

| Version<br>7.0 | Revision Date: 28.09.2024     |      | S Number:<br>816-00029   | Date of last issue: 26.09.2023<br>Date of first issue: 05.11.2014 |  |  |  |
|----------------|-------------------------------|------|--|---|--|--|--|
| SECTION        | SECTION 1. IDENTIFICATION     |      |  |   |  |  |  |
| Produ          | uct identifier                | :    | : Imipenem / Cilastatin Formulation  |   |  |  |  |
| Manu           | afacturer or supplier's       | deta | ils  |   |  |  |  |
| Com            | bany                          | :    | MSD  |   |  |  |  |
| Address        |                               | :    | Avenue Comendador Antônio Loureiro Ramos,<br>nº 1500 – Distrito Industrial<br>Montes Claros – MG, Brazil 39404-620 |   |  |  |  |
| Telep          | Telephone                     |      | +55 (38) 3229 7000   |   |  |  |  |
| Emer           | gency telephone               | :    | +55 (38) 3201 5670   |   |  |  |  |
| E-mail address |                               | :    | EHSDATASTEWARD@msd.com   |   |  |  |  |
| Reco           | mmended use of the            | chem | ical and restricti   | ons on use  |  |  |  |
|                | mmended use<br>ictions on use | :    | Pharmaceutical<br>Not applicable   |   |  |  |  |

#### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification in accordance with ABNT NBR 14725 Standard

| Eye irritation                        | : | Category 2A |
|---------------------------------------|---|-------------|
| Respiratory sensitization             | : | Category 1  |
| Reproductive toxicity                 | : | Category 2  |
| Short-term (acute) aquatic hazard     | : | Category 1  |
| Long-term (chronic) aquatic<br>hazard | : | Category 1  |

#### GHS label elements in accordance with ABNT NBR 14725 Standard

| Hazard pictograms : |  |
|---------------------|--|
| Signal Word :       | Danger   |
| Hazard Statements : | H319 Causes serious eye irritation.<br>H334 May cause allergy or asthma symptoms or breathing<br>difficulties if inhaled.<br>H361d Suspected of damaging the unborn child. |



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|----------------|---------------------------|---|--|
| I              |                           | H410 Very to:   | xic to aquatic life with long lasting effects.   |
| Preca          | autionary Statements      | P261 Avoid b<br>P264 Wash s<br>P273 Avoid re<br>P280 Wear p<br>tion/ face prot  | special instructions before use.<br>reathing dust.<br>kin thoroughly after handling.<br>elease to the environment.<br>rotective gloves/ protective clothing/ eye protec-<br>tection.<br>espiratory protection. |
|                |                           | keep comforta<br>P305 + P351<br>for several mi<br>easy to do. C<br>P308 + P313<br>attention.<br>P337 + P313<br>tention. |  |
|                |                           | <b>Storage:</b><br>P405 Store Ic  | ocked up.  |

#### 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.

#### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

| Chemical name | CAS-No.    | Classification  | Concentration (% w/w) |
|---------------|------------|---|-----------------------|
| Cilastatin    | 81129-83-1 | Eye Irrit., 2A  | >= 50 -< 70           |
| Imipenem      | 74431-23-5 | Resp. Sens., 1A<br>Repr., 2<br>Aquatic Acute, 1<br>Aquatic Chronic, 1 | >= 30 -< 50           |

### SECTION 4. FIRST AID MEASURES

| General advice | <ol> <li>In the case of accident or if you feel unwell, seek medical<br/>advice immediately.</li> </ol> |
|----------------|---|
|                | When symptoms persist or in all cases of doubt seek medical advice.                                     |
| If inhaled     | : If inhaled, remove to fresh air.  |



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| In case of skin contact                       |           | <ul> <li>If not breathing, give artificial respiration.</li> <li>If breathing is difficult, give oxygen.</li> <li>Get medical attention.</li> <li>In case of contact, immediately flush skin with soap and plenty of water.</li> <li>Remove contaminated clothing and shoes.</li> <li>Get medical attention.</li> <li>Wash clothing before reuse.</li> <li>Thoroughly clean shoes before reuse.</li> </ul> |   |  |  |
| In case of eye contact                        |           | :  | In case of contact, for at least 15 min   | immediately flush eyes with plenty of water<br>utes.<br>ove contact lens, if worn. |  |
| If swallowed                                  |           | :  |   | NOT induce vomiting.<br>ion.   |  |
| Most important<br>and effects, bot<br>delayed |           | :  | Causes serious eye irritation.<br>May cause allergy or asthma symptoms or breathing<br>difficulties if inhaled.<br>Suspected of damaging the unborn child.<br>Excessive exposure may aggravate preexisting asthma and<br>other respiratory disorders (e.g. emphysema, bronchitis,<br>reactive airways dysfunction syndrome).<br>Contact with dust can cause mechanical irritation or drying o |  |  |
| Protection of fir                             | st-aiders | <ul> <li>the skin.</li> <li>First Aid responders should pay attention to self-protection<br/>and use the recommended personal protective equipment<br/>when the potential for exposure exists (see section 8).</li> </ul>  |   |  |  |
| Notes to physic                               | ian       |  | •   | cally and supportively.  |  |

### SECTION 5. FIRE-FIGHTING MEASURES

| Suitable extinguishing media          | : | Water spray<br>Alcohol-resistant foam<br>Carbon dioxide (CO2)<br>Dry chemical   |
|---------------------------------------|---|---|
| Unsuitable extinguishing media        | : | None known.   |
| Specific hazards during fire fighting | : | Avoid generating dust; fine dust dispersed in air in sufficient<br>concentrations, and in the presence of an ignition source is a<br>potential dust explosion hazard.<br>Exposure to combustion products may be a hazard to health.                     |
| Hazardous combustion prod-<br>ucts    | : | Carbon oxides   |
| Specific extinguishing meth-<br>ods   | : | Use extinguishing measures that are appropriate to local cir-<br>cumstances and the surrounding environment.<br>Use water spray to cool unopened containers.<br>Remove undamaged containers from fire area if it is safe to do<br>so.<br>Evacuate area. |



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| Special protective equipment for fire-fighters                                |                           | :  |  | e, wear self-contained breathing apparatus.<br>ective equipment.  |
| SECTION   | 6. ACCIDENTAL RELE        | AS | E MEASURES   |   |
| Personal precautions, protec-<br>tive equipment and emer-<br>gency procedures |                           | :  | Follow safe handl  | ective equipment.<br>ing advice (see section 7) and personal<br>ent recommendations (see section 8).  |
| Environmental precautions   |                           | :  | Avoid release to the environment.<br>Prevent further leakage or spillage if safe to do so.<br>Retain and dispose of contaminated wash water.<br>Local authorities should be advised if significant spillages<br>cannot be contained.   |   |
| Methods and materials for containment and cleaning up                         |                           |    | over the area to m<br>Add excess liquid<br>Soak up with inem<br>Avoid dispersal of<br>with compressed<br>Dust deposits sho<br>surfaces, as these<br>released into the<br>Clean up remaining<br>absorbent.<br>Local or national n<br>disposal of this m<br>employed in the c<br>determine which n | aud not be allowed to accumulate on<br>a may form an explosive mixture if they are<br>atmosphere in sufficient concentration.<br>Ing materials from spill with suitable<br>regulations may apply to releases and<br>aterial, as well as those materials and items<br>leanup of releases. You will need to<br>regulations are applicable.<br>5 of this SDS provide information regarding |

| Technical measures      | : | Static electricity may accumulate and ignite suspended dust causing an explosion.   |
|-------------------------|---|---|
| Local/Total ventilation |   | Provide adequate precautions, such as electrical grounding<br>and bonding, or inert atmospheres.<br>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.  |
|                         |   | 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 sensitized individuals, and those susceptible   |
|                         |   | to asthma, allergies, chronic or recurrent respiratory disease, should consult their physician regarding working with                   |



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| Hygie          | ne measures                  | Minimize dust g<br>Keep container<br>Keep away from<br>Take precaution<br>Take care to pre<br>environment.<br>If exposure to c<br>flushing system<br>place.<br>When using do  | <ul> <li>If exposure to chemical is likely during typical use, provide eye<br/>flushing systems and safety showers close to the working</li> </ul> |  |  |  |  |
| Condi          | tions for safe storage       | nated clothing before re-use.<br>Deration of a facility should include review of<br>introls, proper personal protective equipment,<br>gowning and decontamination procedures,<br>ne monitoring, medical surveillance and the<br>rative controls.<br>y labeled containers.<br>b.<br>sed. |  |  |  |  |  |
| Mater          | ials to avoid                | Store in accord   | ance with the particular national regulations.<br>th the following product types:  |  |  |  |  |

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

|            | • | •                   |                 |                    |          |
|------------|---|---------------------|-----------------|--------------------|----------|
| Components |   | CAS-No.             | Value type      | Control parame-    | Basis    |
|            |   |                     | (Form of        | ters / Permissible |          |
|            |   |                     | exposure)       | concentration      |          |
| Cilastatin |   | 81129-83-1          | TWA             | 5 mg/m3 (OEB 1)    | Internal |
| Imipenem   |   | 74431-23-5          | TWA             | 3000 ug/m3 (OEB    | Internal |
|            |   |                     |                 | 1)                 |          |
|            |   | Further information | ation: RSEN, DS | EN                 |          |
|            |   |                     | Wipe limit      | 100 µg/100 cm2     | Internal |

### Ingredients with workplace control parameters

| Engineering measures          | <ul> <li>Use feasible engineering controls to minimize exposure to compound.</li> <li>All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.</li> </ul> |
|-------------------------------|--|
| Personal protective equipment | nt   |
| Respiratory protection        | <ul> <li>If adequate local exhaust ventilation is not available or<br/>exposure assessment demonstrates exposures outside the<br/>recommended guidelines, use respiratory protection.</li> <li>Particulates type</li> </ul>  |
| Hand protection               |  |
| Material                      | Chemical-resistant gloves  |
| Eye protection                | <ul> <li>Wear safety glasses with side shields or goggles.</li> <li>If the work environment or activity involves dusty conditions,<br/>mists or aerosols, wear the appropriate goggles.</li> </ul>   |



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|----------------|--|------|------------------------------------|---|
| Skir           | n and body protection                          | :    |                                    | or other full face protection if there is a contact to the face with dusts, mists, or aboratory coat. |
| SECTIO         | N 9. PHYSICAL AND CH                           | ΞΜΙΟ |                                    | 6   |
| Phy            | sical state                                    | :    | powder                             |   |
| Cole           | or   | :    | white                              |   |
| Odo            | or   | :    | sulfurous                          |   |
| Odd            | or Threshold                                   | :    | No data available                  | 9   |
| pН             |  | :    | No data available                  | 9   |
| Mel            | ting point/freezing point                      | :    | No data available                  | 9   |
| Initia<br>ranç | al boiling point and boiling<br>ge             | :    | No data available                  | )   |
| Flas           | sh point                                       | :    | Not applicable                     |   |
| Eva            | poration rate                                  | :    | Not applicable                     |   |
| Flar           | nmability (solid, gas)                         | :    | May form explosi handling or other | ve dust-air mixture during processing, means.   |
| Flar           | nmability (liquids)                            | :    | Not applicable                     |   |
|                | per explosion limit / Upper<br>nmability limit | :    | No data available                  |   |
|                | ver explosion limit / Lower<br>nmability limit | :    | No data available                  |   |
| Vap            | oor pressure                                   | :    | Not applicable                     |   |
| Rela           | ative vapor density                            | :    | Not applicable                     |   |
| Rela           | ative density                                  | :    | No data available                  | 2   |
| Der            | nsity  | :    | 1 g/cm <sup>3</sup>                |   |
|                | ubility(ies)<br>Water solubility               | :    | No data available                  | 9   |
|                | tition coefficient: n-                         | :    | Not applicable                     |   |
|                | anol/water<br>oignition temperature            | :    | No data available                  | 9   |
| Dec            | composition temperature                        | :    | No data available                  | 9   |
| Viso           | cosity   |      |                                    |   |

### SAFETY DATA SHEET



# Imipenem / Cilastatin Formulation

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|                | Viscosity, dynamic<br>Viscosity, kinematic |     | lo data available<br>lot applicable  | 9   |
| Ex             | plosive properties                         | : N | lot explosive                        |   |
|                | idizing properties<br>lecular weight       |     | The substance o<br>No data available | r mixture is not classified as oxidizing.                         |
|                | rticle characteristics<br>rticle size      | : N | lo data available                    | e   |

### SECTION 10. STABILITY AND REACTIVITY

| Reactivity<br>Chemical stability<br>Possibility of hazardous reac-<br>tions |   | Not classified as a reactivity hazard.<br>Stable under normal conditions.<br>May form explosive dust-air mixture during processing,<br>handling or other means.<br>Can react with strong oxidizing agents. |
|---|---|--|
| Conditions to avoid   | : | Heat, flames and sparks.<br>Avoid dust formation.  |
| Incompatible materials<br>Hazardous decomposition                           |   | Oxidizing agents<br>No hazardous decomposition products are known.   |
| products  | • |  |

#### SECTION 11. TOXICOLOGICAL INFORMATION

| Information on likely routes of exposure                 | :   | Inhalation<br>Skin contact<br>Ingestion<br>Eye contact   |
|--|-----|--|
| <b>Acute toxicity</b><br>Not classified based on availat | ole | information.   |
| Components:  |     |  |
| <b>Cilastatin:</b><br>Acute oral toxicity                | :   | LD50 (Rat): 8.000 mg/kg<br>LD50 (Mouse): 8.000 mg/kg   |
| Imipenem:  |     |  |
| Acute oral toxicity                                      | :   | LD50 (Mouse): 10.000 mg/kg   |
| Acute toxicity (other routes of administration)          | :   | LD50 (Rat): > 2.000 mg/kg<br>Application Route: Intravenous<br>LD50 (Mouse): 1.500 mg/kg<br>Application Route: Intravenous |





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| Skin           | corrosion/irritation                           |                                    |   |
| Not cl         | assified based on av                           | ailable information.               |   |
| <u>Comp</u>    | oonents:                                       |                                    |   |
| Cilast         | tatin:   |                                    |   |
| Speci<br>Resul |  | : Rabbit<br>: No skin irritatio    | on  |
|                | us eye damage/eye<br>es serious eye irritatio  |                                    |   |
| Comp           | oonents:                                       |                                    |   |
| Cilast         | tatin:   |                                    |   |
| Speci<br>Resul |  | : Rabbit<br>: Moderate eye         | irritation  |
| Resp           | iratory or skin sens                           | itization                          |   |
| -              | sensitization<br>assified based on av          | ailable information.               |   |
| -              | iratory sensitization<br>ause allergy or asthr |                                    | hing difficulties if inhaled.                                     |
| <u>Comp</u>    | oonents:                                       |                                    |   |
| Cilast         |  |                                    |   |
| Route<br>Rema  | es of exposure<br>Irks                         | : Skin contact<br>: No data availa | able  |
| Route<br>Rema  | es of exposure<br>Irks                         | : Inhalation<br>: No data availa   | able  |
| Imipe          | nem:   |                                    |   |
| Rema           | rks  | : May cause se<br>of aerosol or c  | nsitization of susceptible persons by inhalation<br>lust.         |
| Route<br>Rema  | es of exposure<br>Irks                         | : Skin contact<br>: Not classified | due to lack of data.  |
| Not cl         | cell mutagenicity<br>assified based on av      | ailable information.               |   |
| <u>Com</u> p   | oonents:                                       |                                    |   |
| Cilast         |  |                                    |   |
| Geno           | toxicity in vitro                              | : Test Type: Mic<br>Result: negati | crobial mutagenesis assay (Ames test)<br>ve                       |
| <br>Imipe      | nem:   |                                    |   |
|                |  |                                    |   |



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|   | Test system: C<br>Result: negativ                                    | Chinese hamster lung cells<br>/e  |
|   | Test Type: reve<br>Result: negativ                                   | erse mutation assay<br>/e   |
|   | Test Type: uns<br>Result: negativ                                    | scheduled DNA synthesis assay<br>/e   |
|   | Test Type: Chr<br>Result: negativ                                    | romosomal aberration<br>/e  |
|   | Test Type: sist<br>Result: negativ                                   | er chromatid exchange assay<br>/e   |
| Genotoxicity in vivo  | Species: Mous  | ute: Intravenous  |
| Carcinogenicity Not classified based on avai                      | ilable information   |   |
| Reproductive toxicity<br>Suspected of damaging the<br>Components: | unborn child.  |   |
| <b>Cilastatin:</b><br>Effects on fertility                        | Application Ro<br>Fertility: LOAE<br>Symptoms: No                    | adverse effects.<br>ects on fertility and early embryonic develop-  |
| II<br>Imipenem:   |  |   |
| Effects on fertility  | Species: Rat, r<br>Application Ro<br>Fertility: LOAE<br>Symptoms: No | tility/early embryonic development<br>male and female<br>ute: Intravenous<br>L: 80 mg/kg body weight<br>adverse effects., Reduced fetal weight.<br>ects on fertility and early embryonic develop-<br>ected.     |
|   | Species: Rat, r<br>Application Ro<br>Fertility: LOAE<br>Symptoms: No | tility/early embryonic development<br>nale and female<br>ute: Subcutaneous<br>L: 320 mg/kg body weight<br>o adverse effects., Reduced fetal weight.<br>ects on fertility and early embryonic develop-<br>ected. |
| Effects on fetal developmen                                       | t : Test Type: Dev   | velopment   |



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|------------------------------------|--|---|---|--|--|--|
|                                    |  | Developmenta<br>Result: Embry<br>spring were de   | bute: Intravenous<br>al Toxicity: LOAEL: 100 mg/kg body weight<br>otoxic effects and adverse effects on the off-<br>etected., No teratogenic effects. |  |  |  |
|                                    |  | Test Type: Development<br>Species: Rabbit<br>Application Route: Intravenous<br>Developmental Toxicity: NOAEL: 60 mg/kg body weight<br>Result: No teratogenic effects. |   |  |  |  |
|                                    |  | Developmenta  | velopment<br>oute: Intravenous<br>al Toxicity: NOAEL: 60 mg/kg body weight<br>atogenic effects.   |  |  |  |
|                                    | roductive toxicity - As-<br>ment   | : Some evidence<br>animal experir   | e of adverse effects on development, based on nents.  |  |  |  |
| Not o<br>STO                       | T-single exposure<br>classified based on avail<br>T-repeated exposure<br>classified based on avail |   |   |  |  |  |
| Rep                                | eated dose toxicity  |   |   |  |  |  |
| Com                                | ponents:   |   |   |  |  |  |
| Cilas                              | statin:  |   |   |  |  |  |
| Spec<br>NOA<br>Appl<br>Expo<br>Rem | EL<br>ication Route<br>osure time  | : Rat<br>: >= 500 mg/kg<br>: Intravenous<br>: 90 Days<br>: No significant   | adverse effects were reported   |  |  |  |
|                                    | EL<br>ication Route<br>osure time  | : Monkey<br>: >= 500 mg/kg<br>: Intravenous<br>: 5 Weeks<br>: No significant  | adverse effects were reported   |  |  |  |
| Imip                               | enem:  |   |   |  |  |  |
| Spec<br>NOA<br>LOA<br>Appl<br>Expo | cies<br>EL   | : Monkey<br>: 60 mg/kg<br>: 150 mg/kg<br>: Intravenous<br>: 6 Months<br>: Kidney  |   |  |  |  |
| Spec<br>NOA                        |  | : Monkey<br>: 120 mg/kg   |   |  |  |  |



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|  | cation Route<br>sure time<br>arks           | : Subcutaneous<br>: 6 Months<br>: No significant a                        | dverse effects were reported   |
| Speci<br>NOAI<br>Applie<br>Expos<br>Rema | EL<br>cation Route<br>sure time             | : Rat<br>: 180 mg/kg<br>: Intravenous<br>: 6 Months<br>: No significant a | dverse effects were reported   |
|  | ies<br>EL<br>cation Route<br>et Organs      | : Rabbit<br>: 150 mg/kg<br>: Intravenous<br>: Kidney                      |  |
| •  | ration toxicity<br>lassified based on avail | lable information.  |  |
|  | rience with human ex                        |   |  |
| Com                                      | ponents:                                    |   |  |
| <b>Imipe</b><br>Inhala                   | enem:<br>ation                              | Dizziness, Drov   | usea, Vomiting, Diarrhea, Fever, hypotension,<br>vsiness, Convulsions, pruritis, Rash<br>cause sensitization of susceptible persons by<br>rosol or dust. |
|  | 12. ECOLOGICAL INF                          | FORMATION   |  |

**Components:** 

Cilastatin:

| Chastatin.  |   |  |
|---|---|--|
| Toxicity to fish                                    | : | LC50 (Pimephales promelas (fathead minnow)): > 111 mg/l<br>Exposure time: 96 h<br>Method: OECD Test Guideline 203            |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): > 99 mg/l<br>Exposure time: 48 h<br>Method: OECD Test Guideline 202                       |
| Toxicity to algae/aquatic plants                    | : | EC50 (Anabaena flos-aquae): > 99 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201                              |
|   |   | EC50 (Pseudokirchneriella subcapitata (green algae)): > 99<br>mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201 |
|   |   | NOEC (Anabaena flos-aquae): 99 mg/l<br>Exposure time: 72 h<br>Method: OECD Test Guideline 201                                |



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|                            |   |   | NOEC (Pseudokir<br>mg/l<br>Exposure time: 72<br>Method: OECD To              |   |
| Toxici<br>icity)           | ty to fish (Chronic tox-                                    | : | EC10 (Pimephale<br>Exposure time: 32<br>Method: OECD To                      |   |
|                            | ty to daphnia and other<br>c invertebrates (Chron-<br>city) | : | EC10 (Daphnia m<br>Exposure time: 21<br>Method: OECD Te                      |   |
| Toxici                     | ty to microorganisms  | : | EC50: > 1.000 mg<br>Exposure time: 3<br>Test Type: Respir<br>Method: OECD To | h<br>ration inhibition  |
| Imipe                      | nem:  |   |  |   |
| Toxici                     | ty to daphnia and other<br>c invertebrates                  | : | EC50 (Daphnia m<br>Exposure time: 48<br>Method: OECD Te                      |   |
| Toxici<br>plants           | ty to algae/aquatic   | : | EC50 (Anabaena<br>Exposure time: 72<br>Method: OECD Te                       |   |
|                            |   |   | NOEC (Anabaena<br>Exposure time: 72<br>Method: OECD Te                       |   |
|                            |   |   | EC50 (Pseudokiro<br>mg/l<br>Exposure time: 72<br>Method: OECD Te             |   |
|                            |   |   | NOEC (Pseudokir<br>mg/l<br>Exposure time: 72<br>Method: OECD Te              |   |
|                            | tor (Acute aquatic tox-                                     | : | 100  |   |
| icity)<br>Toxici<br>icity) | ty to fish (Chronic tox-                                    | : | NOEC (Pimephale<br>Exposure time: 32<br>Method: OECD Te                      |   |
|                            | ty to daphnia and other<br>c invertebrates (Chron-<br>city) | : | NOEC (Daphnia r<br>Exposure time: 21<br>Method: OECD Te                      |   |
| M-Fac<br>toxicity          | ctor (Chronic aquatic<br>y)                                 | : | 10   |   |



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|----------------|---|------|-----------------------------------|---|
| Toxic          | ity to microorganisms                               | :    |                                   |   |
| Persi          | istence and degradabi                               | lity |                                   |   |
| Com            | ponents:  |      |                                   |   |
|                | egradability  | :    | Biodegradation:<br>Exposure time: |   |
| Imipe          | enem:   |      |                                   |   |
| Biode          | egradability  | :    | Biodegradation:<br>Exposure time: |   |
| Bioa           | ccumulative potential                               |      |                                   |   |
| <u>Com</u>     | ponents:  |      |                                   |   |
| Cilas          | statin:   |      |                                   |   |
|                | tion coefficient: n-<br>nol/water                   | :    | log Pow: -3,53                    |   |
| Imipe          | enem:   |      |                                   |   |
|                | tion coefficient: n-<br>nol/water                   | :    | log Pow: < -1                     |   |
| Mobi           | ility in soil                                       |      |                                   |   |
| Com            | ponents:  |      |                                   |   |
| Distri         | statin:<br>bution among environ-<br>al compartments | :    | log Koc: 2,3                      |   |
|                | <b>r adverse effects</b><br>ata available           |      |                                   |   |

| Disposal methods       |   |   |
|------------------------|---|---|
| Waste from residues    | : | Do not dispose of waste into sewer.<br>Dispose of in accordance with local regulations. |
| Contaminated packaging | : |   |





| /ersion<br>′.0   | Revision Date:<br>28.09.2024                        |     | OS Number:<br>816-00029            | Date of last issue: 26.09.2023<br>Date of first issue: 05.11.2014 |
|------------------|---|-----|------------------------------------|---|
| ECTION           | 14. TRANSPORT INFO                                  | ORM | ATION                              |   |
| Inter            | national Regulations                                |     |                                    |   |
| UNR <sup>.</sup> | TDG   |     |                                    |   |
| UN n             | umber   | :   | UN 3077                            |   |
| Prope            | er shipping name                                    | :   | ENVIRONMEN<br>N.O.S.<br>(Imipenem) | TALLY HAZARDOUS SUBSTANCE, SOLID                                  |
| Class            | 5   | :   | 9                                  |   |
|                  | ing group   | :   | III                                |   |
| Labe             |   | :   | 9                                  |   |
| Envir            | onmentally hazardous                                | :   | yes                                |   |
|                  | -DGR  |     |                                    |   |
| UN/IE            |   | :   | UN 3077                            |   |
|                  | er shipping name                                    | :   | (Imipenem)                         | / hazardous substance, solid, n.o.s.                              |
| Class            |   | :   | 9                                  |   |
| Label            | ing group   | ÷   | III<br>Miscellaneous               |   |
|                  | ing instruction (cargo                              | :   | 956                                |   |
| Packi            | ing instruction (passen-<br>ircraft)                | :   | 956                                |   |
|                  | onmentally hazardous                                | :   | yes                                |   |
| IMDO             | G-Code  |     |                                    |   |
|                  | umber   | :   | UN 3077                            |   |
| Prope            | er shipping name                                    | :   | ENVIRONMEN<br>N.O.S.<br>(Imipenem) | TALLY HAZARDOUS SUBSTANCE, SOLID                                  |
| Class            | 5   | :   | 9                                  |   |
| Packi            | ing group   | :   | III                                |   |
| Labe             |   | :   | 9                                  |   |
|                  | Code  | ÷   | F-A, S-F                           |   |
|                  | e pollutant   | ÷   | yes                                |   |
|                  | sport in bulk according<br>pplicable for product as | -   |                                    | RPOL 73/78 and the IBC Code                                       |
| Dom              | estic regulation                                    | -   |                                    |   |
|                  | -   |     |                                    |   |
| ANT<br>UN n      | ı<br>umber  |     | UN 3077                            |   |
|                  | er shipping name                                    | :   |                                    | TALLY HAZARDOUS SUBSTANCE, SOLID                                  |

| UN number                    | : | UN 3077   |
|------------------------------|---|---|
| Proper shipping name         | : | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID,<br>N.O.S.<br>(Imipenem) |
| Class                        | : | 9   |
| Packing group                | : | III   |
| Labels                       | : | 9   |
| Hazard Identification Number | : | 90  |

#### 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





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Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

#### SECTION 15. REGULATORY INFORMATION

| Safety, health and environn mixture  | nental regulations/legisla | ition specific for the subst | ance or |  |
|--|----------------------------|------------------------------|---------|--|
| National List of Carcinogenic<br>(LINACH)                                  | Agents for Humans -        | : Not applicable             |         |  |
| Brazil. List of chemicals contr<br>Police                                  | olled by the Federal       | : Not applicable             |         |  |
| The ingredients of this product are reported in the following inventories: |                            |                              |         |  |
| AICS   | : not determined           |                              |         |  |

| DSL   | : | not determined |
|-------|---|----------------|
| IECSC | : | not determined |

#### **SECTION 16. OTHER INFORMATION**

| Revision Date | : | 28.09.2024 |
|---------------|---|------------|
| Date format   | : | dd.mm.yyyy |

#### Further information

| Sources of key data used to | : | Internal technical data, data from raw material SDSs, OECD |
|-----------------------------|---|--|
| compile the Material Safety |   | eChem Portal search results and European Chemicals Agen-   |
| Data Sheet                  |   | cy, http://echa.europa.eu/                                 |

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 other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; 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; 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 Guide; 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



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Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; 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; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals 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; WHMIS - Workplace Hazardous Materials Information System

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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