according to the OSHA Hazard Communication Standard



Imipenem / Cilastatin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/26/2023 11.3 09/28/2024 15845-00029 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 : 126 E. Lincoln Avenue

Rahway, New Jersey U.S.A. 07065

Telephone : 908-740-4000 Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@merck.com

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical Restrictions on use : Not applicable

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (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, han-

dling or by other means, may form combustible dust concentra-

tions in air.

H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing diffi-

culties 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

and understood.

P261 Avoid breathing dust.

P264 Wash skin thoroughly after handling.

according to the OSHA Hazard Communication Standard



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P280 Wear protective gloves, protective clothing, eye protection and face protection.

P285 In case of inadequate ventilation wear respiratory protec-

tion.

Response:

P304 + P341 IF INHALED: If breathing is difficult, remove per-

son 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 attention. P337 + P313 If eye irritation persists: Get medical attention. P342 + P311 If experiencing respiratory symptoms: Call a doc-

tor.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents and 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

Components

Chemical name	CAS-No.	Concentration (% w/w)
Cilastatin	81129-83-1	50.1
Imipenem	74431-23-5	49

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.

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.

according to the OSHA Hazard Communication Standard



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If easy to do, remove contact lens, if worn.

Get medical attention.

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.

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 (see section 8).

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

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 prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

according to the OSHA Hazard Communication Standard



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Environmental precautions : Avoid release to the environment.

Prevent further leakage or spillage if safe to do so. Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and cleaning up

Surround spill with absorbents and place a damp covering over the area to minimize entry of the material into the air. Add excess liquid to allow the material to enter into solution.

Soak up with inert absorbent material.

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. Clean up remaining materials from spill with suitable

absorbent.

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 Advice on safe handling Use only with adequate ventilation.

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

respiratory irritants or sensitizers.

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.

according to the OSHA Hazard Communication Standard



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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

inert or nuisance dust 50 Million particles per cubic foot

Value type (Form of exposure): TWA (total dust)

Basis: OSHA Z-3

15 mg/m³

Value type (Form of exposure): TWA (total dust)

Basis: OSHA Z-3

5 mg/m³

Value type (Form of exposure): TWA (respirable fraction)

Basis: OSHA Z-3

15 Million particles per cubic foot

Value type (Form of exposure): TWA (respirable fraction)

Basis: OSHA Z-3

Dust, nuisance dust and par-

ticulates

10 mg/m³

Value type (Form of exposure): PEL (Total dust)

Basis: CAL PEL

5 mg/m³

Value type (Form of exposure): PEL (respirable dust fraction)

Basis: CAL PEL

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

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.

according to the OSHA Hazard Communication Standard



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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.

Skin and body protection

Hygiene measures

Work uniform or laboratory coat.

If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the

working place.

When using do not eat, drink or smoke. Wash contaminated clothing before re-use.

The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the

use of administrative controls.

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 : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing,

handling or other means.

Flammability (liquids) : Not applicable

according to the OSHA Hazard Communication Standard



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Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Vapor pressure : Not applicable

Relative vapor density : Not applicable

Relative density : No data available

Density : 1 g/cm³

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

Not applicable

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

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 reac-

tions

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.
Oxidizing agents

Incompatible materials

Hazardous decomposition

products

No hazardous decomposition products are known.

according to the OSHA Hazard Communication Standard



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SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Inhalation Skin contact Ingestion Eye contact

Acute toxicity

Not classified based on available information.

Components:

Cilastatin:

Acute oral toxicity : LD50 (Rat): 8,000 mg/kg

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

Application Route: Intravenous

LD50 (Mouse): 1,500 mg/kg Application Route: Intravenous

Skin corrosion/irritation

Not classified based on available information.

Components:

Cilastatin:

Species : Rabbit

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Components:

Cilastatin:

Species : Rabbit

Result : Moderate eye irritation

Respiratory or skin sensitization

Skin sensitization

Not classified based on available information.

Respiratory sensitization

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

according to the OSHA Hazard Communication Standard



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Components:

Cilastatin:

Routes of exposure : Skin contact Remarks : No data available

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.

Components:

Cilastatin:

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

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.

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OSHANo 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 by NTP.

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Cilastatin:

Effects on fertility : Test Type: Fertility/early embryonic development

Application Route: Intravenous

Fertility: LOAEL: 1,000

Symptoms: No adverse effects.

Result: No effects on fertility and early embryonic

development were detected.

Imipenem:

Effects on fertility : Test Type: Fertility/early embryonic development

Species: Rat, male and female Application Route: Intravenous

Fertility: LOAEL: 80 mg/kg body weight

Symptoms: No adverse effects., Reduced fetal weight. Result: No effects on fertility and early embryonic

development were detected.

Test Type: Fertility/early embryonic development

Species: Rat, male and female Application Route: Subcutaneous Fertility: LOAEL: 320 mg/kg body weight

Symptoms: No adverse effects., Reduced fetal weight. Result: No effects on fertility and early embryonic

development were detected.

Effects on fetal 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

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Developmental Toxicity: NOAEL: 60 mg/kg body weight

Result: No teratogenic effects.

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

STOT-single exposure

Not classified based on available information.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

Cilastatin:

Species : Rat

NOAEL : >= 500 mg/kg
Application Route : Intravenous
Exposure time : 90 Days

Remarks : No significant adverse effects were reported

Species : Monkey
NOAEL : >= 500 mg/kg
Application Route : Intravenous
Exposure time : 5 Weeks

Remarks : No significant adverse effects were reported

Imipenem:

Species : Monkey
NOAEL : 60 mg/kg
LOAEL : 150 mg/kg
Application Route : Intravenous
Exposure time : 6 Months
Target Organs : Kidney

Species : Monkey
NOAEL : 120 mg/kg
Application Route : Subcutaneous
Exposure time : 6 Months

Remarks : No significant adverse effects were reported

Species : Rat
NOAEL : 180 mg/kg
Application Route : Intravenous
Exposure time : 6 Months

Remarks : No significant adverse effects were reported

Species : Rabbit
LOAEL : 150 mg/kg
Application Route : Intravenous
Target Organs : Kidney

according to the OSHA Hazard Communication Standard



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Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Imipenem:

Inhalation Symptoms: Nausea, Vomiting, Diarrhea, Fever, hypotension,

Dizziness, Drowsiness, Convulsions, pruritis, Rash

Remarks: May cause sensitization of susceptible persons by

inhalation of aerosol or dust.

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

Cilastatin:

Toxicity to fish LC50 (Pimephales promelas (fathead minnow)): > 111 mg/l

Exposure time: 96 h

Method: OECD Test Guideline 203

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Daphnia magna (Water flea)): > 99 mg/l

Exposure time: 48 h

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae): > 99 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 99

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae): 99 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 99

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

EC10 (Pimephales promelas (fathead minnow)): > 9.9 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

EC10 (Daphnia magna (Water flea)): > 10 mg/l

Exposure time: 21 d

Method: OECD Test Guideline 211

according to the OSHA Hazard Communication Standard



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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

Method: OECD Test Guideline 202

Toxicity to algae/aquatic

plants

EC50 (Anabaena flos-aquae (cyanobacterium)): 0.0046 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Anabaena flos-aquae (cyanobacterium)): 0.002 mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

EC50 (Pseudokirchneriella subcapitata (green algae)): > 74

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

NOEC (Pseudokirchneriella subcapitata (green algae)): 74

mg/l

Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to fish (Chronic tox-

icity)

NOEC (Pimephales promelas (fathead minnow)): 9.4 mg/l

Exposure time: 32 d

Method: OECD Test Guideline 210

Toxicity to daphnia and other :

aquatic invertebrates (Chron-

ic toxicity)

NOEC (Daphnia magna (Water flea)): 11 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

Persistence and degradability

Components:

Cilastatin:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 27 % Exposure time: 28 d

Method: OECD Test Guideline 301B

according to the OSHA Hazard Communication Standard



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Imipenem:

Biodegradability : Result: Not readily biodegradable.

Biodegradation: 29 % Exposure time: 28 d

Method: OECD Test Guideline 301B

Bioaccumulative potential

Components:

Cilastatin:

Partition coefficient: n-

log Pow: -3.53

octanol/water Imipenem:

Partition coefficient: n-

log Pow: < -1

octanol/water

Mobility in soil Components:

Cilastatin:

Distribution among environ-

mental compartments

: log Koc: 2.3

Other adverse effects

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

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 Environmentally hazardous : yes

IATA-DGR

UN/ID No. : UN 3077

according to the OSHA Hazard Communication Standard



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Proper shipping name : Environmentally hazardous substance, solid, n.o.s.

(Imipenem)

956

Class : 9 Packing group : III

Labels : Miscellaneous

Packing instruction (cargo :

aircraft)

Packing instruction (passen- : 956

ger aircraft)

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.

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 : CL

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.

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.

SECTION 15. REGULATORY INFORMATION

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.

according to the OSHA Hazard Communication Standard



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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

Respiratory or skin sensitization

Reproductive toxicity

Serious eye damage or eye irritation

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.

US State Regulations

Pennsylvania Right To Know

 Cilastatin
 81129-83-1

 Imipenem
 74431-23-5

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

AICS : not determined

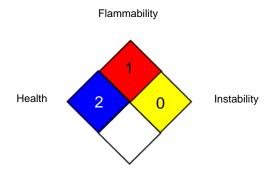
DSL : not determined

IECSC : not determined

SECTION 16. OTHER INFORMATION

Further information

NFPA 704:



Special hazard

HMIS® IV:



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

CAL PEL : California permissible exposure limits for chemical contami-

according to the OSHA Hazard Communication Standard



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nants (Title 8, Article 107)

OSHA Z-3 USA. Occupational Exposure Limits (OSHA) - Table Z-3 Min-

eral Dusts

CAL PEL / PEL Permissible exposure limit OSHA Z-3 / TWA 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; 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 substance; 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; 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

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 Agen-

cy, http://echa.europa.eu/

Revision Date 09/28/2024

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 quidance 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

according to the OSHA Hazard Communication Standard



Imipenem / Cilastatin Formulation

Version Revision Date: SDS Number: Date of last issue: 09/26/2023 11.3 09/28/2024 15845-00029 Date of first issue: 11/05/2014

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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