



Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Levofloxacin USP

30-4711

Section 1: Identification

Product Name Levofloxacin USP
Commercial Name N/A
Product Use Broad-spectrum antibiotic with activity against many gram-positive and gram-negative organisms.
Restrictions On Use Not available
Product Code 30-4711
Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: Acute Toxicity, oral Category 4
CFR 1910.1200
Signal Word DANGER
Hazard Statement(s) Harmful if swallowed. May cause allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Suspected of damaging the unborn child. May cause harm to breast fed children.

Pictogram(s) or Symbol(s)



Precautionary Statement(s):

Prevention Wash thoroughly after handling.
Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth.
Storage Not available.
Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Section 3: Composition/Information on Ingredients

Substance/Mixture Mixture
Components Levofloxacin
% By Weight Levofloxacin: >98%
CAS# 138199-71-0
Molecular Weight 370.3800
Chemical Formula C₁₈H₂₀FN₃O₄·½H₂O
Synonym(s) C18- H₂O -F -N₃- 04.1/21120, 7H- pyrido[1, 2, 3- de] -1, 4- benzoxazine -6- carboxylic acid, " " , 7H- pyrido[1, 2, 3- de] -1, 4- benzoxazine -6- carboxylic acid, "2, 3- dihydro -9- fluoro -3- methyl- 10 -(4- methyl -1- piperazinyl) -7 -oxo - , hemihydrate, (S) - " , "2, 3- dihydro-9-fluoro-3- methyl- 10 -(4- methyl- 1 -pipe razinyl) -7 -oxo - , hemihydrate, (S) " , DR3355, (-)- ofloxacin, (S)- ofloxacin, Levaquin, RWJ- 25213, "fluoroquinolone / fluoroquinoline fluorinated quinolone/ quinoline " , "antibiotic/antibacteriaV antibiotic ".

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
Levofloxacin Hemihydrate	100986-85-4	>98	N/A	N/A
	N/A	N/A	N/A	N/A

Section 4: First-Aid Measures

Inhalation	Move to fresh air. Call a physician if symptoms develop or persist.
Skin Contact	Wash off with soap and water. If skin irritation occurs: Get medical advice/attention.
Eye Contact	Rinse cautiously with water for several minutes. Get medical attention if irritation develops and persists
Ingestion	Rinse mouth thoroughly. If ingestion of a large amount does occur, call a poison control center immediately.
Symptoms/Effects	
Acute	Pharmacologically active material. Occupational exposure may cause physiological effects.
Delayed	Pharmacologically active material. Occupational exposure may cause physiological effects.

Immediate Medical Attention

Provide general supportive measures and treat symptomatically. Administer activated charcoal as a slurry. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, administer phenobarbital or propofol. Monitor for hypotension, dysrhythmias, respiratory depression, and need for endotracheal intubation. Evaluate for hypoglycemia, electrolyte disturbances, and hypoxia. For moderate or severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against *Clostridium difficile* colitis. Hemodialysis is unlikely to be of benefit, Peritoneal dialysis is not effective.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable Extinguishing Media

N/A

Products of Combustion

No unusual fire or explosion hazards noted

Firefighters Special Equipment and Precautions

Wear suitable protective equipment. Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use standard firefighting procedures and consider the hazards of other involved materials.

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Avoid inhalation of dust from the spilled material. Ensure adequate ventilation. Wear appropriate protective equipment and clothing during clean-up. For personal protection, see section 8 of the SDS. Methods and materials for containment and cleaning up: Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS. Environmental precautions: Avoid discharge into drains, water courses or onto the ground.

Section 7: Handling and Storage

Handling: As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Storage: Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	Not available.
Engineering Controls	For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Personal Protection

Eye/face protection: Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available. Skin protection Hand protection: Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Other: Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors. Respiratory protection: Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls. Thermal hazards: Wear appropriate thermal protective clothing, when necessary. General hygiene consideration: Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

Section 9: Physical and Chemical Properties

Appearance	Yellow. Powder. Solid.		
Odor	Odorless.		
Odor Threshold	N/A		
Melting Point	435.2 - 444.2 °F (224 - 229 °	pH	N/A
Freezing Point	N/A	Vapor Pressure	N/A
Boiling Point/Range	N/A	Vapor Density	>1
Decomposition temperature	N/A	Viscosity	N/A
Partition Coefficient: n-octanol/water	N/A	Evaporation Rate	N/A
Flash Point	N/A	Autoignition temperature	N/A
Flammability	N/A	Flammability or Explosive Limits:	
		Lower	N/A
		Upper	N/A
Solubility(ies)	Slightly soluble in water.		
Other	Chloroform: Freely soluble. Methanol: Sparingly soluble. Ethanol: Slightly soluble Chemical family Fluoroquinolone. Molecular formula C18H20FN3O4 Molecular weight 370.38		

Section 10: Stability and Reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical Stability	Material is stable under normal conditions
Hazardous Polymerization	No dangerous reaction known under conditions of normal use
Conditions to Avoid	Contact with incompatible materials.
Incompatible Materials	Oxidizing agents.
Hazardous Decomposition Products	NOx. F-. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

Section 11: Toxicological Information

RTECS	N/A
Acute Toxicity	Harmful if swallowed. Oral LD50 Mouse 1803 mg/kg Rat 1478 mg/kg
Skin Corrosion/Irritation	Not available
Serious Eye Damage/Irritation	Not available
Respiratory or Skin Sensitization	Not available
Germ Cell Mutagenicity	Not available
Carcinogenicity	Not available
Reproductive Toxicity	Not available
Routes of Entry	Ingestion.

Symptoms Related to Exposure

Fluoroquinolones: Gastrointestinal disturbances. Altered taste. Dizziness. Drowsiness. Headache. Sleep disturbances. Slurred speech. Tremors. Restlessness. Convulsions. Skin rash. Joint tenderness or swelling. Numbness or tingling of hands or feet.

Potential Health Effects

Not available

Target Organ(s)

Not available.

Section 12: Ecological Information**Ecotoxicity**

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and Degradability

No data available

Bioaccumulative Potential

No data available

Mobility in Soil

No data available

Other Adverse Effects

No data available

Section 13: Disposal Considerations**Waste Disposal**

Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste. The waste code should be assigned in discussion between the user, the producer and the waste disposal company. Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Disposal of Container

Since emptied containers may retain product residue, follow label warnings even after container is emptied. Empty containers should be taken to an approved waste handling site for recycling or disposal.

Other Considerations

Not available

Section 14: Transport Information**DOT Classification**

Not regulated.

Section 15: Regulatory Information**Regulations**

US federal regulations: This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200 TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D) Not regulated. CERCLA Hazardous Substance List (40 CFR 302.4) Not listed. SARA 304 Emergency release notification Not regulated. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052) Not regulated. SARA 302 Extremely hazardous substance Superfund Amendments and Reauthorization Act of 1986 (SARA) Not listed. YesSARA 311/312 Hazardous chemical Acute toxicity (any route of exposure) Classified hazard categories SARA 313 (TRI reporting) Not regulated. Other federal regulations Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List Not regulated. Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130) Not regulated. Not regulated. Safe Drinking Water Act (SDWA) US state regulations California Proposition 65 California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to www.P65Warnings.ca.gov.

Other

N/A



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Section 16: Other Information

N/A