

SAFETY DATA SHEETS

This SDS packet was issued with item:

078909258

N/A



MATERIAL SAFETY DATA SHEET

Product Name: Meropenem for Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418

Hospira, Inc., Non-Emergency 224-212-2000

Product Name Meropenem for Injection

Synonyms (4R,5S,6S)-3-[[[(3S,5S)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1R)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid trihydrate

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Meropenem Trihydrate

Chemical Formula C₁₇H₂₅N₃O₅S•3H₂O

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Meropenem Trihydrate	91	119478-56-7	CL5446507
Sodium Carbonate	8	497-19-8	VZ4050000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Meropenem Trihydrate	Not Listed	Not Listed	Not Listed
Sodium Carbonate	Not Listed	Not Listed	Not Listed

Emergency Overview Meropenem for Injection is a powder containing meropenem, a carbapenem beta-lactam antibacterial with actions and uses similar to those of imipenem. Clinically, it is used to treat infections caused by susceptible Gram-positive and Gram-negative bacteria. In the workplace, this material should be considered potentially irritating to the skin, eyes and respiratory tract, and a potential sensitizer which may induce allergic reactions in persons known to be sensitized to penicillins and cephalosporins. Based on clinical use, possible target organs include the gastrointestinal system, central nervous system, skin, hematopoietic system, and liver.

Occupational Exposure Potential Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact.

Signs and Symptoms None known from occupational exposure. In clinical use, the most common adverse effects of meropenem include headache, nausea, diarrhea, vomiting, rash, seizures, pruritus, urticaria, thrombocytosis, abdominal pain, and elevated liver enzymes. Some patients with a history of penicillin hypersensitivity have experienced severe hypersensitivity reactions when treated with

Product Name: Meropenem for Injection



another beta-lactam antibiotic.

Medical Conditions Aggravated by Exposure Pre-existing hypersensitivity to meropenem; penicillins, cephalosporins or other lactam-like antibiotics; pre-existing gastrointestinal, skin, hematopoietic, or liver ailments.

4. FIRST AID MEASURES

Eye contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability	None anticipated. However, many organic powders will combust at high temperatures.
Fire & Explosion Hazard	None anticipated. Avoid the creation of dusty environments.
Extinguishing media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	For spilled powder, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Absorb any liquid with an inert absorbent material (e.g. absorbent pad). Dispose of materials according to the applicable federal, state, or local regulations. If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.
-----------------------------------	---

7. HANDLING AND STORAGE

Handling	No special handling required under conditions of normal product use.
Storage	No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.
Special Precautions	No special precautions are required for hazard controls. Employees with known allergies to penicillin and cephalosporin antibiotics should consult a

Product Name: Meropenem for Injection



health and/or safety professional prior to working with open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Type	Exposure limits			Note
		mg/m ³	ppm	µg/m ³	
Sodium Carbonate	Not Applicable	N/A	N/A	N/A	None Established
Meropenem Trihydrate	Not Applicable	N/A	N/A	N/A	None Established

Respiratory protection Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Solid
Color	White to pale yellow crystalline powder.
Odor	NA
Odor Threshold:	NA
pH:	7.3 - 8.3 for freshly constituted aqueous solutions
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	NA
Solubility:	Soluble in water
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined.
Conditions to avoid	Strong oxidizers and strong bases.
Incompatibilities	Not determine.
Hazardous decomposition products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), or sulfur oxides (SOx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Meropenem Trihydrate	100	LD50	Oral	NA	NA	NA
Meropenem	100	LD50	Oral	>5000	mg/kg	Rat, Mouse
Meropenem	100	LD50	Intravenous	2850 2650	mg/kg mg/kg	Rat Mouse
Sodium Carbonate	100	LD50	Oral	4090 6600	mg/kg mg/kg	Rat Mouse

Aspiration Hazard	None anticipated from normal handling of the intact product.
Dermal Irritation/Corrosion	None anticipated from normal handling of the intact product. However, inadvertent contact with this product formulation may be irritating to mucous membranes and the respiratory system.
Ocular Irritation/Corrosion	None anticipated from normal handling of the intact product. However, inadvertent contact of this product formulation with eyes may produce irritation with redness and discomfort.
Dermal or Respiratory Sensitization	None anticipated from normal handling of the intact product. The active ingredient in this product is a potential sensitizer and may induce allergic reactions in persons known to be sensitized to penicillins and cephalosporins. If known to be allergic to penicillins or cephalosporins, consult a health or safety professional prior to handling open containers of this product.
Reproductive Effects	Reproductive studies conducted with meropenem in rats at dosages up to 750 mg/kg/day, and cynomolgus monkeys at dosages of up to 360 mg/kg/day. These studies revealed no evidence of impaired fertility or harm to the fetus due to meropenem, although there were slight changes in fetal body weight at dosages of 250 mg/kg/day. There was increased evidence of abortions at 500 mg/kg in a preliminary study in monkeys.

Product Name: Meropenem for Injection



Mutagenicity	Genetic toxicity studies were performed with meropenem using the bacterial reverse mutation test, the Chinese hamster ovary HGPRT assay, cultured human lymphocytes cytogenic assay, and the mouse micronucleus test. There was no evidence of mutagenic potential found in any of these tests.
Carcinogenicity	The carcinogenic potential of meropenem has not been evaluated.
Target Organ Effects	Based on clinical use, possible target organs include the gastrointestinal system, central nervous system, skin, hematopoietic system, and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product. Information for ingredients is as follows: LC50 = 320 mg/L; 96 Hr.; static Conditions, for Bluegill/Sunfish for sodium carbonate
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Disposal should be performed in accordance with federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:	Not regulated
IMDG STATUS:	Not regulated
ICAO/IATA STATUS:	Not regulated
Transport Comments:	None

15. REGULATORY INFORMATION

USA Regulations

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Meropenem Trihydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Carbonate	Listed	Not Listed	Not Listed	Not Listed	Not Listed

RCRA Status	Not Listed
U.S. OSHA Classification	Possible Sensitizer Target Organ Toxin Possible Irritant

Product Name: Meropenem for Injection

GHS Classification *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class Not Applicable

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not Applicable

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Meropenem Trihydrate

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: R00 - Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:

- ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
- CAS Chemical Abstracts Service Number
- CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
- DOT US Department of Transportation Regulations
- EEL Employee Exposure Limit
- IATA International Air Transport Association
- LD50 Dosage producing 50% mortality
- NA Not applicable/Not available
- NE Not established
- NIOSH National Institute for Occupational Safety and Health
- OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
- Prop 65 California Proposition 65
- RCRA US EPA, Resource Conservation and Recovery Act
- RTECS Registry of Toxic Effects of Chemical Substances
- SARA Superfund Amendments and Reauthorization Act
- STEL 15-minute Short Term Exposure Limit



Product Name: Meropenem for Injection

TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS

Date Prepared: 10/19/2012

Obsolete Date: 10/18/2011

Disclaimer:

The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.



MATERIAL SAFETY DATA SHEET

Product Name: Meropenem for Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418

Hospira, Inc., Non-Emergency 224-212-2000

Product Name Meropenem for Injection

Synonyms (4R,5S,6S)-3-[[[(3S,5S)-5-(Dimethylcarbamoyl)-3-pyrrolidinyl]thio]-6-[(1R)-1-hydroxyethyl]-4-methyl-7-oxo-1-azabicyclo[3.2.0]hept-2-ene-2-carboxylic acid trihydrate

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Meropenem Trihydrate

Chemical Formula C₁₇H₂₅N₃O₅S•3H₂O

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Meropenem Trihydrate	91	119478-56-7	CL5446507
Sodium Carbonate	8	497-19-8	VZ4050000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Meropenem Trihydrate	Not Listed	Not Listed	Not Listed
Sodium Carbonate	Not Listed	Not Listed	Not Listed

Emergency Overview Meropenem for Injection is a powder containing meropenem, a carbapenem beta-lactam antibacterial with actions and uses similar to those of imipenem. Clinically, it is used to treat infections caused by susceptible Gram-positive and Gram-negative bacteria. In the workplace, this material should be considered potentially irritating to the skin, eyes and respiratory tract, and a potential sensitizer which may induce allergic reactions in persons known to be sensitized to penicillins and cephalosporins. Based on clinical use, possible target organs include the gastrointestinal system, central nervous system, skin, hematopoietic system, and liver.

Occupational Exposure Potential Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact.

Signs and Symptoms None known from occupational exposure. In clinical use, the most common adverse effects of meropenem include headache, nausea, diarrhea, vomiting, rash, seizures, pruritus, urticaria, thrombocytosis, abdominal pain, and elevated liver enzymes. Some patients with a history of penicillin hypersensitivity have experienced severe hypersensitivity reactions when treated with

Product Name: Meropenem for Injection



another beta-lactam antibiotic.

Medical Conditions Aggravated by Exposure Pre-existing hypersensitivity to meropenem; penicillins, cephalosporins or other lactam-like antibiotics; pre-existing gastrointestinal, skin, hematopoietic, or liver ailments.

4. FIRST AID MEASURES

Eye contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability None anticipated. However, many organic powders will combust at high temperatures.

Fire & Explosion Hazard None anticipated. Avoid the creation of dusty environments.

Extinguishing media As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal For spilled powder, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Absorb any liquid with an inert absorbent material (e.g. absorbent pad). Dispose of materials according to the applicable federal, state, or local regulations. If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling No special handling required under conditions of normal product use.

Storage No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions No special precautions are required for hazard controls. Employees with known allergies to penicillin and cephalosporin antibiotics should consult a

Product Name: Meropenem for Injection



health and/or safety professional prior to working with open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Type	Exposure limits			Note
		mg/m ³	ppm	µg/m ³	
Sodium Carbonate	Not Applicable	N/A	N/A	N/A	None Established
Meropenem Trihydrate	Not Applicable	N/A	N/A	N/A	None Established

Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Solid
Color	White to pale yellow crystalline powder.
Odor	NA
Odor Threshold:	NA
pH:	7.3 - 8.3 for freshly constituted aqueous solutions
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	NA
Solubility:	Soluble in water
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined.
Conditions to avoid	Strong oxidizers and strong bases.
Incompatibilities	Not determine.
Hazardous decomposition products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), or sulfur oxides (SOx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Meropenem Trihydrate	100	LD50	Oral	NA	NA	NA
Meropenem	100	LD50	Oral	>5000	mg/kg	Rat, Mouse
Meropenem	100	LD50	Intravenous	2850 2650	mg/kg mg/kg	Rat Mouse
Sodium Carbonate	100	LD50	Oral	4090 6600	mg/kg mg/kg	Rat Mouse

Aspiration Hazard	None anticipated from normal handling of the intact product.
Dermal Irritation/Corrosion	None anticipated from normal handling of the intact product. However, inadvertent contact with this product formulation may be irritating to mucous membranes and the respiratory system.
Ocular Irritation/Corrosion	None anticipated from normal handling of the intact product. However, inadvertent contact of this product formulation with eyes may produce irritation with redness and discomfort.
Dermal or Respiratory Sensitization	None anticipated from normal handling of the intact product. The active ingredient in this product is a potential sensitizer and may induce allergic reactions in persons known to be sensitized to penicillins and cephalosporins. If known to be allergic to penicillins or cephalosporins, consult a health or safety professional prior to handling open containers of this product.
Reproductive Effects	Reproductive studies conducted with meropenem in rats at dosages up to 750 mg/kg/day, and cynomolgus monkeys at dosages of up to 360 mg/kg/day. These studies revealed no evidence of impaired fertility or harm to the fetus due to meropenem, although there were slight changes in fetal body weight at dosages of 250 mg/kg/day. There was increased evidence of abortions at 500 mg/kg in a preliminary study in monkeys.

Product Name: Meropenem for Injection



Mutagenicity	Genetic toxicity studies were performed with meropenem using the bacterial reverse mutation test, the Chinese hamster ovary HGPRT assay, cultured human lymphocytes cytogenic assay, and the mouse micronucleus test. There was no evidence of mutagenic potential found in any of these tests.
Carcinogenicity	The carcinogenic potential of meropenem has not been evaluated.
Target Organ Effects	Based on clinical use, possible target organs include the gastrointestinal system, central nervous system, skin, hematopoietic system, and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product. Information for ingredients is as follows: LC50 = 320 mg/L; 96 Hr.; static Conditions, for Bluegill/Sunfish for sodium carbonate
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Disposal should be performed in accordance with federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS:	Not regulated
IMDG STATUS:	Not regulated
ICAO/IATA STATUS:	Not regulated
Transport Comments:	None

15. REGULATORY INFORMATION

USA Regulations

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Meropenem Trihydrate	Not Listed	Not Listed	Not Listed	Not Listed	Not Listed
Sodium Carbonate	Listed	Not Listed	Not Listed	Not Listed	Not Listed

RCRA Status	Not Listed
U.S. OSHA Classification	Possible Sensitizer Target Organ Toxin Possible Irritant

Product Name: Meropenem for Injection

GHS Classification *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class Not Applicable

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not Applicable

Response: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Meropenem Trihydrate

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: R00 - Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and eyes.
S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:

- ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
- CAS Chemical Abstracts Service Number
- CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
- DOT US Department of Transportation Regulations
- EEL Employee Exposure Limit
- IATA International Air Transport Association
- LD50 Dosage producing 50% mortality
- NA Not applicable/Not available
- NE Not established
- NIOSH National Institute for Occupational Safety and Health
- OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
- Prop 65 California Proposition 65
- RCRA US EPA, Resource Conservation and Recovery Act
- RTECS Registry of Toxic Effects of Chemical Substances
- SARA Superfund Amendments and Reauthorization Act
- STEL 15-minute Short Term Exposure Limit



Product Name: Meropenem for Injection

TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS

Date Prepared: 10/19/2012

Obsolete Date: 10/18/2011

Disclaimer:

The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.