SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Imipenem / Cilastatin Formulation

Version 3.10  Revision Date: 27.08.2021  SDS Number: 15830-00024  Date of last issue: 09.04.2021
Date of first issue: 05.11.2014

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
            Piercetown
            A86 HD21 Dunboyne, Ireland
Telephone : 908-740-4000
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
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 (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.
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
This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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>Components</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>
<tr>
<td>Imipenem</td>
<td>74431-23-5</td>
<td>Resp. Sens. 1A; H334 Repr. 2; H361d Aquatic Acute 1; H400 Aquatic Chronic 1; H410</td>
<td>&gt;= 30 - &lt; 50</td>
</tr>
</tbody>
</table>
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</tbody>
</table>

M-Factor (Acute aquatic toxicity): 100
M-Factor (Chronic 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.
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.
Imipenem / Cilastatin Formulation

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.
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:
- 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 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.

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 I.S. EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: powder
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- Colour: white
- Odour: sulphurous
- Odour Threshold: No data available
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- 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
- Flash point: Not applicable
- Auto-ignition temperature: No data available
- Decomposition temperature: No data available
- pH: No data available
- Viscosity: Not available
  - Viscosity, dynamic: No data available
  - Viscosity, kinematic: Not applicable
- Solubility(ies): Water solubility: No data available
- Partition coefficient: n-octanol/water: Not applicable
- Vapour pressure: Not applicable
- Relative density: No data available
- Density: 1 g/cm³
- Relative vapour density: Not applicable
- Particle characteristics: Particle size: No data available

9.2 Other information
- Explosives: Not explosive
- Oxidizing properties: The substance or mixture is not classified as oxidizing.
Evaporation rate : Not applicable
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 hazard classes as defined in Regulation (EC) No 1272/2008
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): > 10,000 mg/kg
LD50 (Mouse): > 10,000 mg/kg

Imipenem:
Acute 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:**

**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.

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

**Components:**

**Cilastatin:**
Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
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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:

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 - 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:**

**Cilastatin:**
- Species: Rat
- NOAEL: >= 500 mg/kg
- Application Route: Intravenous
- Exposure time: 90 Days
- Remarks: No significant adverse effects were reported

- 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.

11.2 Information on other hazards

Endocrine disrupting properties

Product:
Assessment: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

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

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

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-: log Pow: -3.53
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octanol/water

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

Product:
Assessment
: This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:
Assessment
: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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 or ID number

ADN
: UN 3077

ADR
: UN 3077
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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)

ADN : 9
ADR : 9
RID : 9
IMDG : 9
IATA : 9

14.4 Packing group

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

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
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</table>

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

### 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 Maritime transport in bulk according to IMO instruments

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
- **Regulation (EC) No 1005/2009 on substances that deplete the ozone layer:** Not applicable
- **Regulation (EU) 2019/1021 on persistent organic pollu-** : Not applicable
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Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals: Not applicable
REACH - List of substances subject to authorisation (Annex XIV): Not applicable

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

Other regulations:
Take note of Directive 92/85/EEC regarding maternity protection or stricter national regulations, where applicable.
Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where 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.

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.

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;
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Imipenem / Cilastatin Formulation

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; vPvB - Very Persistent and Very Bioaccumulative

Further information

Classification of the mixture:

<table>
<thead>
<tr>
<th>Property</th>
<th>Classification</th>
<th>Calculation method</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye Irrit. 2</td>
<td>H319</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Resp. Sens. 1</td>
<td>H334</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Repr. 2</td>
<td>H361d</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Acute 1</td>
<td>H400</td>
<td>Calculation method</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>H410</td>
<td>Calculation method</td>
</tr>
</tbody>
</table>

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.

IE / EN