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”.

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Date of first issue: 18.10.2017

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

1.3 Details of the supplier of the safety data sheet

Company: MSD
Kilsheean
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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification T.R. SEA No 28848
Eye irritation, Category 2
Respiratory sensitisation, Category 1
Reproductive toxicity, Category 2
Short-term (acute) aquatic hazard, Category 1
Long-term (chronic) aquatic hazard, Category 1

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.

2.2 Label elements

Labelling T.R. SEA No 28848

Hazard pictograms:

Signal word: Danger
Hazard statements: H319 Causes serious eye irritation.
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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 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
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

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No. EC-No. Index-No. Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cilastatin</td>
<td>81129-83-1 279-694-4</td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
</tbody>
</table>
| Imipenem      | 74431-23-5 | Resp. Sens. 1A; H334
Repr. 2; H361d Aquatic Acute 1; H400
Aquatic Chronic 1; H410
M-Factor (Acute aquatic toxicity): 100
M-Factor (Chronic) | >= 30 - < 50 |
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| aquatic toxicity: | 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. 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. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. 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: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention.

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: Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of damaging the unborn child. Excessive exposure may aggravate preexisting asthma and other respiratory disorders (e.g. emphysema, bronchitis, reactive airways dysfunction syndrome). Contact with dust can cause mechanical irritation or drying of the skin.
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<tbody>
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<td>09.04.2021</td>
<td>18.10.2017</td>
</tr>
</tbody>
</table>

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 firefighting: 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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and Urbanization; Regulation on Safety data sheets regarding haz-
ardous substances and mixtures; Part I”.

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6.3 Methods and material for containment and cleaning up
Methods for cleaning up:
- Sweep up or vacuum up spillage and collect in suitable con-
tainer for disposal.
- Avoid dispersal of dust in the air (i.e., clearing dust surfaces
  with compressed air).
- Dust deposits should not be allowed to accumulate on surfac-
es, as these may form an explosive mixture if they are re-
leased into the atmosphere in sufficient concentration.
- Local or national regulations may apply to releases and dis-
posal of this material, as well as those materials and items
employed in the cleanup of releases. You will need to deter-
mine which regulations are applicable.
- Sections 13 and 15 of this SDS provide information regardin

g 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:
- Static electricity may accumulate and ignite suspended dust
  causing an explosion.
- Provide adequate precautions, such as electrical grounding
  and bonding, or inert atmospheres.

Local/Total ventilation:
- Use only with adequate ventilation.

Advice on safe handling:
- Avoid breathing dust.
- Do not swallow.
- Do not get in eyes.
- Avoid prolonged or repeated contact with skin.
- Wash skin thoroughly after handling.
- Handle in accordance with good industrial hygiene and safety
  practice, based on the results of the workplace exposure as-
  sessment.
- Keep container tightly closed.
- Already sensitised individuals should consult their physician
  regarding working with respiratory irritants or sensitisers.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- Take care to prevent spills, waste and minimize release to the
  environment.

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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cilastatin</td>
<td>81129-83-1</td>
<td>TWA</td>
<td>5 mg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Imipenem</td>
<td>74431-23-5</td>
<td>TWA</td>
<td>1000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN

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: 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 143

Filter type: Particulates type (P)
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</tbody>
</table>

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>powder</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
<tr>
<td>Odour</td>
<td>sulphurous</td>
</tr>
<tr>
<td>Odour Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during processing, handling or other means.</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Density</td>
<td>1 g/cm³</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>Water solubility: No data available</td>
</tr>
<tr>
<td></td>
<td>Partition coefficient: n-octanol/water: Not applicable</td>
</tr>
<tr>
<td></td>
<td>Auto-ignition temperature: No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>Viscosity, dynamic: No data available</td>
</tr>
<tr>
<td></td>
<td>Viscosity, kinematic: Not applicable</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>The substance or mixture is not classified as oxidizing.</td>
</tr>
</tbody>
</table>

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9.2 Other information

Flammability (liquids) : Not applicable
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. Can react with strong oxidizing agents.

10.4 Conditions to avoid
Conditions to avoid : Heat, flames and sparks. Avoid dust formation.

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.

Comments:

Cilastatin:
Acute oral toxicity : LD50 (Rat): > 10.000 mg/kg
                                           LD50 (Mouse): > 10.000 mg/kg
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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.

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.
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**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

Genotoxicity in vitro: Test Type: reverse mutation assay  
Result: negative

Genotoxicity in vitro: Test Type: unscheduled DNA synthesis assay  
Result: negative

Genotoxicity in vitro: Test Type: Chromosomal aberration  
Result: negative

Genotoxicity in vitro: Test Type: sister chromatid exchange assay  
Result: negative

**Germ cell mutagenicity**
Not classified based on available information.

**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
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</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Monkey</td>
</tr>
<tr>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td>Developmental Toxicity: LOAEL: 100 mg/kg body weight</td>
</tr>
<tr>
<td>Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rabbit</td>
</tr>
<tr>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 60 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No teratogenic effects</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Test Type: Development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Species: Rat</td>
</tr>
<tr>
<td>Application Route: Intravenous</td>
</tr>
<tr>
<td>Developmental Toxicity: NOAEL: 60 mg/kg body weight</td>
</tr>
<tr>
<td>Result: No teratogenic effects</td>
</tr>
</tbody>
</table>

Reproductive toxicity - Assessment:

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeate dose toxicity

Components:

Cilastatin:

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td>&gt;= 500 mg/kg</td>
<td>Intravenous</td>
<td>90 Days</td>
<td>No significant adverse effects were reported</td>
</tr>
</tbody>
</table>
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Species: Monkey
NOAEL: >= 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.

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:
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</tbody>
</table>

**Toxicity to fish**

<table>
<thead>
<tr>
<th>Species</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pimephales promelas (fathead minnow)</td>
<td>&gt; 111 mg/l</td>
<td>96 h</td>
<td>OECD Test Guideline 203</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Species</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>&gt; 99 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Species</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anabaena flos-aquae</td>
<td>&gt; 99 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

**Toxicity to microorganisms**

| NOEC (Anabaena flos-aquae) | 99 mg/l | 72 h | OECD Test Guideline 201 |

**Toxicity to fish (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Species</th>
<th>EC10</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pimephales promelas (fathead minnow)</td>
<td>&gt; 9.9 mg/l</td>
<td>32 d</td>
<td>OECD Test Guideline 210</td>
</tr>
</tbody>
</table>

**Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)**

<table>
<thead>
<tr>
<th>Species</th>
<th>EC10</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>&gt; 10 mg/l</td>
<td>21 d</td>
<td>OECD Test Guideline 211</td>
</tr>
</tbody>
</table>

**Imipenem:**

**Toxicity to daphnia and other aquatic invertebrates**

<table>
<thead>
<tr>
<th>Species</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daphnia magna (Water flea)</td>
<td>&gt; 78 mg/l</td>
<td>48 h</td>
<td>OECD Test Guideline 202</td>
</tr>
</tbody>
</table>

**Toxicity to algae/aquatic plants**

<table>
<thead>
<tr>
<th>Species</th>
<th>EC50</th>
<th>Exposure time</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anabaena flos-aquae (cyanobacterium)</td>
<td>0.0046 mg/l</td>
<td>72 h</td>
<td>OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.002 mg/l
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SDS Number: 2097413-00011
Date of last issue: 09.04.2021
Date of first issue: 18.10.2017

**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

### 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

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
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”.

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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: 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.

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
# 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".

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### 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)

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<thead>
<tr>
<th>ADN</th>
<th>9</th>
</tr>
</thead>
<tbody>
<tr>
<td>ADR</td>
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<tr>
<td>RID</td>
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<tr>
<td>IMDG</td>
<td>9</td>
</tr>
<tr>
<td>IATA</td>
<td>9</td>
</tr>
</tbody>
</table>

### 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): 956
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<tr>
<td>Packing group</td>
<td>III</td>
</tr>
<tr>
<td>Labels</td>
<td>Miscellaneous</td>
</tr>
</tbody>
</table>

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.

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) | Not applicable |
|Regulation on prevention of major industrial accidents. Reg number 30702 | |

<table>
<thead>
<tr>
<th>E1</th>
<th>ENVIRONMENTAL HAZARDS</th>
</tr>
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<tbody>
<tr>
<td>Quantity 1</td>
<td>100 t</td>
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<tr>
<td>Quantity 2</td>
<td>200 t</td>
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</table>
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Other regulations:

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 : The SDS has been prepared by: Name: Gökhan Ardıç; 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 2025

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
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

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; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration...
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- Eye Irrit. 2: H319 (Calculation method)
- Resp. Sens. 1: H334 (Calculation method)
- Repr. 2: H361d (Calculation method)
- Aquatic Acute 1: H400 (Calculation method)
- Aquatic Chronic 1: H410 (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