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

Imipenem / Cilastatin Formulation

Version: 3.7
Revision Date: 15.07.2020
SDS Number: 15827-00021
Date of last issue: 01.06.2020
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
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
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.

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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

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Registration number</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cilastatin</td>
<td>81129-83-1</td>
<td>279-694-4</td>
<td></td>
<td></td>
<td>Eye Irrit. 2; H319</td>
<td>&gt;= 50 - &lt; 70</td>
</tr>
<tr>
<td>Imipenem</td>
<td>74431-23-5</td>
<td></td>
<td></td>
<td></td>
<td>Resp. Sens. 1A; H334 Repr. 2; H361d Aquatic Acute 1; H400 Aquatic Chronic 1; 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.
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.
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 Material: Chemical-resistant gloves

Skin and body protection: Work uniform or laboratory coat.

Respiratory protection: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
Equipment should conform to BS EN 143

Filter type: Particulates type (P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance: powder
Colour: white
Odour: sulphurous
Odour Threshold: No data available

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

9.2 Other information
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.

Components:

**Cilastatin:**
- 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
  - 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.

Germ cell mutagenicity
Not classified based on available information.

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

Imipenem:
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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
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**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:**  
**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
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<table>
<thead>
<tr>
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<tr>
<td>3.7</td>
<td>15.07.2020</td>
<td>15827-00021</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **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
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12.2 Persistence and degradability

Components:

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

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

12.3 Bioaccumulative potential

Components:

Cilastatin:
Partition coefficient: n-octanol/water  :  log Pow: -3.53

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

12.4 Mobility in soil

Components:

Cilastatin:
Distribution among environmental compartments  :  log Koc: 2.3

12.5 Results of PBT and vPvB assessment
Not relevant
12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product:
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

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

14.4 Packing group

ADN
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9 (ENVIRONM.)

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

RID
Packing group: III
Classification Code: M7
Hazard Identification Number: 90
Labels: 9 (ENVIRONM.)

IMDG
Packing group: III
Labels: 9 (ENVIRONM.)
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)
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**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.

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**SECTION 15: Regulatory information**

**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Not applicable</th>
</tr>
</thead>
<tbody>
<tr>
<td>REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII)</td>
<td></td>
</tr>
<tr>
<td>REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59).</td>
<td></td>
</tr>
<tr>
<td>REACH - List of substances subject to authorisation (Annex XIV)</td>
<td></td>
</tr>
<tr>
<td>Regulation (EC) No 1005/2009 on substances that deplete the ozone layer</td>
<td></td>
</tr>
<tr>
<td>Regulation (EU) 2019/1021 on persistent organic pollutants (recast)</td>
<td></td>
</tr>
<tr>
<td>Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals</td>
<td></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:**

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
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</tbody>
</table>

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

<table>
<thead>
<tr>
<th>Other information</th>
<th>Items where changes have been made to the previous version</th>
</tr>
</thead>
</table>

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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; 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information
Sources of key data used to  Internal technical data, data from raw material SDSs, OECD
## Imipenem / Cilastatin Formulation

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### Classification of the mixture:

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### Classification procedure:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

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