Dog
NOAEL : 22,5 mg/kg
LOAEL : 37,5 mg/kg
Application Route : Oral
Exposure time : 30 Days

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| | |
|-------------------|---|
| Symptoms | : Gastrointestinal disturbance |
| Species | : Dog |
| LOAEL | : 75 mg/kg |
| Application Route | : Oral |
| Exposure time | : 10 Days |
| Symptoms | : Salivation, Gastrointestinal disturbance, Vomiting |
| Species | : Cat |
| LOAEL | : 45 mg/kg |
| Application Route | : Oral |
| Exposure time | : 30 Days |
| Target Organs | : Eye |
| Symptoms | : Salivation, Lachrymation, Gastrointestinal disturbance, Liver disorders |

Components:

Orbifloxacin:

| | |
|-------------------|--|
| Species | : Rat |
| NOAEL | : 20 mg/kg |
| LOAEL | : 80 mg/kg |
| Application Route | : Oral |
| Exposure time | : 3 Months |
| Target Organs | : Testis, Liver, Kidney, spleen |
| Species | : Mouse |
| NOAEL | : 80 mg/kg |
| LOAEL | : 250 mg/kg |
| Application Route | : Oral |
| Exposure time | : 3 Months |
| Species | : Juvenile dog |
| NOAEL | : 50 mg/kg |
| LOAEL | : 250 mg/kg |
| Application Route | : Oral |
| Exposure time | : 14 Days |
| Target Organs | : Heart, Bone |
| Symptoms | : Gastrointestinal disturbance |
| Remarks | : mortality observed |
| Species | : Juvenile dog |
| NOAEL | : 2 mg/kg |
| LOAEL | : 3 mg/kg |
| Application Route | : Oral |
| Exposure time | : 90 Days |
| Target Organs | : Bone |
| Remarks | : No significant adverse effects were reported |
| Species | : Dog |
| NOAEL | : 37,5 mg/kg |
| Application Route | : Oral |

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Exposure time : 30 Days

Species : Cat

NOAEL : 7,5 mg/kg

LOAEL : 22,5 mg/kg

Application Route : Oral

Exposure time : 1 Months

Symptoms : Gastrointestinal disturbance

Lactic acid:

Species : Rat

NOAEL : > 100 mg/kg

Application Route : Ingestion

Exposure time : 13 Weeks

Remarks : Based on data from similar materials

Species : Rat

LOAEL : 886 mg/kg

Application Route : Skin contact

Exposure time : 13 Weeks

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Orbifloxacin:

Ingestion : Symptoms: central nervous system effects, Gastrointestinal disturbance, liver function change, anaphylaxis, Rash
Remarks: May cause photosensitisation.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Lactic acid:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

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 : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100

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Orbifloxacin Liquid Formulation

| | | | |
|----------------|------------------------------|------------------------------|---|
| Version 2.3 | Revision Date: 23.03.2020 | SDS Number: 2569672-00006 | Date of last issue: 13.09.2019 Date of first issue: 27.02.2018 |
|----------------|------------------------------|------------------------------|---|

| | |
|----------------------------|--|
| plants | mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials |
| Toxicity to microorganisms | : EC50 : > 10 - 100 mg/l Exposure time: 3 h Method: OECD Test Guideline 209 Remarks: Based on data from similar materials |

12.2 Persistence and degradability

Components:

Lactic acid:

| | |
|------------------|---|
| Biodegradability | : Result: Not readily biodegradable. Remarks: Based on data from similar materials |
|------------------|---|

12.3 Bioaccumulative potential

Components:

Lactic acid:

| | |
|--|------------------|
| Partition coefficient: n-octanol/water | : log Pow: -0,62 |
|--|------------------|

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Not relevant

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. |

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If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

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

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

| | | |
|--|---|--|
| KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) | : | Conditions of restriction for the following entries should be considered: Number on list 3 |
| Regulation on Persistent Organic Pollutants (Number 30595) | : | Not applicable |
| Regulation on prevention of major industrial accidents. Reg number 30702 | | Not applicable |

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 |

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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

| | |
|-------|--|
| H290 | : May be corrosive to metals. |
| H314 | : Causes severe skin burns and eye damage. |
| H315 | : Causes skin irritation. |
| H318 | : Causes serious eye damage. |
| H361d | : Suspected of damaging the unborn child. |

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

| | |
|-------------|-------------------------|
| Eye Dam. | : Serious eye damage |
| Met. Corr. | : Corrosive to metals |
| Repr. | : Reproductive toxicity |
| Skin Corr. | : Skin corrosion |
| 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

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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 |
| STOT RE 2 | H373 |

Classification procedure:

| |
|-------------------------------------|
| Calculation method |
| Based on product data or assessment |

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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