

Revision date 16-Jun-2025 Version 3 Page 1/14

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira Inc.)

Product Code(s)
PZ03139
Trade Name:
Not applicable
Fluoroquinolone

1.2. Relevant identified uses of the substance or mixture and uses advised against

Recommended Use Pharmaceutical product used as antibiotic agent

1.3. Details of the supplier of the safety data sheet

Hospira, A Pfizer Company 275 North Field Drive Lake Forest, Illinois 60045 1-800-879-3477 Pfizer Ireland Pharmaceuticals

OSG Building

Ringaskiddy, Co. Cork.

Ireland

+353 21 4378701

E-mail address pfizer-MSDS@pfizer.com

1.4. Emergency telephone number

Emergency Telephone Chemtrec 1-800-424-9300 International Chemtrec (24 hours):+1-703-527-3887

Section 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Not classified as hazardous.

OSHA Classification

Hazards not otherwise classified (HNOC)

Not applicable

Hazards classified under paragraph (d)(1)(ii) of 1910.1200

Not applicable

2.2. Label elements

Signal word Not classified

Hazard statements Not classified in accordance with international standards for workplace safety.

2.3. Other hazards

Other hazards

An Occupational Exposure Value has been established for one or more of the ingredients

(see Section 8).

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Revision date 16-Jun-2025 Version 3

PBT & vPvB The product does not contain any substance(s) classified as PBT or vPvB.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors.

Note: This document has been prepared in accordance with standards for workplace safety, which

require the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

Specific

M-Factor

Page 2/14

M-Factor

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

REACH

3.1 Substances

Chemical name

Substances Not applicable

Weight-%

3.2 Mixtures

Hazardous

			(
		registration	Index No)	according to	concentration		(long-term)
		number		Regulation	limit (SCL)		
				(EC) No.			
				1272/2008			
				[CLP]			
Ciprofloxacin	< 1		Not Listed	Aquatic Acute	Not classified	No data	No data
(CAS #:				2 (H401)		available	available
85721-33-1)				Aquatic chronic	;		
				2 (H411)			
Lactic acid	< 1		200-018-0	Eye Dam. 1	Not classified	No data	No data
(CAS #: 50-21-5)				(H318)		available	available
				Skin Irrit. 2			
				(H315)			
+ Hydrochloric Acid	**	-	231-595-7	Press. Gas	Eye Irrit. 2 ::	No data	No data
(CAS #: 7647-01-0)			(017-002-00-2)	Skin Corr. 1A	10%<=C<25%	available	available
			(017-002-01-X)	, ,	Skin Corr. 1B ::		
				Acute Tox. 3	C>=25%		
				(H331)	Skin Irrit. 2 ::		
					10%<=C<25%		
					STOT SE 3 ::		
					C>=10%		
NonHazardous		T		_	,		
Chemical name	Weight-%	REACH	EC No (EU	Classification	Specific	M-Factor	M-Factor
		registration	Index No)	according to	concentration		(long-term)

EC No (EU Classification

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Water (CAS #: 7732-18-5)	*	-	231-791-2	Not classified	Not classified	No data available	No data available
Dextrose (CAS #: 14431-43-7)	*		Not Listed	Not classified	Not classified	No data available	No data available

Full text of H- and EUH-phrases: see section 16

Page 3/14

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Revision date 16-Jun-2025 Version 3

Acute Toxicity Estimate No information available

Chemical name	Oral LD50 mg/kg		Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Water 7732-18-5	89838.9	No data available	No data available	No data available	No data available
Ciprofloxacin 85721-33-1	2000	No data available	No data available	No data available	No data available
Lactic acid 50-21-5	3543	2000	7.94	No data available	No data available
+ Hydrochloric Acid 7647-01-0	238	5010	No data available	No data available	563.3022

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

Additional information

- * Proprietary
- ** to adjust pH

In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret. Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. Non-hazardous ingredients provided for completeness.

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

Inhalation Remove to fresh air. Seek immediate medical attention/advice.

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

Skin contact Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek

medical attention.

Ingestion Never give anything by mouth to an unconscious person. Wash out mouth with water. Do

not induce vomiting unless directed by medical personnel. Seek medical attention

immediately.

4.2. Most important symptoms and effects, both acute and delayed

Most important symptoms and

effects

For information on potential signs and symptoms of exposure, See Section 2 - Hazards

Identification and/or Section 11 - Toxicological Information.

4.3. Indication of any immediate medical attention and special treatment needed

Note to physicians None.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

⁺ Substance with a Union workplace exposure limit

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Revision date 16-Jun-2025 Version 3

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

Fine particles (such as mists) may fuel fires/explosions.

chemical

Hazardous combustion products Formation of toxic gases is possible during heating or fire.

Explosion data

Sensitivity to mechanical impact No information available. **Sensitivity to static discharge** No information available.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Page 4 / 14

Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Personnel involved in clean-up should wear appropriate personal protective equipment (see

Section 8). Minimize exposure.

6.2. Environmental precautions

Environmental precautions Place waste in an appropriately labeled, sealed container for disposal. Care should be

taken to avoid environmental release.

6.3. Methods and material for containment and cleaning up

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean

spill area thoroughly.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

Reference to other sections See section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling

Avoid breathing dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors,

HEPA filtration systems or other equivalent controls.

General hygiene considerations Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Store as directed by product packaging.

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Revision date 16-Jun-2025 Version 3

7.3. Specific end use(s)

Specific use(s) Pharmaceutical product used as. antibiotic agent.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits

Refer to available public information for specific member state Occupational Exposure Limits.

Ciprofloxacin

Pfizer OEL TWA-8 Hr: 600 µg/m³

Ciprofloxacin

Germany TRGS DS RS

+ Hydrochloric Acid

ACGIH OEL (Ceiling) 2 ppm

ACGIH TLV Ceiling: 2 ppm TWA-TMW: 5 ppm; Austria

TWA-TMW: 8 mg/m³; STEL-KZGW: 10 ppm (8 X 5 min);

STEL-KZGW: 15 mg/m3 (8 X 5 min); Bulgaria TWA: 5 ppm;

TWA: 8.0 mg/m³; STEL: 10 ppm;

STEL: 15.0 mg/m³; Czech Republic

8 mg/m³

Ceiling: 15 mg/m³ Denmark

STEL: 5 ppm;

STEL: 8 mg/m3; Estonia TWA: 5 ppm;

TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;

European Union TWA: 5 ppm;

TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³; STEL: 5 ppm;

STEL: 7.6 mg/m³; Germany DFG TWA-MAK: 2 ppm; I(2);

TWA-MAK: 3.0 mg/m³; I(2);

Peak: 4 ppm; Peak: 6 mg/m3;

Germany TRGS TWA-AGW; 2 ppm (exposure factor 2);

TWA-AGW; 3 mg/m³ (exposure factor 2);

TWA-AK: 8 mg/m³; Hungary

TWA-AK: 5 ppm; STEL-CK: 165 mg/m³; STEL-CK: 10 ppm;

Ireland TWA: 8 mg/m³;

TWA: 5 ppm; STEL: 10 ppm; STEL: 15 mg/m3; TWA: 5 ppm;

Italy MDLPS

Finland

PZ03139

Page 5/14

Page 6/14

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Revision date 16-Jun-2025 Version 3

TWA: 8 mg/m³; STEL: 10 ppm; STEL: 15 mg/m³;

Ceiling Limit Value 2 ppm 3.0 mg/m³

Latvia TWA: 5 ppm;
TWA: 8 mg/m³;
STEL: 10 ppm;

STEL: 15 mg/m³;
Netherlands TWA: 5 ppm;
TWA: 8 mg/m³;
STEL: 10 ppm;

STEL: 15 mg/m³;
Poland TWA-NDS: 5 mg/m³;
STEL-NDSCh: 10 mg/m³;

Romania TWA: 5 ppm;

TWA: 8 mg/m³;
STEL: 10 ppm;
STEL: 15 mg/m³;
Russia
MAC: 5 mg/m³
Slovakia
TWA: 5 ppm;

TWA: 8.0 mg/m³;
Ceiling: 15 mg/m³;
Spain
TWA-(VLA-ED): 5 ppm;

TWA-(VLA-ED): 7.6 mg/m³; STEL (VLA-EC): 10 ppm; STEL (VLA-EC): 15 mg/m³;

Switzerland TWA-MAK: 2 ppm; TWA-MAK: 3 mg/m³;

STEL-KZGW: 4 ppm; STEL-KZGW: 6 mg/m³;

U.S. - OSHA - Final PELs - Ceiling Limits 5 ppm 7 mg/m³

OSHA PEL Ceiling: 5 ppm
Ceiling: 7 mg/m³

(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m³

United Kingdom TWA: 1 ppm; gas and aerosol mist

TWA: 2 mg/m³; gas and aerosol mist STEL: 5 ppm; gas and aerosol mist STEL: 8 mg/m³; gas and aerosol mist

8.2. Exposure controls

Engineering controls Engineering controls should be used as the primary means to control exposures. General

room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal protective equipment Refer to applicable national standards and regulations in the selection and use of personal

protective equipment (PPE).

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Hand protection

Revision date 16-Jun-2025 Version 3

Eye/face protection Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the

standards in accordance with EN166, ANSI Z87.1 or international equivalent.).

Impervious gloves (e.g. Nitrile, etc.) are recommended if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in

Page 7/14

accordance with EN374, ASTM F1001 or international equivalent.).

Impervious protective clothing is recommended if skin contact with drug product is possible Skin and body protection

and for bulk processing operations. (Protective clothing must meet the standards in

accordance with EN13982, ANSI 103 or international equivalent.).

Under normal conditions of use, if the applicable Occupational Exposure Limit (OEL) is Respiratory protection

exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL (e.g. particulate respirator with a half mask, P3 filter).

(Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10

or international equivalent.).

Thermal hazards No information available.

Environmental exposure controls No information available.

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Solution **Appearance** Physical state Liquid

Color Clear, colorless to pale yellow Odor No information available. Odor threshold No information available

Values

Property No data available Melting point / freezing point Boiling point or initial boiling point and boiling range No data available No data available Flammability (solid, gas)

Lower and upper explosion limit/flammability limit

Lower explosion limit No data available Upper explosion limit No data available Flash point No data available **Autoignition temperature** No data available

Decomposition temperature

SADT (°C) No data available

3.5 - 4.6

No data available pH (as aqueous solution) No data available Kinematic viscosity No data available Dynamic viscosity Solubility Soluble Water Vapor pressure No data available Density and/or relative density No data available **Bulk density** No data available

Liquid Density No data available Vapor density No data available

Particle characteristics

Particle Size No information available **Particle Size Distribution** No information available

Page 8/14

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Revision date 16-Jun-2025 Version 3

Partition Coefficient: (Method, pH, Endpoint, Value)

Ciprofloxacin

Predicted 7.4 Log D -0.291

9.2. Other information

Molecular formulaMixtureMolecular weightMixture

9.2.1. Information with regard to physical hazard classes

No information available

9.2.2. Other safety characteristics

No information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal conditions.

Explosion data

Sensitivity to mechanical impact No information available. **Sensitivity to static discharge** No information available.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions No information available.

10.4. Conditions to avoid

Conditions to avoid Fine particles (such as dust and mists) may fuel fires/explosions.

10.5. Incompatible materials

Incompatible materials As a precautionary measure, keep away from strong oxidizers.

10.6. Hazardous decomposition products

Hazardous decomposition products No data available.

Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

General Information: The information included in this section describes the potential hazards of the individual

ingredients

Short term Accidental ingestion may cause effects similar to those seen in clinical use.

Known Clinical Effects: Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have

occurred as late as several months after quinolone treatment. The most common adverse reactions associated with the use of quinolones include gastrointestinal distress, such as nausea or diarrhea, and central nervous system (CNS) effects, including insomnia, dizziness, and seizures. Convulsion, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones. The most common adverse effects seen during clinical use of this drug include nausea, diarrhea, vomiting, abnormal liver function tests, increased eosinophils in blood or tissue (eosinophilia), headache,

restlessness.

Acute toxicity

Serious eye damage/eye irritation

Skin corrosion/irritation

Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met.

Page 9/14

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Revision date 16-Jun-2025 Version 3

Respiratory or skin sensitization
STOT - single exposure
STOT - repeated exposure
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.
Based on available data, the classification criteria are not met.

Acute Toxicity: (Species, Route, End Point, Dose)

Ciprofloxacin

Rat Oral LD50 > 2000 mg/kg Rat IV LD 50 207 mg/kg

Lactic acid

Rat Oral LD50 3543 mg/kg

Rabbit Dermal LD50 > 2000 mg/kg

L	Chemical name	Oral LD50	Dermal LD50	Inhalation LC50
	Water	> 90 mL/kg (Rat)	-	-
	Ciprofloxacin	> 2 g/kg (Rat)	-	-
	Lactic acid	= 3543 mg/kg (Rat)	> 2000 mg/kg (Rabbit)	> 7.94 mg/L (Rat)4 h
Ī	+ Hydrochloric Acid	238 - 277 mg/kg (Rat)	> 5010 mg/kg (Rabbit)	= 1.68 mg/L (Rat) 1 h

Acute Toxicity Comments:

A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Lactic acid

Eye Irritation Rabbit Severe

Skin Irritation Rabbit Moderate Severe

<u>+ Hydrochloric Acid</u> Skin irritation Severe Eye irritation Severe

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ) Ciprofloxacin

6 Month(s) Rat Oral 500 mg/kg/day NOAEL None identified

6 Month(s) Dog Oral 30 mg/kg/day NOAEL None identified

6 Month(s) Monkey Intravenous 10 mg/kg/day NOAEL Kidney

3 Month(s) Monkey Oral 45 mg/kg/day NOAEL None identified

Reproduction & Development Toxicity: (Duration, Species, Route, Dose, End Point, Effect(s)) Ciprofloxacin

Reproductive & Fertility Rat Oral 100 mg/kg/day NOAEL No effects at maximum dose

Reproductive & Fertility Rabbit Oral 35 mg/kg/day LOAEL Maternal Toxicity, Not Teratogenic

Embryo / Fetal Development Rat Oral 100 mg/kg/day NOAEL No effects at maximum dose

Peri-/Postnatal Development Rat Subcutaneous 30 mg/kg/day NOAEL No effects at maximum dose

Lactic acid

Reproductive & Fertility Rat Oral 6.25 mg/kg/day NOEL Fertility, Not teratogenic

Genetic Toxicity: (Study Type, Cell Type/Organism, Result) Ciprofloxacin

In Vitro Bacterial Mutagenicity (Ames) Salmonella, E. coli

Negative

In Vitro Cell Transformation Assay Hamster Negative

In Vitro Forward Mutation Assay Mouse Lymphoma Positive

Page 10 / 14

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Revision date 16-Jun-2025 Version 3

In Vivo Micronucleus Mouse Negative

In Vivo Dominant Lethal Assay Mouse Negative

+ Hydrochloric Acid

Bacterial Mutagenicity (Ames) Salmonella

Negative

In Vivo Micronucleus Rat Negative

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Ciprofloxacin

2 Year(s) Rat; Mouse No route specified Not carcinogenic

Carcinogenicity None of the components of this formulation are listed as a carcinogen by IARC, NTP or

OSHA.

+ Hydrochloric Acid

IARC Group 3

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

Section 12: ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should

be avoided.

12.1. Toxicity

Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

Ciprofloxacin

Pseudokirchneriella subcapitata (Green Alga) OECD EC50 96 hours 4.83 mg/L

Brachydanio rerio (Zebra fish) OECD EC50 72 > 100 mg/L Daphnia Magna (Water Flea) OECD EC50 48 hours 65.3 mg/L

Chronic Aquatic Toxicity: (Species, Method, Duration, Endpoint, Result, Adverse Endpoint)

Ciprofloxacin

Lemna minor (Common Duckweed) OECD 7 Day(s) EC50 3.75 mg/L Growth

12.2. Persistence and degradability

Persistence and degradability

Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)

Ciprofloxacin

OECD Activated sludge Ready 0 % After 28 Day(s) Not Ready

12.3. Bioaccumulative potential

Bioaccumulation

Partition Coefficient: (Method, pH, Endpoint, Value)

Ciprofloxacin

Predicted 7.4 Log D -0.291

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Revision date 16-Jun-2025 Version 3

Page 11/14

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessmentBased on available data, the classification criteria are not met.

Chemical name	PBT and vPvB assessment		
Lactic acid	Not PBT/vPvB		
+ Hydrochloric Acid	Not PBT/vPvB PBT assessment does not apply		

12.6. Endocrine disrupting properties

Endocrine disrupting properties Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

PMT or vPvM propertiesBased on available data, the classification criteria are not met.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste from residues/unused products

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

UN number:
UN proper shipping name:
Transport hazard class(es):
Packing group:
Environmental Hazard(s):
Not applicable
Not applicable
Not applicable

Section 15: REGULATORY INFORMATION

Page 12 / 14

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira Inc.)

Revision date 16-Jun-2025 Version 3

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

١	٨/	'n	t۵	r

Not Listed CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Present **TSCA EINECS** 231-791-2 **AICS** Present

Dextrose

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed **EINECS** Not Listed **AICS** Present

Ciprofloxacin

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed Not Listed **EINECS** Schedule 4 Standard for Uniform Scheduling of Medicines and

Poisons (SUSMP)

Lactic acid

CERCLA/SARA Section 313 de minimus % Not Listed **California Proposition 65** Not Listed Present **TSCA EINECS** 200-018-0 **AICS** Present

+ Hydrochloric Acid

CERCLA/SARA Section 313 de minimus % 1.0 % **Hazardous Substances RQs** 5000 lb **California Proposition 65** Not Listed **TSCA** Present **EINECS** 231-595-7 **AICS** Present Standard for Uniform Scheduling of Medicines and Schedule 5 Poisons (SUSMP) Schedule 6

National regulations

Chemical Prohibition Ordinance (ChemVerbotsV)

Not applicable

TRGS 905 Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable Storage of Hazardous Material Not applicable WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Not applicable **Major Accidents Ordinance SR 814.012** Not applicable

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This

Page 13 / 14

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Revision date 16-Jun-2025 Version 3

product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

		(* 1=* 10 1 1), * * * * * * * * * * * * * * * * * * *	
Chemical name Restricte		Restricted substance per REACH	Substance subject to authorization per
		Annex XVII	REACH Annex XIV
	+ Hydrochloric Acid	75	-
	7647-01-0		

Persistent Organic Pollutants

Not applicable

Chemical name	Lower-tier requirements (tons)	Upper-tier requirements (tons)
+ Hydrochloric Acid	25	250
7647-01-0		

Ozone-depleting substances (ODS) Regulation (EU) 2024/590

Not applicable.

Chemical name	Biocidal Products Regulation (EU) No 528/2012 (BPR)
Lactic acid	Simplified procedure - Category 1
50-21-5	
+ Hydrochloric Acid	Product-type 2: Disinfectants and algaecides not intended
7647-01-0	for direct application to humans or animals

Explosives Precursors Marketing and Use (2019/1148)

Not applicable

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

ENCS - Japan Existing and New Chemical Substances

IECSC - China Inventory of Existing Chemical Substances

KECL - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

NZIoC - New Zealand Inventory of Chemicals

TCSI - Taiwan Chemical Substance Inventory

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H331 - Toxic if inhaled H401 - Toxic to aquatic life H411 - Toxic to aquatic life with long lasting effects H318 - Causes serious eye damage H315 - Causes skin irritation H314 - Causes severe skin burns and eye damage

Product Name Ciprofloxacin in 5% Dextrose Injection, USP (Hospira

Inc.)

Revision date 16-Jun-2025 Version 3

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Reason for revision Updated Section 3 - Composition / Information on Ingredients. Updated Section 5 - Fire

Fighting Measures. Updated Section 6 - Accidental Release Measures. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 12

Page 14/14

- Ecological Information.

Revision date 16-Jun-2025

Prepared By Pfizer Global Environment, Health, and Safety

Pfizer Inc believes that the information contained in this Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.