

# SAFETY DATA SHEET

Prepared in accordance with the provisions of KKDIK Annex-2 Regulation, 23.06.2017, No: 30105



## Imipenem / Cilastatin Formulation

|         |                |               |                                 |
|---------|----------------|---------------|---------------------------------|
| Version | Revision Date: | SDS Number:   | Date of last issue: 28.09.2024  |
| 7.2     | 14.04.2025     | 2097413-00020 | Date of first issue: 18.10.2017 |

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

#### 1.1 Product identifier

Trade name : Imipenem / Cilastatin Formulation

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

Use of the Substance/Mixture : Pharmaceutical

Recommended restrictions on use : Not applicable

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

Company : MSD  
Kilsheelan  
Clonmel Tipperary, IE

Telephone : 353-51-601000

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

#### 1.4 Emergency telephone number

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

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification T.R. SEA No 28848 and subsequent amendments

|                                                |                                                                                  |
|------------------------------------------------|----------------------------------------------------------------------------------|
| Eye irritation, Category 2                     | H319: Causes serious eye irritation.                                             |
| Respiratory sensitisation, Category 1          | H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| Reproductive toxicity, Category 2              | H361d: Suspected of damaging the unborn child.                                   |
| Short-term (acute) aquatic hazard, Category 1  | H400: Very toxic to aquatic life.                                                |
| Long-term (chronic) aquatic hazard, Category 1 | H410: Very toxic to aquatic life with long lasting effects.                      |

#### 2.2 Label elements

##### Labelling T.R. SEA No 28848 and subsequent amendments

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- Hazard pictograms :  
- Signal word : Danger
- Hazard statements :  
H319 Causes serious eye irritation.  
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
H361d Suspected of damaging the unborn child.  
H410 Very toxic to aquatic life with long lasting effects.
- Precautionary statements :  
**Prevention:**  
P261 Avoid breathing dust.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.  
**Response:**  
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.  
P391 Collect spillage.

Hazardous components which must be listed on the label:

Imipenem

### 2.3 Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.  
May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

| Chemical name | CAS-No.<br>EC-No.<br>Index-No.<br>KKDIK Registration No. | SEA Classification                                                                                  | Concentration<br>(% w/w) |
|---------------|----------------------------------------------------------|-----------------------------------------------------------------------------------------------------|--------------------------|
| Cilastatin    | 81129-83-1<br>279-694-4                                  | Eye Irrit. 2; H319                                                                                  | >= 50 - < 70             |
| Imipenem      | 74431-23-5                                               | Resp. Sens. 1A;<br>H334<br>Repr. 2; H361d<br>Aquatic Acute 1;<br>H400<br>Aquatic Chronic 1;<br>H410 | >= 30 - < 50             |

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|  |  |                                                                                         |  |
|--|--|-----------------------------------------------------------------------------------------|--|
|  |  | M-Factor (Acute aquatic toxicity):<br>100<br>M-Factor (Chronic aquatic toxicity):<br>10 |  |
|--|--|-----------------------------------------------------------------------------------------|--|

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.<br>When symptoms persist or in all cases of doubt seek medical advice.                                                                |
| Protection of first-aiders | : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).                                           |
| If inhaled                 | : If inhaled, remove to fresh air.<br>If not breathing, give artificial respiration.<br>If breathing is difficult, give oxygen.<br>Get medical attention.                                                               |
| In case of skin contact    | : In case of contact, immediately flush skin with soap and 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     | : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.<br>If easy to do, remove contact lens, if worn.<br>Get medical attention.                                                    |
| 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 | : Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome).<br>Contact with dust can cause mechanical irritation or drying of the skin. Causes serious eye irritation.<br>May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
|-------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

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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  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical

Unsuitable extinguishing media : None known.

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

Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon 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.

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 (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

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

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

Methods for cleaning up : Surround spill with absorbents and place a damp covering over the area to minimise entry of the material into the air. Add excess liquid to allow the material to enter into solution. Soak up with inert absorbent material. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

|                         |   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Technical measures      | : | Static electricity may accumulate and ignite suspended dust causing an explosion.<br>Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Local/Total ventilation | : | Use only with adequate ventilation.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Advice on safe handling | : | Do not breathe dust.<br>Do not swallow.<br>Do not get in eyes.<br>Avoid prolonged or repeated contact with skin.<br>Wash skin thoroughly after handling.<br>Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment<br>Keep container tightly closed.<br>Already sensitised individuals, and those susceptible to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with respiratory irritants or sensitisers.<br>Minimize dust generation and accumulation.<br>Keep container closed when not in use.<br>Keep away from heat and sources of ignition.<br>Take precautionary measures against static discharges.<br>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                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

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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. Keep tightly closed. 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

Dust 15 mg/m<sup>3</sup>  
Value type (Form of exposure): ZOAD/TWA (Total dust)  
Basis: TR OEL DU  
Further information: Allowable occupational exposure limit values of mineral dusts

5 mg/m<sup>3</sup>  
Value type (Form of exposure): ZOAD/TWA (Respirable part)  
Basis: TR OEL DU  
Further information: Allowable occupational exposure limit values of mineral dusts

| Components                      | CAS-No.    | Value type (Form of exposure) | Control parameters             | Basis    |
|---------------------------------|------------|-------------------------------|--------------------------------|----------|
| Cilastatin                      | 81129-83-1 | TWA                           | 5 mg/m <sup>3</sup> (OEB 1)    | Internal |
| Imipenem                        | 74431-23-5 | TWA                           | 3000 ug/m <sup>3</sup> (OEB 1) | Internal |
| Further information: RSEN, DSEN |            |                               |                                |          |
|                                 |            | Wipe limit                    | 100 µg/100 cm <sup>2</sup>     | Internal |

### 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.

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### Personal protective equipment

|                          |   |                                                                                                                                                                                                                                                                                                                |
|--------------------------|---|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Eye/face protection      | : | Wear safety glasses with side shields or goggles.<br>If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.<br>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.<br>Equipment should conform to TS EN 143                                                                                                  |
| Filter type              | : | Particulates type (P)                                                                                                                                                                                                                                                                                          |

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

|                                                  |   |                                                                                 |
|--------------------------------------------------|---|---------------------------------------------------------------------------------|
| Appearance                                       | : | powder                                                                          |
| Colour                                           | : | white                                                                           |
| Odour                                            | : | sulphurous                                                                      |
| 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                                 | : | Not applicable                                                                  |
| Flammability (solid, gas)                        | : | May form explosive dust-air mixture during processing, handling or other means. |
| Flammability (liquids)                           | : | Not applicable                                                                  |
| Upper explosion limit / Upper flammability limit | : | No data available                                                               |
| Lower explosion limit / Lower flammability limit | : | No data available                                                               |
| Vapour pressure                                  | : | Not applicable                                                                  |
| Relative vapour density                          | : | Not applicable                                                                  |
| Relative density                                 | : | No data available                                                               |

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|                                        |   |                                                          |
|----------------------------------------|---|----------------------------------------------------------|
| Density                                | : | 1 g/cm <sup>3</sup>                                      |
| 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, dynamic                     | : | No data available                                        |
| Viscosity, kinematic                   | : | Not applicable                                           |
| Explosive properties                   | : | Not explosive                                            |
| Oxidizing properties                   | : | The substance or mixture is not classified as oxidizing. |

### 9.2 Other information

|                  |   |                   |
|------------------|---|-------------------|
| Molecular weight | : | 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 | : | May form explosive dust-air mixture during processing, handling or other means.<br>Can react with strong oxidizing agents. |
|---------------------|---|----------------------------------------------------------------------------------------------------------------------------|

### 10.4 Conditions to avoid

|                     |   |                                                   |
|---------------------|---|---------------------------------------------------|
| Conditions to avoid | : | Heat, flames and sparks.<br>Avoid dust formation. |
|---------------------|---|---------------------------------------------------|

### 10.5 Incompatible materials

|                    |   |                  |
|--------------------|---|------------------|
| Materials to avoid | : | Oxidizing agents |
|--------------------|---|------------------|

### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

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### 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:

###### Cilastatin:

Acute oral toxicity : LD50 (Rat): 8.000 mg/kg  
LD50 (Mouse): 8.000 mg/kg

###### Imipenem:

Acute oral toxicity : LD50 (Mouse): 10.000 mg/kg  
Acute toxicity (other routes of administration) : LD50 (Rat): > 2.000 mg/kg  
Application Route: Intravenous  
LD50 (Mouse): 1.500 mg/kg  
Application Route: Intravenous

##### Skin corrosion/irritation

Not classified based on available information.

##### Components:

###### Cilastatin:

Species : Rabbit  
Result : No skin irritation

##### Serious eye damage/eye irritation

Causes serious eye irritation.

##### Components:

###### Cilastatin:

Species : Rabbit  
Result : Moderate eye irritation

##### Respiratory or skin sensitisation

##### Skin sensitisation

Not classified based on available information.

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### Respiratory sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

#### Components:

##### **Cilastatin:**

Exposure routes : Skin contact  
Remarks : No data available

Exposure routes : Inhalation  
Remarks : No data available

##### **Imipenem:**

Remarks : May cause sensitisation of susceptible persons by inhalation of aerosol or dust.

Exposure routes : Skin contact  
Remarks : Not classified due to lack of data.

### Germ cell mutagenicity

Not classified based on available information.

#### Components:

##### **Cilastatin:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Result: negative

##### **Imipenem:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster lung cells  
Result: negative

Test Type: reverse mutation assay  
Result: negative

Test Type: unscheduled DNA synthesis assay  
Result: negative

Test Type: Chromosomal aberration  
Result: negative

Test Type: sister chromatid exchange assay  
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test  
Species: Mouse  
Application Route: Intravenous  
Result: negative

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### Carcinogenicity

Not classified based on available information.

### Reproductive toxicity

Suspected of damaging the unborn child.

### Components:

#### Cilastatin:

Effects on fertility : Test Type: Fertility/early embryonic development  
Application Route: Intravenous  
Fertility: LOAEL: 1.000  
Symptoms: No adverse effects  
Result: No effects on fertility and early embryonic development were detected.

#### Imipenem:

Effects on fertility : Test Type: Fertility/early embryonic development  
Species: Rat, male and female  
Application Route: Intravenous  
Fertility: LOAEL: 80 mg/kg body weight  
Symptoms: No adverse effects, Reduced foetal weight  
Result: No effects on fertility and early embryonic development were detected.

Test Type: Fertility/early embryonic development  
Species: Rat, male and female  
Application Route: Subcutaneous  
Fertility: LOAEL: 320 mg/kg body weight  
Symptoms: No adverse effects, Reduced foetal weight  
Result: No effects on fertility and early embryonic development were detected.

Effects on foetal development : Test Type: Development  
Species: Monkey  
Application Route: Intravenous  
Developmental Toxicity: LOAEL: 100 mg/kg body weight  
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

Test Type: Development  
Species: Rabbit  
Application Route: Intravenous  
Developmental Toxicity: NOAEL: 60 mg/kg body weight  
Result: No teratogenic effects

Test Type: Development  
Species: Rat  
Application Route: Intravenous  
Developmental Toxicity: NOAEL: 60 mg/kg body weight  
Result: No teratogenic effects

Reproductive toxicity - As- : Some evidence of adverse effects on development, based on

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assessment animal experiments.

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

Not classified based on available information.

### Repeated dose toxicity

#### Components:

##### **Cilastatin:**

|                   |                                                |
|-------------------|------------------------------------------------|
| Species           | : Rat                                          |
| NOAEL             | : $\geq 500$ mg/kg                             |
| Application Route | : Intravenous                                  |
| Exposure time     | : 90 Days                                      |
| Remarks           | : No significant adverse effects were reported |

|                   |                                                |
|-------------------|------------------------------------------------|
| Species           | : Monkey                                       |
| NOAEL             | : $\geq 500$ mg/kg                             |
| Application Route | : Intravenous                                  |
| Exposure time     | : 5 Weeks                                      |
| Remarks           | : No significant adverse effects were reported |

##### **Imipenem:**

|                   |               |
|-------------------|---------------|
| Species           | : Monkey      |
| NOAEL             | : 60 mg/kg    |
| LOAEL             | : 150 mg/kg   |
| Application Route | : Intravenous |
| Exposure time     | : 6 Months    |
| Target Organs     | : Kidney      |

|                   |                                                |
|-------------------|------------------------------------------------|
| Species           | : Monkey                                       |
| NOAEL             | : 120 mg/kg                                    |
| Application Route | : Subcutaneous                                 |
| Exposure time     | : 6 Months                                     |
| Remarks           | : No significant adverse effects were reported |

|                   |                                                |
|-------------------|------------------------------------------------|
| Species           | : Rat                                          |
| NOAEL             | : 180 mg/kg                                    |
| Application Route | : Intravenous                                  |
| Exposure time     | : 6 Months                                     |
| Remarks           | : No significant adverse effects were reported |

|                   |               |
|-------------------|---------------|
| Species           | : Rabbit      |
| LOAEL             | : 150 mg/kg   |
| Application Route | : Intravenous |
| Target Organs     | : Kidney      |

### Aspiration toxicity

Not classified based on available information.

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### Experience with human exposure

#### Components:

##### **Imipenem:**

Inhalation : Symptoms: Nausea, Vomiting, Diarrhoea, Fever, hypotension, Dizziness, Drowsiness, Convulsions, pruritis, Rash  
Remarks: May cause sensitisation of susceptible persons by inhalation of aerosol or dust.

## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

##### **Cilastatin:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): > 111 mg/l  
Exposure time: 96 h  
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 99 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae): > 99 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 99 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 99 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 99 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

Toxicity to microorganisms : EC50 : > 1.000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : EC10: > 9,9 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

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Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : EC10: > 10 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

### Imipenem:

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 78 mg/l  
Exposure time: 48 h  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (Anabaena flos-aquae (cyanobacterium)): 0,0046 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0,002 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 74 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 74 mg/l  
Exposure time: 72 h  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 100

Toxicity to microorganisms : EC50 : > 1.000 mg/l  
Exposure time: 3 h  
Test Type: Respiration inhibition  
Method: OECD Test Guideline 209

Toxicity to fish (Chronic toxicity) : NOEC: 9,4 mg/l  
Exposure time: 32 d  
Species: Pimephales promelas (fathead minnow)  
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 11 mg/l  
Exposure time: 21 d  
Species: Daphnia magna (Water flea)  
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 10

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### 12.2 Persistence and degradability

#### Components:

##### **Cilastatin:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 27 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

##### **Imipenem:**

Biodegradability : Result: Not readily biodegradable.  
Biodegradation: 29 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### 12.3 Bioaccumulative potential

#### Components:

##### **Cilastatin:**

Partition coefficient: n-octanol/water : log Pow: -3,53

##### **Imipenem:**

Partition coefficient: n-octanol/water : log Pow: < -1

### 12.4 Mobility in soil

#### Components:

##### **Cilastatin:**

Distribution among environmental compartments : log Koc: 2,3

### 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 : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Waste management needs to comply with provisions laid down in Waste Management Regulation (TR Official Gazette, 2015, Number: 29314) and with the respective national provisions legally enforced  
Dispose of in accordance with local regulations.

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Contaminated packaging : According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities. Do not dispose of waste into sewer. Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product. Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### 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. (Imipenem) |
| ADR  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem) |
| RID  | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem) |
| IMDG | : ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem) |
| IATA | : Environmentally hazardous substance, solid, n.o.s. (Imipenem) |

#### 14.3 Transport hazard class(es)

|      | Class | Subsidiary risks |
|------|-------|------------------|
| ADN  | : 9   |                  |
| ADR  | : 9   |                  |
| RID  | : 9   |                  |
| IMDG | : 9   |                  |
| IATA | : 9   |                  |

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### 14.4 Packing group

#### ADN

|                              |       |
|------------------------------|-------|
| Packing group                | : III |
| Classification Code          | : M7  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |

#### ADR

|                              |       |
|------------------------------|-------|
| Packing group                | : III |
| Classification Code          | : M7  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |
| Tunnel restriction code      | : (-) |

#### RID

|                              |       |
|------------------------------|-------|
| Packing group                | : III |
| Classification Code          | : M7  |
| Hazard Identification Number | : 90  |
| Labels                       | : 9   |

#### IMDG

|               |            |
|---------------|------------|
| Packing group | : III      |
| Labels        | : 9        |
| 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 |
|---------------------------|-------|

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### 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.

## 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) : Not applicable

Regulation on Persistent Organic Pollutants (Number 30595 and subsequent amendments published) : Not applicable

Regulation on prevention of major industrial accidents. Reg number 30702

|    |                       | Quantity 1 | Quantity 2 |
|----|-----------------------|------------|------------|
| E1 | ENVIRONMENTAL HAZARDS | 100 t      | 200 t      |

#### Other regulations:

T.R. Regulation on Classification, Labeling and Packaging of Substances and Mixtures, dated December 11, 2013 and numbered 28848 from the Ministry of Environment and Urbanization and the subsequent amendments published.

Regulation on Import and Export of Certain Hazardous Chemicals, No. 32087, 2023 : Not applicable

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

AICS : not determined

DSL : not determined

IECSC : not determined

### 15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

## SECTION 16: Other information

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

The SDS has been prepared by: Name: Gökhan Ardiç; Contact email: sds@chemleg.com; Telephone number: +90 216 706 1307; Certificate Number: Lonca KDU 34 / 2020.08; Certificate Date: 22 September 2020; Valid Until: 22 September

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### Full text of H-Statements

|       |                                                                              |
|-------|------------------------------------------------------------------------------|
| H319  | : Causes serious eye irritation.                                             |
| H334  | : May cause allergy or asthma symptoms or breathing difficulties if inhaled. |
| H361d | : Suspected of damaging the unborn child.                                    |
| H400  | : Very toxic to aquatic life.                                                |
| H410  | : Very toxic 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

|                      |                                                                                          |
|----------------------|------------------------------------------------------------------------------------------|
| Aquatic Acute        | : Short-term (acute) aquatic hazard                                                      |
| Aquatic Chronic      | : Long-term (chronic) aquatic hazard                                                     |
| Eye Irrit.           | : Eye irritation                                                                         |
| Repr.                | : Reproductive toxicity                                                                  |
| Resp. Sens.          | : Respiratory sensitisation                                                              |
| TR OEL DU            | : Türkiye. Regulation on Dust Control. Occupational Dust Exposure Limit Values (Annex 1) |
| TR OEL DU / ZOAD/TWA | : Time Weighted Average Value                                                            |

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECS - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN

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- 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:

|                   |       |
|-------------------|-------|
| Eye Irrit. 2      | H319  |
| Resp. Sens. 1     | H334  |
| Repr. 2           | H361d |
| Aquatic Acute 1   | H400  |
| Aquatic Chronic 1 | H410  |

### Classification procedure:

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