

SAFETY DATA SHEETS

This SDS packet was issued with item:

078009697

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

078009689



A Pfizer Company

SAFETY DATA SHEET

Revision date: 17-May-2018

Version: 2.0

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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

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3. COMPOSITION / INFORMATION ON INGREDIENTS

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

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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 firefighting 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. Cleanup 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.

Ciprofloxacin

Pfizer OEL TWA-8 Hr: 600µg/m³

Hydrochloric Acid

ACGIH Ceiling Threshold Limit: 2 ppm

Australia PEAK 5 ppm

7.5 mg/m³

Austria OEL - MAKs 5 ppm

8 mg/m³

Belgium OEL - TWA 5 ppm

8 mg/m³

Bulgaria OEL - TWA 5 ppm

8.0 mg/m³

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

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.)

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.)

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

| | | | |
|---------------------------|--------------------|--------------------------|---------------------------------|
| Physical State: | Solution | Color: | Clear, colorless to pale yellow |
| Odor: | No data available. | Odor Threshold: | No data available. |
| Molecular Formula: | Mixture | Molecular Weight: | Mixture |

| | |
|-------------------------------------|--------------------|
| Solvent Solubility: | No data available |
| Water Solubility: | No data available |
| Solubility: | Soluble: Water |
| pH: | 3.5 - 4.6 |
| Melting/Freezing Point (°C): | No data available |
| Boiling Point (°C): | No data available. |

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

Ciprofloxacin

Predicted 7.4 Log D -0.291

Lactic acid

No data available

Dextrose

No data available

Water for injection

No data available

Hydrochloric Acid

No data available

Decomposition Temperature (°C): No data available.

Evaporation Rate (Gram/s): No data available

Vapor Pressure (kPa): No data available

Vapor Density (g/ml): No data available

Relative Density: No data available

Viscosity: No data available

Flammability:

Autoignition Temperature (Solid) (°C): No data available

Flammability (Solids): No data available

Flash Point (Liquid) (°C): No data available

Upper Explosive Limits (Liquid) (% by Vol.): No data available

Lower Explosive Limits (Liquid) (% by Vol.): No data available

10. STABILITY AND REACTIVITY

Reactivity: No data available

Chemical Stability: Stable under normal conditions of use.

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10. STABILITY AND REACTIVITY

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

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

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11. TOXICOLOGICAL INFORMATION

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

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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 2270 kg |

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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.

Reasons for Revision: Updated Section 8 - Exposure Controls / Personal Protection.

Revision date: 17-May-2018
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