



# MATERIAL SAFETY DATA SHEET

Revision date: 04-Sep-2009

Version: 1.0

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

Pfizer Inc  
Pfizer Pharmaceuticals Group  
235 East 42nd Street  
New York, New York 10017  
1-212-573-2222

Pfizer Ltd  
Ramsgate Road  
Sandwich, Kent  
CT13 9NJ  
United Kingdom  
+00 44 (0)1304 616161  
Emergency telephone number:  
ChemSafe (24 hours): +44 (0)208 762 8322

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

### Material Name: Ciprofloxacin Injection

Trade Name: Not applicable  
Chemical Family: Fluoroquinolone  
Intended Use: Pharmaceutical product used as antibiotic agent

## 2. HAZARDS IDENTIFICATION

Appearance: Clear, colorless to pale yellow solution

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

### Additional Hazard Information:

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. Convulsions, increased intracranial pressure, and toxic psychosis have been reported in patients receiving quinolones.

EU Indication of danger: Not classified

Australian Hazard Classification (NOHSC): Non-Hazardous Substance. Non-Dangerous Goods.

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates 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.

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
Ciprofloxacin	85721-33-1	Not listed	Not Listed	1

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## 3. COMPOSITION/INFORMATION ON INGREDIENTS

Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**
Lactic acid	50-21-5	200-018-0	Not Listed	*

Ingredient	CAS Number	EU EINECS/ELINCS List	Classification	%
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 R phrases mentioned in this Section, see Section 16**

## 4. 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.

**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.

## 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

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

**Fire Fighting Procedures:** During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

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

## 6. ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**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.

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

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**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

**General 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. 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.

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

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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	Listed
Belgium OEL - TWA	Listed
Bulgaria OEL - TWA	Listed
Cyprus OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Estonia OEL - TWA	Listed
Germany - TRGS 900 - TWAs	2 ppm
	3 mg/m <sup>3</sup>
Germany (DFG) - MAK	2 ppm MAK
	3.0 mg/m <sup>3</sup> MAK
Greece OEL - TWA	Listed
Hungary OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Italy OEL - TWA	Listed
Japan - OELs - Ceilings	5 ppm
	7.5 mg/m <sup>3</sup>
Latvia OEL - TWA	Listed
Lithuania OEL - TWA	Listed
Luxembourg OEL - TWA	Listed
Malta OEL - TWA	Listed
Netherlands OEL - TWA	Listed
Poland OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed
Spain OEL - TWA	Listed

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

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

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Hands:** Wear impervious gloves if skin contact is possible.  
**Eyes:** Safety glasses or goggles  
**Skin:** Use protective clothing (uniforms, lab coats, disposable coveralls, etc.) in both production and laboratory areas.  
**Respiratory protection:** 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.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Solution	<b>Color:</b>	Clear, colorless to pale yellow
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	Mixture
<b>Solubility:</b>	Soluble: Water		
<b>pH:</b>	3.3-3.9		

### 10. STABILITY AND REACTIVITY

**Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** Fine particles (such as dust and mists) may fuel fires/explosions.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

### 11. TOXICOLOGICAL INFORMATION

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

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

##### **Ciprofloxacin**

Rat Oral LD50 > 2000 mg/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

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### 11. TOXICOLOGICAL INFORMATION

#### 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

*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

### 12. ECOLOGICAL INFORMATION

#### Environmental Overview:

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

### 13. DISPOSAL CONSIDERATIONS

#### Disposal Procedures:

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

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

### 15. REGULATORY INFORMATION

#### EU Indication of danger:

Not classified

#### OSHA Label:

Non-hazardous in accordance with international standards for workplace safety.

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## 15. REGULATORY INFORMATION

### Canada - WHMIS: Classifications

WHMIS hazard class:  
None required

### Hydrochloric Acid

CERCLA/SARA 313 Emission reporting	1.0% de minimis concentration acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	2270 kg final RQ 5000 lb final RQ
CERCLA/SARA - Section 302 Extremely Hazardous TPQs	500 lb TPQ gas only
CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs	5000 lb
Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 5 Schedule 6
EU EINECS/ELINCS List	231-595-7

### Lactic acid

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
EU EINECS/ELINCS List	200-018-0

### Water for injection

Inventory - United States TSCA - Sect. 8(b)	Listed
Australia (AICS):	Listed
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

## 16. OTHER INFORMATION

### Text of R phrases mentioned in Section 3

R35 - Causes severe burns.  
R25 - Toxic if swallowed.

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

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

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**End of Safety Data Sheet**