SAFETY DATA SHEET

Product Name: Levofloxacin Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
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. HAZARD(S) IDENTIFICATION

Emergency Overview

Levofloxacin Injection is a solution containing the L-isomer of racemic ofloxacin, a quinolone antibiotic indicated for acute and chronic bacterial infections. 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.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Sensitization – Skin	1
	Sensitization - Respiratory	1
	STOT – RE	2

Label Element(s)

Pictogram

Signal Word Danger

Hazard Statement(s)

May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
May cause damage to organs through prolonged or repeated exposure

2. HAZARD(S) IDENTIFICATION: continued

Precautionary Statement(s)

Prevention

Do not breathe vapors/spray
In case of inadequate ventilation, wear respiratory protection
Wear protective gloves
Wash hands thoroughly after handling
Contaminated work clothing must not be allowed out of the workplace

Response

Get medical attention if you feel unwell.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

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.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Levofloxacin Hemihydrate
Chemical Formula $C_{18}H_{20}FN_3O_4 \bullet ½ H_2O$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Levofloxacin Hemihydrate	≤2.5	100986-85-4	UU8815550

Non-hazardous ingredients include Water for Injection; some preparations also may contain 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.

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 such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting

No special provisions required beyond normal firefighting equipment such as flame

Procedures	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 control 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

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Levofloxacin Hemihydrate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

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	Clear yellow to a greenish-yellow solution
Odor	NA
Odor Threshold	NA
pH	The pH ranges from 3.8 to 5.8 for the 0.5% aqueous solution.
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	From pH 0.6 to 5.8, the solubility of levofloxacin is approximately 100 mg/mL
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	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 active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Levofloxacin Hemihydrate	100	LD50	Oral	1478 1803 > 250	mg/kg mg/kg mg/kg	Rat Mouse Monkey (f)

LD 50: Dosage that produces 50% mortality.

11. TOXICOLOGICAL INFORMATION: continued

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. 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 hypotension, and tachycardia.
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	None anticipated from normal handling of this product. 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.
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.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat 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.

Notes:
1. EC50: Concentration in water that produces 50% mortality in Daphnia sp.
2. LC50: Concentration in water that produces 50% mortality in fish.
3. EC50: Concentration in water that produces 50% inhibition of growth in algae.

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.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Regulated, if shipment of single or inner packagings are >5L liquids, or >5KG of solids.
Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s. (Levofloxacin Hemihydrate)
Hazard Class	9
UN Number	UN3802
Packing Group	III
Reportable Quantity	NA
ICAO/IATA STATUS	Regulated, if shipment of single or inner packagings are >5L liquids, or >5KG of solids.
Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s. (Levofloxacin Hemihydrate)
Hazard Class	9
UN Number	UN3802
Packing Group	III
Reportable Quantity	NA
IMDG STATUS	Regulated, if shipment of single or inner packagings are >5L liquids, or >5KG of solids.
Proper Shipping Name	Environmentally hazardous substance, liquid, n.o.s. (Levofloxacin Hemihydrate)
Hazard Class	9
UN Number	UN3802
Packing Group	III
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

Transport Comments: Shipments of single or inner packagings of < or = 5L liquids, or < or = 5KG solids are not regulated as long as the general packaging provisions are met

Product Name: Levofloxacin Injection

Hospira

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP 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	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Do not breathe vapors/spray
In case of inadequate ventilation, wear respiratory protection
Wear protective gloves
Wash hands thoroughly after handling
Contaminated work clothing must not be allowed out of the workplace

Response

Get medical attention if you feel unwell.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

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.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

Collect spillage. Avoid release to the environment.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	R42/43: May cause sensitization by inhalation and skin contact
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection S61: Avoid release into the environment

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
LD_{50}	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
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