1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Imipenem / Cilastatin / Relebactam Formulation

Manufacturer or supplier’s details
Company : MSD
Address : JL Raya Pandaan KM. 48
           Pandaan, Jawa Timur - Indonesia
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATATESTWARD@msd.com
Telefax : 908-735-1496

Recommended use of the chemical and restrictions on use
Recommended use : Pharmaceutical

2. HAZARDS IDENTIFICATION

GHS Classification
Serious eye damage/eye irritation : Category 2A
Respiratory sensitisation : Category 1
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2 (Kidney)
Short-term (acute) aquatic hazard : Category 1
Long-term (chronic) aquatic hazard : Category 1

GHS label elements
Hazard pictograms :  
Signal word : Danger
Hazard statements : H319 Causes serious eye irritation.
                   H334 May cause allergy or asthma symptoms or breathing
Precautionary statements:

**Prevention:**
- P201 Obtain special instructions before use.
- P202 Do not handle until all safety precautions have been read and understood.
- P260 Do not breathe dust.
- P264 Wash skin thoroughly after handling.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P284 Wear respiratory protection.

**Response:**
- P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P308 + P313 IF exposed or concerned: Get medical advice/attention.
- P337 + P313 IF eye irritation persists: Get medical advice/attention.
- P391 Collect spillage.

**Storage:**
- P405 Store locked up.

**Disposal:**
- P501 Dispose of contents/container to an approved waste disposal plant.

Other hazards which do not result in classification:
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance/Mixture: Mixture

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Imipenem</td>
<td>74431-23-5</td>
<td>&gt;= 30 &lt; 60</td>
</tr>
<tr>
<td>Relebactam</td>
<td>1174020-13-3</td>
<td>&gt;= 10 &lt; 30</td>
</tr>
</tbody>
</table>
4. 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.

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.

Most important symptoms and effects, both acute and delayed : Causes serious eye irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. 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.

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.

Notes to physician : Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Suitable extinguishing media : Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical

Unsuitable extinguishing media : None known.

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
Metal oxides

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.

Special protective equipment for firefighters:
- In the event of fire, wear self-contained breathing apparatus.
- Use personal protective equipment.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:
- Use personal protective equipment.
- Follow safe handling advice and personal protective equipment recommendations.

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.

Methods and materials for containment and 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.

7. HANDLING AND STORAGE

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.

Conditions for safe storage: Keep in properly labelled containers. Store locked up. Keep tightly closed. Store in accordance with the particular national regulations.

Materials to avoid: Do not store with the following product types: Strong oxidizing agents

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydrogen ([R{[R^\ast,S^\ast-(Z)]}-7-[(2-amino-2-carboxylatoethyl)thio]-2-[(2,2-dimethylcyclopro-]pyl]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>Relebactam</td>
<td>1174020-13-3</td>
<td>TWA</td>
<td>0.3 mg/m3 (OEB 2)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Further information: RSEN

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

Respiratory protection: Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

Filter type: Particulates type

Hand protection: Chemical-resistant gloves

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
Skin and body protection: Work uniform or laboratory coat.

Hygiene measures: Ensure that eye flushing systems and safety showers are located 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder

Colour: No data available

Odour: No data available

Odour Threshold: No data available

pH: No data available

Melting point/freezing point: No data available

Initial boiling point and boiling range: No data available

Flash point: No data available

Evaporation rate: No data available

Flammability (solid, gas): May form explosive dust-air mixture during processing, handling or other means.

Flammability (liquids): No data available

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapour pressure: No data available

Relative vapour density: No data available

Relative density: No data available

Density: No data available

Solubility(ies): No data available

Water solubility: No data available

Partition coefficient: n-octanol/water: No data available
10. STABILITY AND REACTIVITY

Reactivity: Not classified as a reactivity hazard.
Chemical stability: Stable under normal conditions.
Possibility of hazardous reactions: May form explosive dust-air mixture during processing, handling or other means. Can react with strong oxidizing agents.

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

Incompatible materials: Oxidizing agents

Hazardous decomposition products: No hazardous decomposition products are known.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure: Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity: 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:**
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:**

**Sodium hydrogen [R-[R*,S*-](Z)]-7-[(2-amino-2-carboxyloatoethyl)thio]-2-[[2,2-dimethylcyclopropyl]carbonyl][amino]hept-2-enoate:**
- **Species**: Rabbit
- **Result**: No skin irritation

**Relebactam:**
- **Method**: EpiDerm
- **Result**: No skin irritation

**Serious eye damage/eye irritation**
Causes serious eye irritation.

**Components:**

**Sodium hydrogen [R-[R*,S*-](Z)]-7-[(2-amino-2-carboxyloatoethyl)thio]-2-[[2,2-dimethylcyclopropyl]carbonyl][amino]hept-2-enoate:**
- **Species**: Rabbit
- **Result**: Moderate eye irritation

**Relebactam:**
- **Result**: No eye irritation
- **Method**: Bovine cornea (BCOP)

**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 [R-[R*,S*-](Z)]-7-[(2-amino-2-carboxyloatoethyl)thio]-2-[[2,2-dimethylcyclopropyl]carbonyl][amino]hept-2-enoate:**
- **Exposure routes**: Skin contact
- **Remarks**: No data available
- **Exposure routes**: Inhalation
- **Remarks**: No data available
SAFETY DATA SHEET

Imipenem / Cilastatin / Relebactam Formula- tion

Version 3.9  Revision Date: 04/24/2019  SDS Number: 67739-00015  Date of last issue: 2019/02/07
Date of first issue: 2015/02/27

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.

Relebactam:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Dermal
Result: Not a skin sensitizer.

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

Relebactam:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES) Result: negative

Test Type: Chromosome aberration test in vitro Result: negative
Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis) Species: Rat Application Route: Intraperitoneal injection Result: negative

Germ cell mutagenicity - Assessment : Weight of evidence does not support classification as a germ cell mutagen.

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 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.

Relebactam:
Effects on fertility: Test Type: Pre-/postnatal development
Species: Rat
Application Route: Subcutaneous
Fertility: NOAEL: 450 mg/kg body weight

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Intraperitoneal injection
Embryo-foetal toxicity: NOAEL: 450 mg/kg body weight
Result: No effects on foetal development

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Intraperitoneal injection
Embryo-foetal toxicity: NOAEL: 450 mg/kg body weight
Result: No effects on foetal development

Test Type: Development
Species: Rat
Application Route: Intravenous
Developmental Toxicity: NOAEL: >= 450 mg/kg body weight
Result: No effects on fertility and early embryonic development were detected.

Test Type: Development
Species: Rabbit
Application Route: Intravenous
Developmental Toxicity: NOAEL: 450 mg/kg body weight
Result: No effects on foetal development

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
May cause damage to organs (Kidney) through prolonged or repeated exposure.

Components:

Relebactam:
Target Organs: Kidney
Assessment: May cause damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:


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

Relebactam:

Species: Rat, female
NOAEL: 150 mg/kg
Application Route: Intravenous
Exposure time: 30 d
SAFETY DATA SHEET

Imipenem / Cilastatin / Relebactam Formula-

Species: Rat, male
NOAEL: 450 mg/kg
Application Route: Intravenous
Exposure time: 30 d

Species: Monkey
NOAEL: 25 mg/kg
Application Route: Intravenous
Exposure time: 30 d

Species: Monkey
NOAEL: 37.5 mg/kg
Application Route: Intravenous
Exposure time: 30 d

Species: Monkey
NOAEL: 50 mg/kg
LOAEL: 150 mg/kg
Application Route: Intravenous
Exposure time: 3 Months
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.

Relebactam:
Skin contact: Symptoms: Pain, Discomfort, Diarrhoea, Abdominal pain, insomnia, Nausea, sore throat, Vertigo

12. ECOLOGICAL INFORMATION

Ecotoxicity

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

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

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 99 mg/l</th>
</tr>
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<tr>
<th>Method</th>
<th>NOEC (Anabaena flos-aquae): 99 mg/l</th>
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</tbody>
</table>

Method: OECD Test Guideline 201

Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50: &gt; 1,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
<tr>
<td></td>
<td>Test Type: Respiration inhibition</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 209</td>
</tr>
</tbody>
</table>

Method: OECD Test Guideline 201

Imipenem:

Toxicity to daphnia and other aquatic invertebrates

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

Method: OECD Test Guideline 201

Toxicity to algae/aquatic plants

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Anabaena flos-aquae (cyanobacterium)): 0.0058 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
</tr>
<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0025 mg/l</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 72 h</td>
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<tr>
<td></td>
<td>Method: OECD Test Guideline 201</td>
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</table>

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 74 mg/l</th>
</tr>
</thead>
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<td>Method: OECD Test Guideline 201</td>
</tr>
</tbody>
</table>

M-Factor (Acute aquatic toxicity) : 100
M-Factor (Chronic aquatic toxicity) : 10

Toxicity to microorganisms

<table>
<thead>
<tr>
<th>Method</th>
<th>EC50: &gt; 1,000 mg/l</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Exposure time: 3 h</td>
</tr>
</tbody>
</table>
Test Type: Respiration inhibition
Method: OECD Test Guideline 209

**Relebactam:**

Toxicity to daphnia and other aquatic invertebrates:
- EC50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
- EC50 (Americamysis): > 100 mg/l
  Exposure time: 96 h

Toxicity to algae/aquatic plants:
- EC50 (Pseudokirchneriella subcapitata (green algae)): 86 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Pseudokirchneriella subcapitata (green algae)): 12 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- EC50 (Anabaena flos-aquae (cyanobacterium)): > 11 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201
- NOEC (Anabaena flos-aquae (cyanobacterium)): 11 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

Toxicity to fish (Chronic toxicity):
- NOEC (Pimephales promelas (fathead minnow)): 9.2 mg/l
  Exposure time: 32 d
  Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
- NOEC (Daphnia magna (Water flea)): 2.7 mg/l
  Exposure time: 21 d
  Method: OECD Test Guideline 211

Toxicity to microorganisms:
- EC50: > 1,000 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209
- NOEC: 96.3 mg/l
  Exposure time: 3 h
  Test Type: Respiration inhibition
  Method: OECD Test Guideline 209

**Persistence and degradability**

**Components:**


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

**Relebactam:**

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 11.3 %
Exposure time: 28 d
Method: OECD Test Guideline 314

**Bioaccumulative potential**

**Components:**

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

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

**Imipenem:**

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

**Relebactam:**

Partition coefficient: n-octanol/water : log Pow: < -2

**Mobility in soil**

**Components:**

**Relebactam:**

Distribution among environmental compartments : log Koc: 2.3

**Other adverse effects**

No data available

**13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues : Dispose of in accordance with local regulations.
Contaminated packaging : Empty containers should be taken to an approved waste han-
14. TRANSPORT INFORMATION

**International Regulations**

**UNRTDG**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)
- Class: 9
- Packing group: III
- Labels: 9

**IATA-DGR**
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Imipenem)
- Class: 9
- Packing group: III
- Labels: Miscellaneous
- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes

**IMDG-Code**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Imipenem)
- Class: 9
- Packing group: III
- Labels: 9
- EmS Code: F-A, S-F
- Marine pollutant: yes

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**
- Not applicable for product as supplied.

**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.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
Minister of Industry Regulation No. 23/M-IND/PER/4/2013 concerning the Revision of Minister of Industry Regulation No. 87/M-IND/PER/9/2009 concerning Globally Harmonized System of Classification and Labelling of Chemicals.

Regulation of the Minister of Health No. 472 of 1996 on the Safeguarding of Substances Hazardous to Health
Hazardous substances that must be registered : Not applicable

Government Regulation No. 74 of 2001 on the Management of Hazardous and Toxic Substances
Hazardous substances approved for use : Not applicable
Prohibited substances : Not applicable
Restricted substances : Not applicable

Regulation of the Minister of Trade No. 44 of 2009 on Procurement, Distribution and Supervision of Hazardous Materials
Types of Hazardous Materials governed by Import Regulations : Not applicable
Types of Hazardous Materials of which the Distribution and Supervision is Regulated : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

16. OTHER INFORMATION

Further information

Date format : yyyy/mm/dd

Full text of other abbreviations
AICS - Australian Inventory of Chemical Substances; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; CPR - Controlled Products Regulations; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); 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; ERG - Emergency Response
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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