

Imipenem / Cilastatin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/19/2017
5.1 10/18/2017 15845-00011 Date of first issue: 11/05/2014

SECTION 1. IDENTIFICATION

Product name : Imipenem / Cilastatin Formulation

Manufacturer or supplier's details

Company name of supplier : Merck & Co., Inc
Address : 2000 Galloping Hill Road
Kenilworth - New Jersey - USA 1685
Telephone : 908-740-4000
Telefax : 908-735-1496
Emergency telephone : 1-908-423-6000
E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with 29 CFR 1910.1200**

Combustible dust

Eye irritation : Category 2A
Respiratory sensitization : Category 1
Reproductive toxicity : Category 2

GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : If small particles are generated during further processing, handling or by other means, may form combustible dust concentrations in air.
H319 Causes serious eye irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H361d Suspected of damaging the unborn child.

Precautionary Statements :

Prevention:

P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read

Imipenem / Cilastatin Formulation

Version 5.1 Revision Date: 10/18/2017 SDS Number: 15845-00011 Date of last issue: 09/19/2017
 Date of first issue: 11/05/2014

and understood.
 P261 Avoid breathing dust.
 P264 Wash skin thoroughly after handling.
 P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
 P285 In case of inadequate ventilation wear respiratory protection.

Response:

P304 + P341 IF INHALED: If breathing is difficult, 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.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

Contact with dust can cause mechanical irritation or drying of the skin.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Sodium hydrogen [R-[R*,S*-(Z)]]-7-[(2-amino-2-carboxylatoethyl)thio]-2-[[[(2,2-dimethylcyclopropyl)carbonyl]amino]hept-2-enoate	81129-83-1	>= 50 - < 70
Imipenem	74431-23-5	>= 30 - < 50

SECTION 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.

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

- 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.
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.
-

SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : None known.
- Specific hazards during fire fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon 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 fire-fighters : In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

SECTION 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.

SECTION 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.
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 labeled containers.
Store locked up.

Imipenem / Cilastatin Formulation

Version 5.1 Revision Date: 10/18/2017 SDS Number: 15845-00011 Date of last issue: 09/19/2017
 Date of first issue: 11/05/2014

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sodium hydrogen [R-[R*,S*-(Z)]]-7-[(2-amino-2-carboxylatoethyl)thio]-2-[[[(2,2-dimethylcyclopropyl)carbonyl]amino]hept-2-enoate	81129-83-1	TWA	5 mg/m ³ (OEB 1)	Merck
Imipenem	74431-23-5	TWA	5 mg/m ³ (OEB 1)	Merck
Further information: DSEN, RSEN				
		Wipe limit	0.1 mg/100 cm ²	Merck

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 : General and local exhaust ventilation is recommended to maintain vapor exposures below recommended limits. Where concentrations are above recommended limits or are unknown, appropriate respiratory protection should be worn. Follow OSHA respirator regulations (29 CFR 1910.134) and use NIOSH/MSHA approved respirators. Protection provided by air purifying respirators against exposure to any hazardous chemical is limited. Use a positive pressure air supplied respirator if there is any potential for uncontrolled release, exposure levels are unknown, or any other circumstance where air purifying respirators may not provide adequate protection.

Hand protection
 Material : 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 potential for direct contact to the face with dusts, mists, or aerosols.

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : powder

Color : white

Odor : sulfurous

Odor 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 : Not applicable

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

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1 g/cm³

Solubility(ies)

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity	:	
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Molecular weight	:	No data available
Particle size	:	No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Dust can form an explosive mixture in air. Can react with strong oxidizing agents.
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Information on likely routes of exposure**

Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Ingredients:

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

Imipenem / Cilastatin Formulation

Version 5.1 Revision Date: 10/18/2017 SDS Number: 15845-00011 Date of last issue: 09/19/2017
Date of first issue: 11/05/2014

LD50 (Mouse): > 10,000 mg/kg

Imipenem:

Acute oral toxicity : LD50 Oral (Mouse): 10,000 mg/kg

Acute toxicity (other routes of administration) : LD50 (Mouse): 1,650 mg/kg
Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Ingredients:

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

Species: Rabbit
Result: No skin irritation

Imipenem:

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Ingredients:

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

Species: Rabbit
Result: Moderate eye irritation

Imipenem:

Species: Rabbit
Result: Mild eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Ingredients:

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

Routes of exposure: Skin contact
Remarks: No data available

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

Routes of exposure: Inhalation

Remarks: No data available

Imipenem:

Remarks: May cause sensitization of susceptible persons by inhalation of aerosol or dust.

Routes of exposure: Skin contact

Remarks: Not classified due to lack of data.

Germ cell mutagenicity

Not classified based on available information.

Ingredients:

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: reverse mutation assay
Result: negative

Imipenem:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Test system: Chinese hamster lung cells
Result: negative

Test Type: reverse mutation assay
Result: negative

Test Type: unscheduled DNA synthesis assay
Result: negative

Test Type: Chromosomal aberration
Result: negative

Test Type: sister chromatid exchange assay
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Intravenous
Result: negative

Carcinogenicity

Not classified based on available information.

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

NTP

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

inhalation of aerosol or dust.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Ingredients:

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

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 : EC50 (Anabaena flos-aquae): > 99 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 99 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 99 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 99 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

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

Imipenem:

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

Toxicity to algae : EC50 (Anabaena flos-aquae (cyanobacterium)): 0.0058 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.0025 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

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

M-Factor (Chronic aquatic toxicity) : 10

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

Persistence and degradability

Ingredients:

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

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

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

Imipenem:

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

Bioaccumulative potential

Ingredients:

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

Partition coefficient: n-octanol/water : log Pow: -3.51

Imipenem:

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

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

octanol/water

Mobility in soil

No data available

Other adverse effects

No data available

SECTION 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 handling site for recycling or disposal.
If not otherwise specified: Dispose of as unused product. |

SECTION 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 |

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

Domestic regulation

49 CFR

UN/ID/NA number	:	UN 3077
Proper shipping name	:	Environmentally hazardous substance, solid, n.o.s. (Imipenem)
Class	:	9
Packing group	:	III
Labels	:	CLASS 9
ERG Code	:	171
Marine pollutant	:	yes(Imipenem)
Remarks	:	Above applies only to containers over 119 gallons or 450 liters., Shipment by ground under DOT is non-regulated; however it may be shipped per the applicable hazard classification to facilitate multi-modal transport involving ICAO (IATA) or IMO.

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards	:	Combustible dust Serious eye damage or eye irritation Respiratory or skin sensitization Reproductive toxicity
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SARA 313	:	This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.
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US State Regulations

Pennsylvania Right To Know

Sodium hydrogen [R-[R*,S*-(Z)]]-7-[(2-amino-2-carboxylatoethyl)thio]-2-[[[2,2-dimethylcyclopropyl)carbonyl]amino]hept-2-enoate	81129-83-1
Imipenem	74431-23-5

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

The ingredients of this product are reported in the following inventories:

Imipenem / Cilastatin Formulation

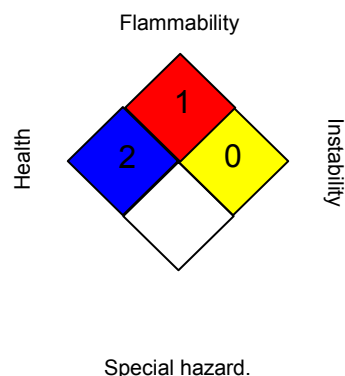
Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA:



HMIS® IV:

HEALTH	*	2
FLAMMABILITY	3	
PHYSICAL HAZARD	0	

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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 sub-

Imipenem / Cilastatin Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 09/19/2017
5.1	10/18/2017	15845-00011	Date of first issue: 11/05/2014

stance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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

Revision Date : 10/18/2017

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

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.

US / Z8