

### **SAFETY DATA SHEET**

1. <u>Identification</u>

Product Identifier: Levofloxacin Injection, USP

**Synonyms:** (S)-(-)-Ofloxacin

National Drug Code (NDC): 17478-107-20

17478-107-30

Recommended Use: Pharmaceutical.

Company: Akorn, Inc.

1925 West Field Court, Suite 300

Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

2. <u>Hazard(s) Identification</u>

Physical Hazards: Not classifiable. Health Hazards: Not classifiable.

Symbol(s):None.Signal Word:None.Hazard Statement(s):None.

Precautionary Statement(s): P260 Do not breathe dust/fume/gas/mist/vapors/spray.

P305 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if P351 present and easy to do. Continue rinsing.

+

P338

P337 If eye irritation persists, get medical

+ advice/attention.

P313

P264 Wash hands after handling.

Hazards Not Otherwise Classified: Not classifiable.

**Supplementary Information:** While this material is not classifiable as hazardous under

the OSHA standard, this SDS contains valuable

information critical to safe handling and proper use of the product. This SDS should be retained and available for

employees and other users of this product.



#### **Composition/Information on Ingredients** 3.

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Levofloxacin	138199-71-0	(S)-(-)- Ofloxacin	C <sub>18</sub> H <sub>20</sub> FN <sub>3</sub> O <sub>4</sub> •½H <sub>2</sub> O	370.38	2.5%

<sup>\*</sup>The formula also contains Sodium Hydroxide, Hydrochloride Acid, and Water for Injection with pH ranging

### 4.

**Signs and Symptoms:** 

g from 3.8 to 5.8.  First Aid Measures	
Ingestion:	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
Eye Contact:	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Skin Contact:	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Inhalation:	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
Protection of First-Aiders:	Use personal protective equipment (see section 8).

Convulsions and toxic psychoses have been reported in patients receiving quinolones, including levofloxacin. Quinolones may also cause increased intracranial pressure and central nervous system stimulation which may lead to tremors, restlessness, anxiety,

lightheadedness, confusion, hallucinations, paranoia, depression, nightmares, insomnia, and, rarely, suicidal thoughts or acts. These reactions may occur after the



first dose. Serious and occasionally fatal hypersensitivity or anaphylactic reactions have been reported in patients receiving therapy with guinolones, including levofloxacin. Some reactions have been accompanied by cardiovascular collapse, hypotension/shock, seizure, loss of consciousness, tingling, angioedema (including tongue, laryngeal, throat, or facial edema/swelling), airway obstruction (including bronchospasm, shortness of breath, and acute respiratory distress), dyspnea, urticarial, itching and other serious skin reactions. Clinical manifestations of sensitivity may include: fever, rash or severe dermatologic reactions, vasculitis, arthralgia, myalgia, serum sickness, allergic pneumonitis, interstitial nephritis, acute renal insufficiency or failure, hepatitis, jaundice, acute hepatic necrosis or failure, anemia (including hemolytic and aplastic), thrombocytopenia (including thrombocytopenic purpura), leukopenia, agranulocytosis, pancytopenia, and/or other hematologic abnormalities.

Medical Conditions Aggravated by Exposure:

Levofloxacin should be used with caution in patients with a known or suspected CNS disorder that may predispose to seizures or lower the seizure threshold (e.g. severe cerebral arteriosclerosis, epilepsy, certain drug therapy, renal dysfunction). Levofloxacin should be administered with caution in the presence of renal insufficiency. Levofloxacin should be avoided in patients with known prolongation of the QT interval, patients with uncorrected hypokalemia, and patients receiving class 1A or class III antiarrhythmic agents. It can be presumed that levofloxacin will be excreted in human milk. Levofloxacin should be used by nursing mothers only if the potential benefit justifies the potential risk to the infant. No adequate and well-controlled

risk to the infant. No adequate and well-controlled studies have been conducted in pregnant women.

Levofloxacin should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Notes to Physician:

Levofloxacin should be discontinued immediately

- at the first appearance of skin rash or any other hypersensitivity
- if the patient experiences symptoms of neuropathy or alterations of sensation
- if the patient experiences pain, inflammation or rupture of a tendon
- if a hypoglycemic reaction occurs
- if photosensitivity occurs



5. Firefighting Measures

Flammability: None anticipated for this aqueous product.

Suitable Extinguishing Media: Use water spray, dry chemical, carbon dioxide or foam

extinguishing media as appropriate for surrounding fire

and materials.

Unsuitable Extinguishing Media: Not determined.

**Special Fire Fighting Procedures:** No special provisions required beyond normal firefighting

equipment such as flame and chemical resistant clothing

and self-contained breathing apparatus.

Specific Hazards Arising from the Chemical:

**Hazardous Combustion Products:** May emit toxic fumes.

Other Specific Hazards: Not determined.

Special Protective Equipment/

Precautions for Firefighters: Wear self-contained breathing apparatus and full and

protective gear.

6. <u>Accidental Release Measures</u>

Personal Precautions: Use personal protective equipment recommended in

Section 8 of this document and isolate the hazard area.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:**Wear approved respiratory protection, chemically

compatible gloves and protective clothing. Wipe up spillage or collect spillage using an absorbent material. Place in a appropriately-labeled container for proper disposal according to applicable local, state, and federal regulations. Wash the spill site thoroughly but do not allow large amounts of waste materials to enter

drains or water courses.

**Environmental Precautions:** Not determined.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

7. Handling and Storage

Precautions for Safe Handling: Handle in accordance with product label and/or product

insert information. Handle in accordance with good

industrial hygiene and safety practices.

Conditions for Safe Storage, Including Any Incompatibilities:

Store according to label and/or product insert

information. Store away from oxidizing agents and acids.

Specific End Use: Pharmaceuticals.



## 8. Exposure Controls/Personal Protection

#### **Occupational Exposure Guidelines:**

Common or Chemical Name	Employee Exposure Limits		
Levofloxacin	Not established.		

Engineering Controls: Engineering controls should be used as the primary

means to control exposures.

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.

**Eyes Protection:** Not required for the normal use of this product. Safety

glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the

work area.

**Hand Protection:** Not required for the normal use of this product.

Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should

be avoided due to the risk of latex allergy.

**Skin Protection:** Not required for the normal use of this product. Wear

protective laboratory coat, apron, or disposable garment

when working with large quantities.



## 9. **Physical and Chemical Properties**

**Physical State/Color:** Clear, yellow to greenish-yellow liquid solution.

Odor: No data available.
Odor Threshold: No data available.

**pH:** 3.8 to 5.8.

**Melting Point:** No data available.

Freezing Point: Aqueous. Boiling Point: Aqueous.

Flash Point:

Evaporation Rate:

Flammability (solid, gas):

Flammability Limit - Lower:

Flammability Limit - Upper:

No data available.

No data available.

No data available.

No data available.

Vapor Pressure: Aqueous.

Vapor Density:No data available.Relative Density:No data available.

**Solubility(ies):** From pH 0.6 – 5.8, approximately 100 mg/mL.

**Partition Coefficient** 

(n-octanol/water):No data available.Auto-Ignition Temperature:No data available.Decomposition Temperature:No data available.Viscosity:No data available.

## 10. Stability and Reactivity

**Reactivity:** No data available.

Chemical Stability: Stable under recommended storage conditions.

Possibility of Hazardous Reactions: No data available.

Conditions to Avoid (e.g., static

**discharge, shock, or vibration):** Prolonged light exposure.

Incompatible Materials: No data available.

**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

## Information on the Likely Routes of Exposure:

**Inhalation:** May cause irritation to the respiratory system.

**Ingestion:** May cause irritation.

**Skin Contact:** May cause skin irritation.

**Eye Contact:** May cause irritation.



Symptoms Related to the Physical,

**Chemical and Toxicological** 

Characteristics:

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

Delayed and Immediate Effects of

**Exposure:** 

No data available.

**Acute Toxicity:** 

Compound	Percent	Species	Route	Type	Dose
Levofloxacin	100%	Rat	Oral	LD <sub>50</sub>	1,478 mg/kg
Levofloxacin	100%	Mouse	Oral	LD <sub>50</sub>	1,803 mg/kg
Levofloxacin	100%	Monkey	Oral	LD <sub>50</sub>	>250 mg/kg
		(Female)			

Acute Toxicity – Dermal:

Acute Toxicity – Inhalation:

Corrosivity:

No data available.

No data available.

**Dermal Irritation:** 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.

**Eye Irritation:** 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.

**Toxicokinetics/Metabolism:** No data available.

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.

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.



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.

National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on

Cancer (IARC):

Not considered to be a carcinogen.

Occupational Safety and Health

Administration (OSHA): Not considered to be a carcinogen.

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. Levelloyacin

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.

**Aspiration Hazard:** None anticipated from normal handling of this product.

## 12. <u>Ecological Information</u>

#### **Ecotoxicity**

#### Aquatic:

Compound	Species	Test Type	Dose
Levofloxacin	Microcystis aeruginosa (cyanobacterium)	$EC_{50}$	7.9 mcg/L
Levofloxacin	Lemma minor (duckweed)	$EC_{50}$	51 mcg/L
Levofloxacin	Pseudokirchmeriella subcapitata	EC <sub>50</sub>	7.4 mg/L
	(green algae)		
Levofloxacin	Daphnia magna (48-hour survival, static	LC <sub>50</sub> (48Hr)	>10 mg/L
	with renewal)		
Levofloxacin	Fish – Fathead Minnows (7-day early life	LC <sub>50</sub> (7days)	>10 mg/L
	stage survival and growth)		

Terrestrial:

Persistence and Degradability:

Bioaccumulative Potential:

Mobility in Soil:

Mobility in Environment:

Other Adverse Effects:

No data available.

No data available.

No data available.

No data available.

## 13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.



# 14. <u>Transport Information</u>

UN Number: UN 3082.

**UN Proper Shipping Name:** Environmentally hazardous substance, liquid, n.o.s.

(Levofloxacin Hemihydrate).

Transport Hazard Class(es): 9.

Packing Group: III.

**Department of Transportation:** Regulated.

**International Air Transport** 

Association (IATA): Regulated.

**International Maritime Dangerous** 

Good (IMDG): Regulated.

**Transport Comments:** This material is not regulated as hazardous material for

ground transport under the DOT hazardous materials

regulations.

## 15. Regulatory Information

**US Federal Regulations:** 

**Toxic Substance Control Act** 

(TSCA): Not listed.

**CERCLA Hazardous Substance** 

and Reportable Quantity: Not listed.

SARA 313: Not listed. SARA 302: Not listed.

**State Regulations** 

California Proposition 65: Not listed.

### 16. Other Information

Not made with natural rubber latex.

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**Revision Number: 1** 

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