SAFETY DATA SHEETS

This SDS packet was issued with item:

078009689

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

078009697

SAFETY DATA SHEET

Product Name: Ciprofloxacin in 5% Dextrose Injection, USP

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
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	Ciprofloxacin in 5% Dextrose Injection, USP
Synonyms	1-cyclopropyl-6-fluoro-1, 4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid.

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Ciprofloxacin in 5% Dextrose Injection is a solution containing ciprofloxacin, a fluoroquinolone antibiotic. In clinical use, this material is used to treat susceptible infections. In the workplace, this material should be considered potentially irritating to mucus membranes, eyes, and respiratory system, and a possible sensitizer. Persons with known allergies to quinolone antibiotics should consult a health and/or safety professional prior to working with open containers of this material. Based on clinical use, possible target organs include the gastrointestinal system, nervous system, genitourinary system, liver, skin, cardiovascular system, hematological system, and musculoskeletal system.

U.S. OSHA GHS Classification

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

Health Hazards	**Hazard Class**	**Hazard Category**
	Sensitization – Skin	1
	Sensitization - Respiratory	1
	STOT – RE	2

Label Element(s)

Pictogram

Signal Word Danger

Hazard Statement(s)

May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
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
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 Ciprofloxacin
Chemical Formula $C_{17}H_{18}FN_3O_3$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Ciprofloxacin	0.2	85721-33-1	VB1993800

Non-hazardous ingredients include Water for Injection and dextrose. Hazardous ingredients present at less than 1% may include lactic acid; hydrochloric acid is added to adjust the pH.

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 aqueous product.

Fire & Explosion Hazard

None anticipated for this aqueous product.

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 Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. 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 quinolone 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**
Ciprofloxacin	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hour 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 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 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	A clear, colorless to slightly yellowish solution
Odor	NA
Odor Threshold	NA
pH	3.5 - 4.6
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	Soluble in dilute (0.1N) hydrochloric acid; practically insoluble in water and ethanol
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 hydrogen fluoride.
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Ciprofloxacin	100	LD50	Oral	> 2000 5000	mg/kg mg/kg	Rat Mouse
Ciprofloxacin	100	LD50	Intravenous	207 122	mg/kg mg/kg	Rat Mouse
Ciprofloxacin Hydrochloride	100	LD50	Oral	> 5000	mg/kg	Rat, Mouse, Monkey
Ciprofloxacin Hydrochloride	100	LD50	Intravenous	300 258	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 have included nausea, diarrhea, vomiting, headache, dizziness, rashes, urticaria, eosinophilia, fever, chills, photo-sensitivity, nephritis, dysuria, increased serum creatinine, increased serum enzymes, joint pain and inflammation, stiffness, arthropathy, leukopenia, altered platelet counts, pancytopenia, anemia, palpitation, hypertension, and angina. During therapy with quinolones, a moderate to severe phototoxicity, characterized by an exaggerated sunburn reaction, may occur following exposure to sunlight.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/Corrosion	None anticipated from normal handling of this product.
Ocular Irritation/Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation and redness.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. During clinical use, serious and sometimes fatal anaphylactic reactions have been reported in some patients following first-time quinolone therapy.
Reproductive Effects	None anticipated from normal handling of this product. In fertility studies, no evidence of impairment was noted in rats given oral dosages up to 100 mg/kg. Reproduction studies conducted in rats and mice at oral dosages up to 100 mg/kg showed no evidence of harm to the fetus due to ciprofloxacin. In rabbits, oral ciprofloxacin at dosages of 30 and 100 mg/kg produced gastrointestinal toxicity, maternal weight loss and an increased incidence of abortion; no teratogenicity was noted at either dosage level. Intravenous administration at dosages up to 20 mg/kg was not associated with maternal toxicity, and no embryotoxicity or teratogenicity was observed.
Mutagenicity	Ciprofloxacin was negative in six and positive in two *in vitro* assays for mutagenicity including the Salmonella/Microsome Test (Negative); the *E. coli* DNA Repair Assay (Negative); the Mouse Lymphoma Cell Forward Mutation Assay (Positive); the Chinese Hamster V_{79} Cell HGPRT Test (Negative); the Syrian Hamster Embryo Cell Transformation Assay (Negative); the *Saccharomyces cerevisiae* Point Mutation Assay (Negative); the *Saccharomyces cerevisiae* Mitotic Crossover and Gene Conversion Assay (Negative); and the Rat Hepatocyte DNA Repair Assay (Positive). Ciprofloxacin was negative in three *in vivo* test systems including the Rat Hepatocyte DNA Repair Assay; the Mouse Micronucleus Test, and a Dominant Lethal Test in mice.
Carcinogenicity	Long-term studies in rats and mice indicated no carcinogenic or tumorigenic effects due to ciprofloxacin following daily oral dosages up to 250 and 750 mg/kg to rats and mice, respectively. Results from photo co-carcinogenicity testing indicate that ciprofloxacin does not reduce the time to appearance of UV-induced skin tumors as compared to vehicle control.
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, genitourinary system, liver, skin, cardiovascular system,

hematological system, and musculoskeletal system.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product. Information for ciprofloxacin, an ingredient in this product, is provided below: EC50 = 0.61 mg/L in bacteria (activated sludge) EC50 = 2.97 mg/L in S. capricornutum (green algae, eukaryote) EC50 = 0.005 mg/L in M. aeruginosa (cyanobacteria, prokaryote) NOEC = 60 mg/L in Daphnia magna (48 hour) NOEC = 100 mg/L in B. Rerio (72 hour) (Zebrafish)
Persistence/Biodegradability	Not determined for product. Information for ciprofloxacin, an ingredient in this product, is provided below: Not readily degradable in a biodegradation assay.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

Notes:
1. NOEC = no-observed-effect-concentration
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EC50: Concentration in water that produces 50% inhibition of growth in algae.

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	Regulated, if shipment of single or inner packagings are >5L liquids, or >5KG of solids.
Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s. (Ciprofloxacin)
Hazard Class	9
UN Number	UN3802
Packing Group	III
Reportable Quantity	NA
ICAO/IATA STATUS	Regulated, if shipment of single or inner packagings are >5L liquids, or >5KG of solids.
Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s. (Ciprofloxacin)
Hazard Class	9
UN Number	UN3802
Packing Group	III
Reportable Quantity	NA
IMDG STATUS	Regulated, if shipment of single or inner packagings are >5L liquids, or >5KG of solids.
Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s. (Ciprofloxacin)
Hazard Class	9
UN Number	UN3802
Packing Group	III
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations
Transport Comments: Shipments of single or inner packagings of < or = 5L liquids, or < or = 5KG solids are not regulated as long as the general packaging provisions are met.

Product Name: Ciprofloxacin in 5% Dextrose Injection, USP

15. REGULATORY INFORMATION

US TSCA Status	Exempt
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

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 dust/vapors/spray.
In case of inadequate ventilation, wear respiratory protection.
Wear protective gloves.
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.

Collect spillage. Avoid release into the environment.

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 S61: Avoid release into the environment.

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

MSDS Coordinator: Hospira GEHS
Date Prepared: June 6, 2014
Date Revised January 5, 2015

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