



A Pfizer Company

# SAFETY DATA SHEET

Revision date: 23-Aug-2016

Version: 1.0

Page 1 of 9

## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Ciprofloxacin in 5% Dextrose Injection, USP (Hospira Inc.)

**Trade Name:** Not applicable  
**Chemical Family:** Fluoroquinolone

### Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

**Intended Use:** Pharmaceutical product used as antibiotic agent

### 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

**Emergency telephone number:**  
**CHEMTREC (24 hours):** 1-800-424-9300  
**Contact E-Mail:** pfizer-MSDS@pfizer.com

**Emergency telephone number:**  
**International CHEMTREC (24 hours):** +1-703-527-3887

## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### Label Elements

**Signal Word:** Not Classified  
**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

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

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

### Hazardous

## SAFETY DATA SHEET

Material Name: Ciprofloxacin in 5% Dextrose Injection, USP  
(Hospira Inc.)  
Revision date: 23-Aug-2016

Page 2 of 9

Version: 1.0

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

| Ingredient        | CAS Number | EU EINECS/ELINCS List | GHS Classification  | %   |
|-------------------|------------|-----------------------|---|-----|
| Ciprofloxacin     | 85721-33-1 | Not Listed            | Aquatic Acute 2 (H401)<br>Aquatic chronic 2 (H411)                            | < 1 |
| Lactic acid       | 50-21-5    | 200-018-0             | Eye Dam. 1 (H318)<br>Skin Irrit. 2 (H315)                                     | < 1 |
| Hydrochloric Acid | 7647-01-0  | 231-595-7             | STOT SE 3 (H335)<br>Skin Corr. 1A (H314)<br>Press. Gas<br>Acute Tox. 3 (H331) | **  |

| Ingredient          | CAS Number | EU EINECS/ELINCS List | GHS Classification | % |
|---------------------|------------|-----------------------|--------------------|---|
| Dextrose            | 14431-43-7 | Not Listed            | Not Listed         | * |
| Water for injection | 7732-18-5  | 231-791-2             | Not Listed         | * |

**Additional Information:**

\* Proprietary  
\*\* to adjust pH  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

**Description of First Aid Measures**

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**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.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

**Most Important Symptoms and Effects, Both Acute and Delayed**

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** None known

**Indication of the Immediate Medical Attention and Special Treatment Needed**

**Notes to Physician:** None

### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

## SAFETY DATA SHEET

Material Name: Ciprofloxacin in 5% Dextrose Injection, USP  
(Hospira Inc.)  
Revision date: 23-Aug-2016

Page 3 of 9

Version: 1.0

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as mists) may fuel fires/explosions.

### Advice for Fire-Fighters

During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

## 6. ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

### Environmental Precautions

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

### Methods and Material for Containment and Cleaning Up

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## 7. HANDLING AND STORAGE

### Precautions for 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 hands and any exposed skin after removal of PPE. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. 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.

### Conditions for Safe Storage, Including any Incompatibilities

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical product used as antibiotic agent

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### Control Parameters

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

### Hydrochloric Acid

|                                |                       |
|--------------------------------|-----------------------|
| ACGIH Ceiling Threshold Limit: | 2 ppm                 |
| Australia PEAK                 | 5 ppm                 |
|                                | 7.5 mg/m <sup>3</sup> |
| Austria OEL - MAKs             | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Belgium OEL - TWA              | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Bulgaria OEL - TWA             | 5 ppm                 |
|                                | 8.0 mg/m <sup>3</sup> |
| Cyprus OEL - TWA               | 5 ppm                 |
|                                | 8 mg/m <sup>3</sup>   |
| Czech Republic OEL - TWA       | 8 mg/m <sup>3</sup>   |

## SAFETY DATA SHEET

Material Name: Ciprofloxacin in 5% Dextrose Injection, USP  
(Hospira Inc.)  
Revision date: 23-Aug-2016

Page 4 of 9

Version: 1.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

|                           |                       |
|---------------------------|-----------------------|
| Estonia OEL - TWA         | 5 ppm                 |
|                           | 8 mg/m <sup>3</sup>   |
| Germany - TRGS 900 - TWAs | 2 ppm                 |
|                           | 3 mg/m <sup>3</sup>   |
| Germany (DFG) - MAK       | 2 ppm                 |
|                           | 3.0 mg/m <sup>3</sup> |
| Greece OEL - TWA          | 5 ppm                 |
|                           | 7 mg/m <sup>3</sup>   |
| Hungary OEL - TWA         | 8 mg/m <sup>3</sup>   |
| Ireland OEL - TWAs        | 5 ppm                 |
|                           | 8 mg/m <sup>3</sup>   |
| Italy OEL - TWA           | 5 ppm                 |
|                           | 8 mg/m <sup>3</sup>   |
| Japan - OELs - Ceilings   | 2 ppm                 |
|                           | 3.0 mg/m <sup>3</sup> |
| Latvia OEL - TWA          | 5 ppm                 |
|                           | 8 mg/m <sup>3</sup>   |
| Lithuania OEL - TWA       | 5 ppm                 |
|                           | 8 mg/m <sup>3</sup>   |
| Luxembourg OEL - TWA      | 5 ppm                 |
|                           | 8 mg/m <sup>3</sup>   |
| Malta OEL - TWA           | 5 ppm                 |
|                           | 8 mg/m <sup>3</sup>   |
| Netherlands OEL - TWA     | 8 mg/m <sup>3</sup>   |
| Poland OEL - TWA          | 5 mg/m <sup>3</sup>   |
| Portugal OEL - TWA        | 5 ppm                 |
|                           | 8 mg/m <sup>3</sup>   |
| Romania OEL - TWA         | 5 ppm                 |
|                           | 8 mg/m <sup>3</sup>   |
| Slovakia OEL - TWA        | 5 ppm                 |
|                           | 8.0 mg/m <sup>3</sup> |
| Slovenia OEL - TWA        | 5 ppm                 |
|                           | 8 mg/m <sup>3</sup>   |
| Spain OEL - TWA           | 5 ppm                 |
|                           | 7.6 mg/m <sup>3</sup> |
| Switzerland OEL -TWAs     | 2 ppm                 |
|                           | 3.0 mg/m <sup>3</sup> |
| Vietnam OEL - TWAs        | 5 mg/m <sup>3</sup>   |

#### Ciprofloxacin

**Pfizer Occupational Exposure Band (OEB):** OEB 2 (control exposure to the range of 100ug/m<sup>3</sup> to < 1000ug/m<sup>3</sup>)

#### 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).

##### Hands:

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.)

## SAFETY DATA SHEET

Material Name: Ciprofloxacin in 5% Dextrose Injection, USP  
(Hospira Inc.)  
Revision date: 23-Aug-2016

Page 5 of 9

Version: 1.0

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Eyes:** 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.)

**Skin:** 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.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

|   |                    |                          |                                 |
|---|--------------------|--------------------------|---------------------------------|
| <b>Physical State:</b>                                      | Solution           | <b>Color:</b>            | Clear, colorless to pale yellow |
| <b>Odor:</b>  | No data available. | <b>Odor Threshold:</b>   | No data available.              |
| <b>Molecular Formula:</b>                                   | Mixture            | <b>Molecular Weight:</b> | Mixture                         |
| <b>Solvent Solubility:</b>                                  | No data available  |                          |                                 |
| <b>Water Solubility:</b>                                    | No data available  |                          |                                 |
| <b>Solubility:</b>  | Soluble: Water     |                          |                                 |
| <b>pH:</b>  | 3.5 - 4.6          |                          |                                 |
| <b>Melting/Freezing Point (°C):</b>                         | No data available  |                          |                                 |
| <b>Boiling Point (°C):</b>                                  | No data available. |                          |                                 |
| <b>Partition Coefficient: (Method, pH, Endpoint, Value)</b> |                    |                          |                                 |
| <b>Ciprofloxacin</b>  |                    |                          |                                 |
| Predicted 7.4 Log D   | -0.291             |                          |                                 |
| <b>Lactic acid</b>  |                    |                          |                                 |
| No data available   |                    |                          |                                 |
| <b>Dextrose</b>   |                    |                          |                                 |
| No data available   |                    |                          |                                 |
| <b>Water for injection</b>                                  |                    |                          |                                 |
| No data available   |                    |                          |                                 |
| <b>Hydrochloric Acid</b>                                    |                    |                          |                                 |
| No data available   |                    |                          |                                 |
| <b>Decomposition Temperature (°C):</b>                      | No data available. |                          |                                 |
| <b>Evaporation Rate (Gram/s):</b>                           | No data available  |                          |                                 |
| <b>Vapor Pressure (kPa):</b>                                | No data available  |                          |                                 |
| <b>Vapor Density (g/ml):</b>                                | No data available  |                          |                                 |
| <b>Relative Density:</b>                                    | No data available  |                          |                                 |
| <b>Viscosity:</b>   | No data available  |                          |                                 |
| <b>Flammability:</b>  |                    |                          |                                 |
| <b>Autoignition Temperature (Solid) (°C):</b>               | No data available  |                          |                                 |
| <b>Flammability (Solids):</b>                               | No data available  |                          |                                 |
| <b>Flash Point (Liquid) (°C):</b>                           | No data available  |                          |                                 |
| <b>Upper Explosive Limits (Liquid) (% by Vol.):</b>         | No data available  |                          |                                 |
| <b>Lower Explosive Limits (Liquid) (% by Vol.):</b>         | No data available  |                          |                                 |

## SAFETY DATA SHEET

Material Name: Ciprofloxacin in 5% Dextrose Injection, USP  
(Hospira Inc.)  
Revision date: 23-Aug-2016

Page 6 of 9

Version: 1.0

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

##### 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 207mg/kg

##### Lactic acid

Rat Oral LD50 3543 mg/kg  
Rabbit Dermal LD50 > 2000 mg/kg

##### 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

#### 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

##### Lactic acid

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

## SAFETY DATA SHEET

Material Name: Ciprofloxacin in 5% Dextrose Injection, USP  
(Hospira Inc.)  
Revision date: 23-Aug-2016

Page 7 of 9

Version: 1.0

### 11. TOXICOLOGICAL INFORMATION

#### 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

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

**Hydrochloric Acid**  
**IARC:** Group 3 (Not Classifiable)

### 12. ECOLOGICAL INFORMATION

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

#### **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 Hours > 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

#### **Persistence and Degradability:**

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

##### **Ciprofloxacin**

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

#### **Bio-accumulative Potential:**

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

##### **Ciprofloxacin**

Predicted 7.4 Log D -0.291

**Mobility in Soil:** No data available

## SAFETY DATA SHEET

Material Name: Ciprofloxacin in 5% Dextrose Injection, USP  
(Hospira Inc.)  
Revision date: 23-Aug-2016

Page 8 of 9

Version: 1.0

### 13. DISPOSAL CONSIDERATIONS

**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 waste water 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.

### 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.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### Ciprofloxacin

|  |            |
|--|------------|
| CERCLA/SARA 313 Emission reporting                         | Not Listed |
| California Proposition 65                                  | Not Listed |
| Standard for the Uniform Scheduling for Drugs and Poisons: | Schedule 4 |
| EU EINECS/ELINCS List                                      | Not Listed |

#### Lactic acid

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting          | Not Listed |
| California Proposition 65                   | Not Listed |
| Inventory - United States TSCA - Sect. 8(b) | Present    |
| Australia (AICS):                           | Present    |
| EU EINECS/ELINCS List                       | 200-018-0  |

#### Dextrose

|                                    |            |
|------------------------------------|------------|
| CERCLA/SARA 313 Emission reporting | Not Listed |
| California Proposition 65          | Not Listed |
| Australia (AICS):                  | Present    |
| EU EINECS/ELINCS List              | Not Listed |

#### Hydrochloric Acid

|   |                    |
|---|--------------------|
| CERCLA/SARA 313 Emission reporting                                | 1.0 %              |
| CERCLA/SARA Hazardous Substances and their Reportable Quantities: | 5000 lb<br>2270 kg |



## SAFETY DATA SHEET

Material Name: Ciprofloxacin in 5% Dextrose Injection, USP  
(Hospira Inc.)  
Revision date: 23-Aug-2016

Page 9 of 9

Version: 1.0

### 15. REGULATORY INFORMATION

|  |            |
|--|------------|
| CERCLA/SARA - Section 302 Extremely Hazardous TPQs                 | 500 lb     |
| CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs | 5000 lb    |
| California Proposition 65  | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                        | Present    |
| Australia (AICS):  | Present    |
| Standard for the Uniform Scheduling for Drugs and Poisons:         | Schedule 5 |
| EU EINECS/ELINCS List  | Schedule 6 |
|  | 231-595-7  |

#### Water for injection

|   |            |
|---|------------|
| CERCLA/SARA 313 Emission reporting                              | Not Listed |
| California Proposition 65                                       | Not Listed |
| Inventory - United States TSCA - Sect. 8(b)                     | Present    |
| Australia (AICS):   | Present    |
| REACH - Annex IV - Exemptions from the obligations of Register: | Present    |
| EU EINECS/ELINCS List   | 231-791-2  |

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in 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  
Specific target organ toxicity, single exposure; Respiratory tract irritation-Cat.3; H335 - May cause respiratory irritation

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

**Revision date:** 23-Aug-2016  
Product Stewardship Hazard Communication

**Prepared by:** Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material 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.

**End of Safety Data Sheet**