MATERIAL SAFETY DATA SHEET

Product Name: Levofloxacin Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.
275 North Field Drive
Lake Forest, Illinois USA
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;
International 1-703-527-3887; Australia (02) 8014 4880

Hospira, Inc., Non-Emergency
224-212-2000

Product Name
Levofloxacin Injection

Synonyms
(-)-(S)-9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyridol[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid hemihydrate; (S)-Ofloxacin.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Levofloxacin Hemihydrate

Chemical Formula
C_{18}H_{20}FN_3O_4 \cdot \frac{1}{2} H_2O

Preparation
Non-hazardous ingredients include Water for Injection and possibly dextrose. Hazardous ingredients present at less than 1% may include hydrochloric acid and/or sodium hydroxide which are used to adjust pH of some preparations.

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levofloxacin Hemihydrate</td>
<td>\leq 2.5</td>
<td>100986-85-4</td>
<td>UU8815550</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levofloxacin Hemihydrate</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Levofloxacin Injection is a solution containing the L-isomer of racemic ofloxacin, a quinolone antibiotic indicated for acute and chronic bacterial infections. No adverse effects are anticipated from normal handling of the intact container. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract, and a possible photosensitizer. Based on clinical use, possible target organs include the gastrointestinal system, the central nervous system, cardiovascular system, the hematopoietic system, and skin.

Occupational Exposure Potential
Minimal occupational exposure is anticipated from normal handling of the intact container. Avoid liquid aerosol generation and inadvertent skin contact.

Signs and Symptoms
No signs or symptoms of exposure are anticipated from normal handling of the intact container. Based on clinical use of this product in patients, following an accidental occupational exposure, possible adverse effects may include gastrointestinal upset with nausea or diarrhea, headache, skin rash, urticaria, joint pain, alterations in normal blood parameters, hypertension or
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hypotension, and tachycardia.

Medical Conditions Aggravated by Exposure
Hypersensitivity to levofloxacin or other quinolone antimicrobial agents. Pre-existing gastrointestinal system, central nervous system, cardiovascular system, hematopoietic system, or skin ailments.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Levofloxacin is not efficiently removed by hemodialysis or peritoneal dialysis. Under qualified medical supervision, the stomach may be emptied if indicated. The patient should be observed and appropriate hydration maintained.

5. FIRE FIGHTING MEASURES

Flammability
None anticipated for this aqueous product.

Fire & Explosion Hazard
None anticipated for this aqueous product.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal fire fighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling
No special handling required for hazard control under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions
None anticipated during the normal use of this product. Persons with known allergies to levofloxacin or other quinolone antibiotics should consult a health or safety professional prior to handling open containers of this material.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m³</th>
<th>ppm</th>
<th>µg/m³</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levofloxacin Hemihydrate</td>
<td>Not Applicable</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>None Established</td>
</tr>
</tbody>
</table>

**Respiratory protection**

Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

**Skin protection**

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

**Eye protection**

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

**Engineering Controls**

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

**Appearance/Physical State**

- Liquid

**Color**

- Clear yellow to greenish-yellow

**Odor**

- NA

**Odor Threshold:**

- NA

**pH:**

- 3.8 to 5.8 for the 0.5% aqueous solution

**Melting point/Freezing point:**

- NA

**Initial Boiling Point/Boiling Point Range:**

- NA

**Evaporation Rate:**

- NA

**Flammability (solid, gas):**

- NA

**Upper/Lower Flammability or Explosive Limits:**

- NA

**Vapor Pressure:**

- NA

**Vapor Density:**

- NA

**Specific Gravity:**

- NA

**Solubility:**

- From pH 0.6 to 5.8, approximately 100 mg/mL

**Partition coefficient: n-octanol/water:**

- NA

**Auto-ignition temperature:**

- NA

**Decomposition temperature:**

- NA
10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined.

Conditions to avoid
Not determined.

Incompatibilities
Not determined.

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx) and hydrogen fluoride.

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
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</thead>
<tbody>
<tr>
<td>Levofloxacin Hemihydrate</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>1478</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1803</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>&gt; 250</td>
<td>mg/kg</td>
<td>Monkey (female)</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. In clinical use, some quinolone antibiotics, including levofloxacin, may produce phototoxicity characterized by an exaggerated sunburn-like reaction upon exposure to sunlight.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. In clinical use, allergic reactions to quinolone antibiotics, including levofloxacin, may occur in some patients. Rarely, these reactions may be severe and sometimes fatal.

Reproductive Effects
In studies in rats, oral dosages of levofloxacin as high as 360 mg/kg/day, or intravenous dosages of levofloxacin as high as 160 mg/kg/day did not impair fertility or reproductive performance. Levofloxacin was not teratogenic in rats at oral dosages as high as 810 mg/kg/day, or intravenous dosages as high as 160 mg/kg/day. An oral dosage of 810 mg/kg/day in rats produced a decrease in fetal body weights and an increase in fetal mortality. No teratogenicity was noted in rabbits at oral dosages as high as 50 mg/kg/day, or intravenous dosages as high as 25 mg/kg/day.
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Mutagenicity Levofloxacin was negative in the bacterial reverse mutation assay (Ames plus E. coli) with and without metabolic activation; negative in the HGPRT mutation assay in Chinese hamster cells; negative in the mouse micronucleus assay in vivo; negative in the SCE assay in vivo in mice.; negative in the unscheduled DNA synthesis (UDS) assay for genotoxicity, and; negative in the dominant lethal assay in mice. Levofloxacin produced a dose-dependent increase in chromosomal aberrations in an in vitro cytogenetic assay in Chinese hamster lung cells. Levofloxacin was also weakly positive in the sister chromatid exchange (SCE) assay in vitro in Chinese hamster lung cells.

Carcinogenicity In a 2-year feeding study in rats, levofloxacin was not carcinogenic at dietary dosages up to 100 mg/kg/day. Levofloxacin was not photo-carcinogenic in a study of skin tumors in hairless albino mice.

Target Organ Effects None known from occupational exposure. Based on clinical use, possible target organs include the gastrointestinal system, the central nervous system, cardiovascular system, the hematopoietic system, and skin.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity Not determined for product. Information for levofloxacin is as follows:

EC50 = 7.9 mcg/L in Microcystis aeruginosa (cyanobacterium)
EC50 = 51 mcg/L in Lemma minor (duckweed)
EC50 = 7.4 mg/L in Pseudokirchmeriella subcapitata (green algae)

Daphnia (48-hour survival, static with renewal)
LC50(48 hours, static) > 10 mg/L for Daphnia magna

Fish (7-day early life stage survival and growth)
LC50 (7 days) > 10 mg/L in fathead minnows (Pimephales promelas)

Persistence/Biodegradability Not determined for product.

Bioaccumulation Not determined for product.

Mobility in Soil Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements. Disposal of liquid waste into open sewers is not recommended unless approved by local wastewater permitting agency.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state and local regulations.
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14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Regulated
Proper Shipping Name: Environmentally hazardous substance, liquid, n.o.s. (Levofloxacin Hemihydrate)
Hazard Class: 9
UN number: UN 3082
Packing group: III
Reportable Quantity: N/A

IMDG STATUS: Regulated
Proper Shipping Name: Environmentally hazardous substance, liquid, n.o.s. (Levofloxacin Hemihydrate)
Hazard Class: 9
UN number: UN 3082
Packing group: III
Reportable Quantity: N/A

ICAO/IATA STATUS: Regulated
Proper Shipping Name: Environmentally hazardous substance, liquid, n.o.s. (Levofloxacin Hemihydrate)
Hazard Class: 9
UN number: UN 3082
Packing group: III
Reportable Quantity: N/A

Transport Comments: This material is not regulated as hazardous material for ground transport under the DOT hazardous materials regulations.

15. REGULATORY INFORMATION

USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
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<tr>
<td>Levofloxacin Hemihydrate</td>
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RCRA Status Not Listed
U.S. OSHA
Classification Possible Sensitizer
Target Organ Toxin
Possible Irritant

GHS Classification
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class Not Applicable
Hazard Category Not Applicable
Signal Word Not Applicable
Symbol Not Applicable
Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
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Hazard Statement

Response:
IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Levofloxacin Hemihydrate.

Classification(s): Not Applicable
Symbol: Not Applicable
Indication of Danger: Not Applicable
Risk Phrases: Not Applicable
Safety Phrases:
$23$ - Do not breathe vapor.
$24$ - Avoid contact with skin.
$25$ - Avoid contact with eyes.
$29$ - Do not empty into drains.
$37/39$ - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:
ACGIH TLV American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS Chemical Abstracts Service Number
CERCLA US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT US Department of Transportation Regulations
EEL Employee Exposure Limit
IATA International Air Transport Association
LD50 Dosage producing 50% mortality
NA Not applicable/Not available
NE Not established
NIOSH National Institute for Occupational Safety and Health
OSHA PEL US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65 California Proposition 65
RCRA US EPA, Resource Conservation and Recovery Act
RTECS Registry of Toxic Effects of Chemical Substances
SARA Superfund Amendments and Reauthorization Act
STEL 15-minute Short Term Exposure Limit
TSCA Toxic Substance Control Act
TWA 8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
Date Prepared: 10/13/2011
Obsolete Date: 12/17/2010
Product Name: Levofloxacin Injection

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