SAFETY DATA SHEETS

This SDS packet was issued with item:

078909241

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078544096

Hospira

MATERIAL SAFETY DATA SHEET

Product Name: Tazicef® (Ceftazidime for Injection, USP)

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Distributor Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone Hospira, Inc.	CHEMTREC: 800 424-9300 224 212-2055
Manufacturer Name And Address	Sandoz GmbH Biochemiestrasse. 10 A-6250 Kundl,/ Tirol Austria
Product Name	Tazicef ® (Ceftazidime for Injection, USP)
Synonyms	None

2. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Ceftazidime pentahydrate
Chemical Formula $C_{22}H_{32}N_6O_{12}S_2$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Ceftazidime pentahydrate	90	78439-06-2	NA
Sodium bicarbonate	10	144-55-8	NA

3. HAZARD INFORMATION

Emergency Overview	In clinical use, this material is used as an antibiotic to treat infection. May cause sensitization by inhalation and skin contact. Ceftazidime may cause severe allergic reactions.
Occupational Exposure Potential	Information on the absorption of this compound via ingestion, inhalation or skin contact is not available. Workplace overexposure may include symptoms of hypersensitivity such as rash, itching, difficulty breathing, nausea, or diarrhea.
Signs and Symptoms	Data on this class of compound (cephalosporins) suggest the following: allergic reaction, eye irritation, rash, itching, difficulty breathing, nausea, or anaphylactic shock.
Medical Conditions Aggravated by Exposure	Hypersensitivity to penicillin or cephalosporin compounds.

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:	Non-flammable
Fire & Explosion Hazard:	Powders dispersed in air and subjected to an ignition source could explode.
Extinguishing Media:	Use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	Collect spilled powder using techniques that minimize powder migration. 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.
Storage	No special storage required for hazard control. For product protection store at controlled room temperature of 20-25°C (68-77°F).
Special Precautions	No special precautions related to hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines	None established.
Respiratory Protection	Respiratory protection is not needed during normal product use. Should powder inhalation be an exposure risk use of an approved respirator would be prudent practice.
Skin Protection	If contact with unprotected skin is likely, glove use is prudent practice.
Eye Protection	Eye protection is not required during expected product use conditions but may be warranted if eye contact is likely.
Engineering Controls	Engineering controls are not needed during normal product use conditions.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	White to slight yellow powder
Odor	Not Determined
Boiling Point	Not Determined
Freezing Point	Not Determined
Vapor Pressure	Not Determined
Vapor Density (Air=1)	Not Applicable
Evaporation Rate	Not Applicable
Bulk Density	Not Determined
Specific Gravity	Not Determined
Solubility	Water: 30 g/l, 25 degrees C
pH	Not Determined

10. STABILITY AND REACTIVITY

Chemical Stability	Stable under standard use and storage conditions.
Incompatibilities	May react with strong oxidizing agents.
Hazardous Decomposition Products	May emit toxic smoke.
Hazardous Polymerization	Will not occur.

11. TOXICOLOGICAL INFORMATION:

Acute Toxicity – Oral:

Ingredient(s)	Percent	Test Type	Value	Units	Species
Ceftazidime	100	LD50	>2000	mg/kg	Rats

LD50 is dosage producing 50% mortality.
Product contains approximately 90% Ceftazidime.

Mutagenicity	Not mutagenic in bacterial or mammalian cells.
Reproductive Effects	No effects identified.

Target Organ Effects	Blood effects include decreased red blood cell count and increased white blood cell count. Other target organs include liver and kidneys.

12. ECOLOGICAL INFORMATION:

Aquatic Toxicity	Not Available

13. DISPOSAL CONSIDERATIONS:

Waste Disposal	Disposal should be performed in accordance with the 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

DOT	Not Regulated

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

TSCA Status	Not Regulated
CERCLA Status	Not Regulated
SARA Status	Not Regulated
RCRA Status	Not Regulated
PROP 65 (Calif.)	Not Regulated

Notes: TSCA Toxic Substance Control Act
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
SARA Superfund Amendments and Reauthorization Act
RCRA US EPA, Resource Conservation and Recovery Act
Prop 65, California Proposition 65

16. OTHER INFORMATION:

MSDS Coordinator	Global Occupational Toxicology
Date Prepared	September 15, 2005
Date Revised	October 21, 2008

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SAFETY DATA SHEET

Product Name: Tazicef® (Ceftazidime for Injection, USP)

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name(s) And Addresses	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Sandoz GmbH Biochemiestrasse. 10 A-6250 Kundl,/ Tirol Austria
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	Tazicef® (Ceftazidime for Injection, USP)	
Synonyms	Pentahydrate of pyridinium, 1-[[7-[[(2-amino-4-thiazolyl)[(1-carboxy-1-methylethoxy) imino] acetyl]amino]-2-carboxy-8-oxo-5-thia-1-azabicyclo(4.2.0.) oct-2-en-3-yl] methyl]-, hydroxide, inner salt, [6R-[6α,7β(Z)]].	

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Tazicef® (Ceftazidime for Injection, USP) is a powder containing ceftazidime, a semisynthetic, broad-spectrum, beta-lactam antibiotic for parenteral administration. 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, nervous system, skin, hematopoietic system, and liver.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Eye Damage/Irritation	2A
	Sensitization – Skin	1
	Sensitization – Respiratory	1
	STOT - RE	2

Label Element(s)

Pictogram

Signal Word

Danger

Hazard Statement(s)

Causes serious eye irritation
May cause an allergic skin reaction
May cause allergic or asthmatic symptoms or breathing difficulties if inhaled
May cause damage to organs through prolonged or repeated exposure.

2. HAZARD(S) IDENTIFICATION: continued

Precautionary Statement(s)

Prevention

Do not breathe dust/vapors/spray
In case of inadequate ventilation, wear respiratory protection
Wear protective gloves
Wear eye protection/face protection
Wash hands thoroughly after handling
Contaminated work clothing must not be allowed out of the workplace

Response

Get medical attention if you feel unwell.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

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.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Ceftazidime Pentahydrate

Chemical Formula $C_{22}H_{22}N_6O_7S_2 \bullet 5\ H_2O$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Ceftazidime Pentahydrate	88	78439-06-2	UU2230000
Sodium Carbonate	≤12	497-19-8	VZ4050000

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 for this product. However, many organic powders will combust at elevated temperatures.

Fire & Explosion Hazard

None anticipated for this product. Avoid the generation of dusty environments.

Extinguishing Media

As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

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 control 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 the spill occurs after reconstitution, absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling

No special handling required for hazard control 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 required for hazard control. Persons with known allergies to penicillin and cephalosporin antibiotics should consult a health and/or safety professional prior to handling open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Ceftazidime Pentahydrate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established
Sodium Carbonate	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

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	White to slight yellow powder
Odor	NA
Odor Threshold	NA
pH	The pH of freshly reconstituted solutions usually ranges from 5.0 to 7.5.
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	NA
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
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), and 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
Ceftazidime Pentahydrate	100	LD50	Intravenous	6100 6300	mg/kg mg/kg	Rat Mouse
Ceftazidime	100	LD50	Oral	>20000 >20000	mg/kg mg/kg	Rat Mouse
Ceftazidime	100	LD50	Intravenous	5800 6300 >2000	mg/kg mg/kg mg/kg	Rat Mouse Rabbit
Sodium Carbonate	100	LD50	Oral	4090 6600	mg/kg mg/kg	Rat Mouse

LD 50: Dosage that produces 50% mortality.

11. TOXICOLOGICAL INFORMATION: continued

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. In clinical use, adverse effects may include diarrhea, nausea, vomiting, abdominal pain, a metallic taste; adverse hematological effects have included eosinophilia, a positive Coombs' test without hemolysis, and thrombocytosis; hypersensitivity reactions have included pruritus, rash (maculopapular or erythematous), urticaria, photosensitivity, angioedema, and fever; adverse central nervous system reactions may include headache, dizziness and paresthesia. Seizures have been reported with several cephalosporins, including ceftazidime; transient increases in serum concentrations of AST (SGOT) and other liver enzymes may also occur; transient increases in BUN and/or serum creatinine concentrations and other renal effects have also been reported.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	None anticipated from normal handling of the intact product. However, inadvertent contact with this product formulation may be irritating to skin, and severely 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 severe irritation with redness and discomfort.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. However, the active ingredient in this product is a potential sensitizer and may induce allergic reactions in persons allergic 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	None anticipated from normal handling of this product. Reproduction studies have been performed in mice and rats at doses up to 40 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to ceftazidime.
Mutagenicity	However, a mouse micronucleus test and an Ames test were both negative for mutagenic effects.
Carcinogenicity	Long-term studies in animals have not been performed to evaluate carcinogenic potential.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs include the gastrointestinal system, nervous system, skin, hematopoietic system, and liver.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product. 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.

Notes:
1. LC50: Concentration in water that produces 50% mortality in fish.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the 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
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt. However, sodium carbonate is listed on the U.S. TSCA inventory.
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

15. REGULATORY INFORMATION: continued

GHS/CLP 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	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Do not breathe vapor or spray
Wash hands after handling

Response

Get medical attention if you feel unwell.

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.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s) NA
Symbol NA
Indication of Danger NA

Risk Phrases

R42/43 - May cause sensitization by inhalation and skin contact

Safety Phrases

S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with 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
LD_{50}	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

16. OTHER INFORMATION: continued

MSDS Coordinator: Hospira GEHS
Date Prepared: October 17, 2012
Date Revised: June 02, 2014

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