SAFETY DATA SHEET

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
Chemical Family: 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

Hospira UK Limited
Horizon
Honey Lane
Hurley
Maidenhead, SL6 6RJ
United Kingdom

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

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).

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.

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Substances Not applicable

3.2 Mixtures

Hazardous

Chemical name	Weight-%	REACH Registration Number	EC No	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-term)
Ciprofloxacin (CAS #: 85721-33-1)	< 1		Not Listed	Aquatic Acute 2 (H401) Aquatic chronic 2 (H411)	Not Listed	No data available	No data available
Lactic acid (CAS #: 50-21-5)	< 1		200-018-0	Eye Dam. 1 (H318) Skin Irrit. 2 (H315)	Not Listed	No data available	No data available
+ Hydrochloric Acid (CAS #: 7647-01-0)	**	-	231-595-7	Acute Tox. 3 (H331) Skin Corr. 1A (H314) Press. Gas	Eye Irrit. 2 :: 10%<=C<25% Skin Corr. 1B :: C>=25% Skin Irrit. 2 :: 10%<=C<25% STOT SE 3 :: C>=10%	No data available	No data available

NonHazardous

Chemical name	Weight-%	REACH Registration Number	EC 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 as hazardous	Not Listed	No data available	No data available
Dextrose (CAS #: 14431-43-7)	*		Not Listed	Not classified as hazardous	Not Listed	No data available	No data available

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

Acute Toxicity Estimate

No information available

Chemical name	Oral LD50	Dermal LD50	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

Chemical name	Oral LD50	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapor - mg/L	Inhalation LC50 - 4 hour - gas - ppm
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

Additional information

* Proprietary
** to adjust pH
+ Substance with a Union workplace exposure limit
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

Suitable Extinguishing Media Use extinguishing agent suitable for type of surrounding fire.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the chemical Fine particles (such as mists) may fuel fires/explosions.

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

5.3. Advice for firefighters

Special protective equipment for Firefighters should wear self-contained breathing apparatus and full firefighting turnout

fire-fighters gear. 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.

For emergency responders Use personal protection recommended in Section 8.

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 vapor or mist. Avoid contact with eyes, skin and 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.

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

+ Hydrochloric Acid

ACGIH OEL (Ceiling)	2 ppm
ACGIH TLV	Ceiling: 2 ppm

Austria	5 ppm 8 mg/m³ STEL 10 ppm STEL 15 mg/m³
Bulgaria	STEL: 10 ppm STEL: 15.0 mg/m³ 5 ppm 8.0 mg/m³
Czech Republic	8 mg/m³ Ceiling: 15 mg/m³
Denmark	Ceiling: 5 ppm Ceiling: 8 mg/m³
Estonia	5 ppm 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
Finland	STEL: 5 ppm STEL: 7.6 mg/m³
Germany	2 ppm 3.0 mg/m³ Ceiling / Peak: 4 ppm Ceiling / Peak: 6 mg/m³
Germany	2 ppm 3 mg/m³
Hungary	8 mg/m³ STEL: 16 mg/m³
Ireland	8 mg/m³ 5 ppm STEL: 10 ppm STEL: 15 mg/m³
Italy	5 ppm 8 mg/m³ STEL: 10 ppm STEL: 15 mg/m³
Ceiling Limit Value	2 ppm 3.0 mg/m³
Latvia	5 ppm 8 mg/m³ STEL: 10 ppm STEL: 15 mg/m³
Netherlands	8 mg/m³ STEL: 15 mg/m³
Poland	STEL: 10 mg/m³ 5 mg/m³
Romania	5 ppm 8 mg/m³ STEL: 10 ppm STEL: 15 mg/m³
Russia	MAC: 5 mg/m³
Slovakia	5 ppm 8.0 mg/m³
Spain	5 ppm 7.6 mg/m³ STEL: 10 ppm STEL: 15 mg/m³

Switzerland	2 ppm 3 mg/m³ STEL: 4 ppm STEL: 6 mg/m³
U.S. - OSHA - Final PELs - Ceiling Limits	5 ppm 7 mg/m³
OSHA PEL	(vacated) Ceiling: 5 ppm (vacated) Ceiling: 7 mg/m³ Ceiling: 5 ppm Ceiling: 7 mg/m³
United Kingdom	TWA: 1 ppm TWA: 2 mg/m³ STEL: 5 ppm STEL: 8 mg/m³

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.

Environmental exposure controls No information available.

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

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.).

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

Skin and body protection Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations. (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.).

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

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

Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state	Solution
Color	Clear, colorless to pale yellow
Odor	No information available.
Odor threshold	No information available
Molecular formula	Mixture
Molecular weight	Mixture

Property	**Values**
pH	3.5 - 4.6

Melting point / freezing point	No data available
Boiling point / boiling range	
Flash point	No information available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Flammability Limit in Air	
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure	No data available
Vapor density	No data available
Relative density	No data available
Water solubility	No data available
Solubility(ies)	Soluble Water
Partition coefficient	No data available
Autoignition temperature	No data available
Decomposition temperature	No data available
Kinematic viscosity	No data available
Dynamic viscosity	No data available
Particle characteristics	
Particle Size	No information available
Particle Size Distribution	No information available
Explosive properties	No information available

Partition Coefficient: (Method, pH, Endpoint, Value)
Ciprofloxacin
Predicted 7.4 Log D -0.291

9.2. Other information
No information available

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 data available.
10.2. Chemical stability
Stability Stable under normal conditions.
Explosion data
Sensitivity to Mechanical Impact No data available.
Sensitivity to Static Discharge No data 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: (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

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
+ 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

+ Hydrochloric Acid

Skin irritation Severe
Eye irritation Severe

Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

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

STOT - single exposure No information available.

STOT - repeated exposure No information available.

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
Reproductive toxicity No information available.

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
In Vivo Micronucleus Mouse Negative
In Vivo Dominant Lethal Assay Mouse Negative
+ Hydrochloric Acid
Bacterial Mutagenicity (Ames) *Salmonella* Negative
In Vivo Micronucleus Rat Negative
Germ cell mutagenicity No information available.

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 (Not Classifiable)

11.2. Information on other hazards
11.2.1. Endocrine disrupting properties
Endocrine disrupting properties No information available.

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

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No information available.

Chemical name	PBT and vPvB assessment
Lactic acid	The substance is not PBT / vPvB
+ Hydrochloric Acid	The substance is not PBT / vPvB PBT assessment does not apply

12.6. Endocrine disrupting properties

Endocrine disrupting properties No information available.

12.7. Other adverse effects
No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

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

Special precautions for user: Not applicable

Section 15: REGULATORY INFORMATION

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

Water

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
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
EINECS	Not Listed
Standard for Uniform Scheduling of Medicines and Poisons (SUSMP)	Schedule 4

Lactic acid

CERCLA/SARA Section 313 de minimus %	Not Listed
California Proposition 65	Not Listed
TSCA	Present
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 Poisons (SUSMP)	Schedule 5 Schedule 6

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 at work

Authorizations and/or restrictions on use:

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

Chemical name	Restricted substance per REACH Annex XVII	Substance subject to authorization per REACH Annex XIV
+ Hydrochloric Acid - 7647-01-0	Use restricted. See item 75.	

Persistent Organic Pollutants

Not applicable

Ozone-depleting substances (ODS) regulation (EC) 1005/2009

Not applicable

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

Chemical name	EU - Biocides
+ Hydrochloric Acid - 7647-01-0	Product-type 2: Disinfectants and algaecides not intended for direct application to humans or animals

Legend:
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances
AICS - Australian Inventory of Chemical Substances

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 H-Statements referred to under section 3
Acute toxicity, inhalation-Cat.3; H331 - Toxic if inhaled Hazardous to the aquatic environment, acute toxicity-Cat.2; H401 - Toxic to aquatic life Hazardous to the aquatic environment, chronic toxicity-Cat.2; H411 - Toxic to aquatic life with long lasting effects Serious eye damage/eye irritation-Cat.1; H318 - Causes serious eye damage Skin corrosion/irritation-Cat.2; H315 - Causes skin irritation Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage

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 - Ecological Information.

Revision date 28-Jun-2022

Prepared By Pfizer Global Environment, Health, and Safety

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