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
   Shotton Lane
   NE23 3JU Cramlington NU - Great Britain
   Telephone : 44 1 670 59 30 00
   Telefax : 908-735-1496
   E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
   1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
   Classification (REGULATION (EC) No 1272/2008)
   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 (REGULATION (EC) No 1272/2008)
   Hazard pictograms :

   Signal word : Danger
   Hazard statements : H319 Causes serious eye irritation.
   H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
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.
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.</th>
<th>EC-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydrogen [R-[R*,S*-(-Z)]]-7-[(2-amino-2-carboxylatoethyl)thio]-2-[(2,2-dimethylcyclopropyl)carbonyl]amino]hept-2-enoate</td>
<td>81129-83-1 279-694-4</td>
<td>Eye Irrit.2; H319</td>
<td>&gt;= 50 - &lt; 70</td>
<td></td>
</tr>
<tr>
<td>Imipenem</td>
<td>74431-23-5</td>
<td></td>
<td>Resp. Sens.1A; H334 Repr.2; H361d Aquatic Acute1; H400 Aquatic Chronic1; H410 M-Factor (Acute aquatic toxicity): 100 M-Factor (Chronic aquatic toxicity): 10</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>

For explanation of abbreviations see section 16.
**SAFETY DATA SHEET**

according to Regulation (EC) No. 1907/2006

**Imipenem / Cilastatin Formulation**

Version 3.3  
Revision Date: 09/13/2019  
SDS Number: 15839-00017  
Date of last issue: 24.04.2019  
Date of first issue: 05.11.2014

---

**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.

**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 and personal protective equipment recommendations.

6.2 Environmental precautions

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

6.3 Methods and material for containment and cleaning up

Methods for cleaning up:
- Sweep up or vacuum up spillage and collect in suitable container for disposal.
- 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. 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:
- 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:
- Do not breathe dust.
- Do not swallow.
- Do not get in 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.
- 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 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.
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Imipenem / Cilastatin Formulation

Version 3.3 Revision Date: 09/13/2019 SDS Number: 15839-00017 Date of last issue: 24.04.2019 Date of first issue: 05.11.2014

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>Sodium hydrogen [R-[R*,S*-(Z)]]-7-[(2-amino-2-carboxyethyl)(thio)-2-[(2,2-(dimethylcyclopropyl)carbonyl)amino]hept-2-enoate</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 ug/m3 (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Further information</td>
<td></td>
<td></td>
<td>RSEN</td>
<td></td>
</tr>
</tbody>
</table>

8.2 Exposure controls

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

Personal protective equipment

Eye protection: Wear safety glasses with side shields or goggles.
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Hand protection
Material: Chemical-resistant gloves

Skin and body protection: Work uniform or laboratory coat.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties
### Imipenem / Cilastatin Formulation

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</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</td>
<td>No data available</td>
</tr>
<tr>
<td>range</td>
<td></td>
</tr>
<tr>
<td>Flash point</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>May form explosive dust-air mixture during</td>
</tr>
<tr>
<td></td>
<td>processing, handling or other means.</td>
</tr>
<tr>
<td>Upper explosion limit / Upper</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Lower explosion limit / Lower</td>
<td>No data available</td>
</tr>
<tr>
<td>flammability limit</td>
<td></td>
</tr>
<tr>
<td>Vapour pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapour density</td>
<td>No data available</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></td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Auto-ignition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td></td>
</tr>
<tr>
<td>Viscosity, dynamic</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity, kinematic</td>
<td>No data available</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</td>
</tr>
<tr>
<td></td>
<td>oxidizing.</td>
</tr>
</tbody>
</table>

#### 9.2 Other information

- Flammability (liquids): No data available
- Molecular weight: 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.

Components:

Acute oral toxicity: LD50 (Rat): > 10.000 mg/kg
LD50 (Mouse): > 10.000 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
Skin corrosion/irritation
Not classified based on available information.

**Components:**

Sodium hydrogen \([\text{R}^*\text{S}^*-(Z)]\)-7-[(2-amino-2-carboxyloatoethyl)thio]-2-[(2,2-dimethylcyclopropyl)carbonyl]amino]hept-2-enoate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>No skin irritation</td>
</tr>
</tbody>
</table>

Serious eye damage/eye irritation
Causes serious eye irritation.

**Components:**

Sodium hydrogen \([\text{R}^*\text{S}^*-(Z)]\)-7-[(2-amino-2-carboxyloatoethyl)thio]-2-[(2,2-dimethylcyclopropyl)carbonyl]amino]hept-2-enoate:

<table>
<thead>
<tr>
<th>Species</th>
<th>Rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Result</td>
<td>Moderate eye irritation</td>
</tr>
</tbody>
</table>

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:**

Sodium hydrogen \([\text{R}^*\text{S}^*-(Z)]\)-7-[(2-amino-2-carboxyloatoethyl)thio]-2-[(2,2-dimethylcyclopropyl)carbonyl]amino]hept-2-enoate:

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>No data available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Inhalation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Imipenem:**

<table>
<thead>
<tr>
<th>Remarks</th>
<th>May cause sensitisation of susceptible persons by inhalation of aerosol or dust.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Skin contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remarks</td>
<td>Not classified due to lack of data.</td>
</tr>
</tbody>
</table>

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

**Sodium hydrogen [R-[R*,S*(Z)]-7-{[2-amino-2-carboxylatoethyl]thio}2-{[[2,2-dimethylcyclopropyl]carbonyl]amino}hept-2-enoate:**

- 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

**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:**

**Sodium hydrogen [R-[R*,S*(Z)]-7-{[2-amino-2-carboxylatoethyl]thio}2-{[[2,2-dimethylcyclopropyl]carbonyl]amino}hept-2-enoate:**

- 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
<table>
<thead>
<tr>
<th>Test Type</th>
<th>Species</th>
<th>Application Route</th>
<th>Developmental Toxicity</th>
<th>LOAEL/NOAEL</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fertility/early embryonic development</td>
<td>Rat, male and female</td>
<td>Subcutaneous</td>
<td></td>
<td>320 mg/kg body weight</td>
<td>No adverse effects, Reduced foetal weight</td>
</tr>
<tr>
<td>Development</td>
<td>Monkey</td>
<td>Intravenous</td>
<td>LOAEL: 100 mg/kg body weight</td>
<td></td>
<td>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</td>
</tr>
<tr>
<td>Development</td>
<td>Rabbit</td>
<td>Intravenous</td>
<td>NOAEL: 60 mg/kg body weight</td>
<td></td>
<td>Test Type: DevelopmentSpecies: Rabbit Application Route: Intravenous Developmental Toxicity: NOAEL: 60 mg/kg body weight Result: No teratogenic effects</td>
</tr>
<tr>
<td>Development</td>
<td>Rat</td>
<td>Intravenous</td>
<td>NOAEL: 60 mg/kg body weight</td>
<td></td>
<td>Test Type: DevelopmentSpecies: Rat Application Route: Intravenous Developmental Toxicity: NOAEL: 60 mg/kg body weight Result: No teratogenic effects</td>
</tr>
</tbody>
</table>

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

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.

Repeated dose toxicity

Components:

**Sodium hydrogen [R-[R*,S*-(Z)]]-7-[(2-amino-2-carboxylatoethyl)thio]-2-[(2,2-dimethylcyclopropyl)carbonyl]amino]hept-2-enoate:**

<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>
<tr>
<td>Monkey</td>
<td>&gt;= 500 mg/kg</td>
<td>Intravenous</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rat</td>
<td></td>
<td>Intravenous</td>
<td></td>
</tr>
<tr>
<td>Monkey</td>
<td></td>
<td>Intravenous</td>
<td></td>
</tr>
</tbody>
</table>
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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:**


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

**Imipenem:**

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

Toxicity to algae/aquatic plants:
EC50 (Anabaena flos-aquae (cyanobacterium)): 0,0058 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0,0025 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
Imipenem / Cilastatin Formulation

12.2 Persistence and degradability

**Components:**

Sodium hydrogen \([R-[R^*,S^*-(Z)]-7-[(2-amino-2-carboxylatoethyl)thio]-2-[(2,2-dimethylcyclopropyl)carbonyl]amino]hept-2-enoate:

Biodegradability

- Result: rapidly degradable
- Biodegradation: 96 %
- Exposure time: 23 hrs

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:**

Sodium hydrogen \([R-[R^*,S^*-(Z)]-7-[(2-amino-2-carboxylatoethyl)thio]-2-[(2,2-dimethylcyclopropyl)carbonyl]amino]hept-2-enoate:

Partition coefficient: n-octanol/water

- log Pow: -3.53

Imipenem:

Partition coefficient: n-octanol/water

- log Pow: < -1

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.
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

<table>
<thead>
<tr>
<th>ADN</th>
<th>ADR</th>
<th>RID</th>
<th>IMDG</th>
<th>IATA</th>
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14.2 UN proper shipping name

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<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)</td>
<td>ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)</td>
<td>Environmentally hazardous substance, solid, n.o.s. (Imipenem)</td>
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</table>

14.3 Transport hazard class(es)

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14.4 Packing group

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<td>Classification Code: M7</td>
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<td>Hazard Identification Number: 90</td>
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<td>Labels: 9</td>
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</table>
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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Imipenem / Cilastatin Formulation

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Young people under the age of 18 are not allowed to use or be exposed to the product professionally. Young people above the age of 15 are, however, except from this rule if the product is a necessary part of their education.

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.

Full text of H-Statements
H319 : Causes serious eye irritation.
H334 : May cause allergy or asthma symptoms or breathing difficul-
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Imipenem / Cilastatin Formulation

Version 3.3
Revision Date: 09/13/2019
SDS Number: 15839-00017
Date of last issue: 24.04.2019
Date of first issue: 05.11.2014

H361d: Suspected of damaging the unborn child.
H400: Very toxic to aquatic life.
H410: Very toxic to aquatic life with long lasting effects.

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

Further information

Classification of the mixture:
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.

NO / EN