SAFETY DATA SHEET

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

Product Identifier

Material Name: Levofloxacin Injection (Hospira, Inc.)

Trade Name: Not established
Chemical Family: Mixture

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

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 required
Hazard Statements:
Non-hazardous 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
3. COMPOSITION / INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>215-185-5</td>
<td>Skin Corr.1A (H314)</td>
<td>**</td>
</tr>
<tr>
<td>HYDROCHLORIC ACID</td>
<td>7647-01-0</td>
<td>231-595-7</td>
<td>Skin Corr.1B (H314)</td>
<td>**</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>STOT SE 3 (H335)</td>
<td></td>
</tr>
<tr>
<td>Levofloxacin</td>
<td>100986-85-4</td>
<td>Not Listed</td>
<td>Acute Tox. 4 (H302)</td>
<td>&lt;= 2.5</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Aquatic Acute 3 (H402)</td>
<td></td>
</tr>
</tbody>
</table>

Additional Information:  
* Proprietary  
** to adjust pH  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.  
In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

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**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.
Fire / Explosion Hazards: Fine particles (such as dust and 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 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.

Conditions for Safe Storage, Including any Incompatibilities
- Storage Conditions: Store as directed by product packaging.
- Specific end use(s): Pharmaceutical drug product

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Sodium hydroxide
- ACGIH Ceiling Threshold Limit: 2 mg/m³
- Australia PEAK: 2 mg/m³
- Austria OEL - MAKs: 2 mg/m³
- Bulgaria OEL - TWA: 2.0 mg/m³
- Czech Republic OEL - TWA: 1 mg/m³
- Estonia OEL - TWA: 1 mg/m³
- France OEL - TWA: 2 mg/m³
- Greece OEL - TWA: 2 mg/m³
- Hungary OEL - TWA: 2 mg/m³
- Japan - OELs - Ceilings: 2 mg/m³
- Latvia OEL - TWA: 0.5 mg/m³
- OSHA - Final PELS - TWAs: 2 mg/m³
- Poland OEL - TWA: 0.5 mg/m³
- Slovakia OEL - TWA: 2 mg/m³
- Slovenia OEL - TWA: 2 mg/m³
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sweden</td>
<td>OEL - TWAs</td>
<td>1 mg/m³</td>
</tr>
<tr>
<td>Switzerland</td>
<td>OEL - TWAs</td>
<td>2 mg/m³</td>
</tr>
</tbody>
</table>

#### HYDROCHLORIC ACID

<table>
<thead>
<tr>
<th>Country</th>
<th>Limit Type</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Ceiling Threshold Limit</td>
<td></td>
<td>2 ppm</td>
</tr>
<tr>
<td>Australia</td>
<td>PEAK</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7.5 mg/m³</td>
</tr>
<tr>
<td>Austria</td>
<td>MAKs</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Belgium</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
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<tr>
<td></td>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8.0 mg/m³</td>
</tr>
<tr>
<td>Cyprus</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>OEL - TWA</td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Estonia</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
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<tr>
<td></td>
<td></td>
<td>8 mg/m³</td>
</tr>
<tr>
<td>Germany</td>
<td>TRGS 900</td>
<td>2 ppm</td>
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<tr>
<td></td>
<td>TWAs</td>
<td>3 mg/m³</td>
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<tr>
<td>Germany (DFG)</td>
<td>MAK</td>
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<td></td>
<td></td>
<td>3.0 mg/m³</td>
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<tr>
<td>Greece</td>
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<td></td>
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<td>7 mg/m³</td>
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<tr>
<td>Hungary</td>
<td>OEL - TWA</td>
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<td>Ireland</td>
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<td>5 ppm</td>
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<tr>
<td></td>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Italy</td>
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<td></td>
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</tr>
<tr>
<td>Japan</td>
<td>OELs - Ceilings</td>
<td>2 ppm</td>
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<td>3.0 mg/m³</td>
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<tr>
<td>Latvia</td>
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<td>8 mg/m³</td>
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<tr>
<td>Lithuania</td>
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<td></td>
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<td>8 mg/m³</td>
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<tr>
<td>Luxembourg</td>
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<td></td>
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<tr>
<td>Malta</td>
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<td>5 ppm</td>
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<tr>
<td></td>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Netherlands</td>
<td>OEL - TWA</td>
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</tr>
<tr>
<td>Poland</td>
<td>OEL - TWA</td>
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<td>Portugal</td>
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<td></td>
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<td>Romania</td>
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<tr>
<td></td>
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<td>8 mg/m³</td>
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<tr>
<td>Slovakia</td>
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<td>8.0 mg/m³</td>
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<tr>
<td>Slovenia</td>
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<tr>
<td></td>
<td></td>
<td>8 mg/m³</td>
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<tr>
<td>Spain</td>
<td>OEL - TWA</td>
<td>5 ppm</td>
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<tr>
<td></td>
<td></td>
<td>7.6 mg/m³</td>
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<tr>
<td>Switzerland</td>
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<td>2 ppm</td>
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<tr>
<td></td>
<td></td>
<td>3.0 mg/m³</td>
</tr>
<tr>
<td>Vietnam</td>
<td>OEL - TWAs</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Levofloxacin

Pfizer Occupational Exposure Band (OEB):

OEB 2 (control exposure to the range of 100ug/m³ to < 1000ug/m³)

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). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

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.)

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: Liquid
Odor: No data available.
Molecular Formula: Mixture
Color: Clear yellow to greenish/yellow
Odor Threshold: No data available.
Molecular Weight: Mixture

Solvent Solubility: No data available
Water Solubility: No data available
pH: 3.8-5.8
Melting/Freezing Point (°C): No data available
Boiling Point (°C): No data available.
Partition Coefficient: (Method, pH, Endpoint, Value)

Dextrose

No data available

Sodium hydroxide

No data available

HYDROCHLORIC ACID

No data available

Levofloxacin

Predicted 7.0  Log P 1.49

Water for Injection

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

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 dust and mists) may fuel fires/explosions.
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.
Known Clinical Effects: 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. Photosensitivity reactions have occurred in people taking this drug. Quinolones may effect connective tissue structures. Tendonitis and tendon rupture have occurred as late as several months after quinolone treatment. Clinical use may cause effect on the musculoskeletal system, heart.

Acute Toxicity: (Species, Route, End Point, Dose)
Sodium hydroxide
Mouse IP LD50 40 mg/kg

HYDROCHLORIC ACID
Rat Oral LD50 238-277 mg/kg

Levofloxacin
Rat Oral LD50 1478 mg/kg
Mouse Oral LD50 1803 mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)
Sodium hydroxide
Eye Irritation Rabbit Severe
Skin Irritation Rabbit Severe
11. TOXICOLOGICAL INFORMATION

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

Levofloxacin
7 Day(s) Dog Oral 10 mg/kg/day LOAEL Connective tissue, Skeletal muscle
7 Day(s) Rat Oral 300 mg/kg/day LOAEL Connective tissue, Skeletal muscle
1 Month(s) Rat Oral 200 mg/kg/day NOEL Blood
6 Month(s) Rat Oral 20 mg/kg/day NOEL None identified
1 Month(s) Monkey Oral 30 mg/kg/day NOEL None identified
6 Month(s) Monkey Oral 62.5 mg/kg/day NOEL None identified

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Levofloxacin
Reproductive & Fertility Rat Oral360 mg/kg/day NOAEL Negative
Embryo / Fetal Development Rat Oral 160 mg/kg/day NOAEL Fetal mortality
Embryo / Fetal Development Rabbit Oral 50 mg/kg/day NOAEL Negative

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

HYDROCHLORIC ACID
Bacterial Mutagenicity (Ames) Salmonella Negative
In Vivo Micronucleus Rat Negative

Levofloxacin
In Vitro Bacterial Mutagenicity (Ames) Salmonella , E. coli Negative
In Vitro HGPRT Forward Gene Mutation Assay Chinese Hamster Ovary (CHO) cells Negative
In Vivo Micronucleus Mouse Negative
In Vivo Dominant Lethal Assay Mouse Negative
In Vitro Chromosome Aberration Hamster Positive

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

Levofloxacin
2 Year(s) Rat Oral 100 mg/kg/day NOAEL Not carcinogenic

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: Releases to the environment should be avoided.

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

Levofloxacin
Daphnia magna (Water Flea) EC50 48 Hours 320 mg/L
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
15. REGULATORY INFORMATION

Dextrose

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

Sodium hydroxide

- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **CERCLA/SARA Hazardous Substances and their Reportable Quantities**: 1000 lb, 454 kg
- **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**: 215-185-5

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

**HYDROCHLORIC ACID**

- **CERCLA/SARA 313 Emission reporting**: 1.0 %
- **CERCLA/SARA Hazardous Substances and their Reportable Quantities**: 5000 lb, 2270 kg
- **CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs**: 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**: 231-595-7

Levofloxacin

- **CERCLA/SARA 313 Emission reporting**: Not Listed
- **California Proposition 65**: Not Listed
- **EU EINECS/ELINCS List**: Not Listed

16. OTHER INFORMATION

Text of CLP/GHS Classification abbreviations mentioned in Section 3
Specific target organ toxicity, repeated exposure-Cat.2; H373 - May cause damage to organs through prolonged or repeated exposure
Skin corrosion/irritation-Cat.1A; Skin corrosion/irritation-Cat.1B; H314 - Causes severe skin burns and eye damage
Acute toxicity, oral-Cat.4; H302 - Harmful if swallowed
Hazardous to the aquatic environment, acute toxicity-Cat.3; H402 - Harmful to aquatic life

Data Sources: Pfizer proprietary drug development information. Safety data sheets for individual ingredients.

Revision date: 02-Oct-2016
Prepared by: Product Stewardship Hazard Communication
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