

Levofloxacin Injection in 5% Dextrose

Safety Data Sheet

According to Federal Register / Vol. 89, No. 98 / Monday, May 20, 2024 / Rules and Regulations
Date of Issue: 06/16/2025

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Levofloxacin Injection in 5% Dextrose

1.2 Recommended Use and Restrictions on Use

Use Of The Substance/Mixture : Fluoroquinolone antibiotic for intravenous administration

Restrictions On Use : No additional information available

1.3. Name, Address, and Telephone of the Responsible Party

WG Critical Care, LLC.

120 Route 17 North, Suite 115

Paramus, NJ 07652 USA

+ 1-888-493-0861

www.wgcriticalcare.com/

Email: wgccquality@wgcriticalcare.com

1.4. Emergency Telephone Number

Emergency Number : +1-866-562-4708 (ProPharma)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US Classification

Respiratory sensitization, Category 1

H334

Skin sensitization, Category 1

H317

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: H317 - May cause an allergic skin reaction.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary Statements (GHS-US)

: P261 - Avoid breathing mist, spray, or vapors.

P272 - Contaminated work clothing must not be allowed out of the workplace.

P280 - Wear eye protection, protective gloves and clothing.

P284 - In case of inadequate ventilation wear respiratory protection.

P302+P352 - If on skin: Wash with plenty of soap and water.

P304+P340 - If inhaled: Remove person to fresh air and keep at rest in a position comfortable for breathing.

P321 - Specific treatment (see Section 4 of this Safety Data Sheet).

P333+P313 - If skin irritation or rash occurs: Get medical advice or attention.

P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.

P362+P364 - Take off contaminated clothing and wash it before reuse.

P501 - Dispose of contents and/or container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulations.

2.3 Hazards associated with known or reasonably anticipated uses

This product is a pharmaceutical product designed for administration to a patient by a qualified medical professional. No other uses are anticipated. If this product is used in unforeseeable chemical processes and not used as intended or reasonable, the hazards listed in Section 2.3 cannot cover all chemistries. Therefore, a Process Hazard Analysis (PHA) or other hazard assessment for additional specific end uses should be performed to ensure that hazards are fully understood, and adequate safety measures are in place. See Section 10 for relevant reactivity and stability information.

2.4. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.5. Unknown Acute Toxicity (GHS-US)

No data available

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Synonyms	Product Identifier	%*	GHS US classification
Water	AQUA	(CAS-No.) 7732-18-5	80 – 100	Not classified.
Dextrose monohydrate	.alpha.-d-Glucopyranose monohydrate	(CAS-No.) 14431-43-7	3 – 7	Comb. Dust
Levofloxacin	7H-Pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid, 9-fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-, (3S)- / Levofloxacin anhydrous / (S)-9-Fluoro-3-methyl-10-(4-methylpiperazin-1-yl)-7-oxo-2,3-dihydro-7H-[1,4]oxazino[2,3,4-ij]quinoline-6-carboxylic acid	(CAS-No.) 100986-85-4	0.1 – 1	Acute Tox. 4 (Oral), H302 Resp. Sens. 1, H334 Skin Sens. 1, H317
Hydrochloric acid [^] [^] - pH adjustment only	Hydrogen chloride / Muriatic acid / HYDROCHLORIC ACID / Hydrochloric acid, anhydrous	(CAS-No.) 7647-01-0	< 0.1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318 STOT SE 3, H335 Aquatic Acute 2, H401
Sodium hydroxide [^] [^] - pH adjustment only	Caustic soda / Sodium hydroxide (Na(OH)) / SODIUM HYDROXIDE / LYE / Lye solution	(CAS-No.) 1310-73-2	< 0.1	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Skin Corr. 1A, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402

* - The actual concentration of ingredient(s) is withheld as a trade secret in accordance with the OSHA Hazard Communication Standard 29 CFR 1910.1200. Percentages are listed in weight-by-weight percentage (w/w%) for liquid and solid ingredients. Gas ingredients are listed in volume-by-volume percentage (v/v%). Full text of H-phrases: see section 16.

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible). If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Wash affected area with soap and water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

First-aid Measures After Eye Contact: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for at least 15 minutes. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: May cause allergy or asthma symptoms or breathing difficulties if inhaled. Skin sensitization.

Symptoms/Injuries After Inhalation: Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: Inhalation may cause allergic respiratory reaction with asthma-like symptoms and difficulty breathing. Repeated and prolonged exposure may cause an allergic skin reaction.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand. Treat needlestick exposures symptomatically to include monitoring for anaphylaxis.

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SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Solutions do not burn. Use extinguishing media appropriate for surrounding fire.

Unsuitable Extinguishing Media: None known.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Product is not flammable.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Oxides of carbon, nitrogen, and sodium, fluorinated compounds, chlorine compounds.

Other Information: No additional information available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe vapor, mist or spray. Do not get in eyes, on skin, or on clothing. If product is biologically contaminated, follow all institutional protocols concerning the potential release of pathogens.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Absorb and/or contain spill with inert material. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Material may be biologically contaminated with pathogenic organisms during use.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray. Contaminated sharps should be handled with care and discarded immediately or as soon as possible in containers that are closable, puncture-resistant, leak proof on sides and bottoms, and appropriately labeled. Contact your local health department for referral to a syringe disposal program. In hospital and workplace settings, contaminated sharps are to be handled in accordance with established protocols.

Handling Temperature: See Section 7.2, Storage, for suggested temperature range.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

Storage Temperature: 20 – 25 °C (68 – 77 °F). DO NOT FREEZE!

7.3. Specific End Use(s)

Fluoroquinolone antibiotic for intravenous administration

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Hydrochloric acid (7647-01-0)		
USA ACGIH	ACGIH OEL C	2 ppm
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL C	7 mg/m³
USA NIOSH	NIOSH REL C	5 ppm
USA IDLH	IDLH	50 ppm
USA OSHA	OSHA PEL C	7 mg/m³
USA OSHA	OSHA PEL C	5 ppm
Sodium hydroxide (1310-73-2)		
USA ACGIH	ACGIH OEL C	2 mg/m³
USA NIOSH	NIOSH REL C	2 mg/m³
USA IDLH	IDLH	10 mg/m³
USA OSHA	OSHA PEL TWA	2 mg/m³

8.2. Exposure Controls

Appropriate Engineering Controls	: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.
Personal Protective Equipment	: Gloves. Protective clothing. Protective goggles or glasses. Insufficient ventilation: wear respiratory protection.
	
Materials for Protective Clothing	: Chemically resistant materials and fabrics.
Hand Protection	: Wear protective gloves.
Eye and Face Protection	: Chemical goggles or safety glasses.
Skin and Body Protection	: Wear suitable protective clothing.
Respiratory Protection	: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
Thermal Hazard Protection	: Not applicable.
Environmental Exposure Controls	: Avoid unnecessary release into the environment.
Other Information	: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Liquid
Color	: Clear yellow to greenish yellow liquid
Odor	: No data available
pH	: 3.8 – 5.8
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: Water: Miscible/soluble
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity, Kinematic	: No data available

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Particle characteristics : No data available

9.2. Other Information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability

Stable under recommended handling and storage conditions (see section 7).

10.3. Possibility of Hazardous Reactions, Including those Associated with Foreseeable Emergencies

Hazardous polymerization will not occur.

10.4. Conditions to Avoid

Direct sunlight, extremely high or low temperatures, and incompatible materials. Under fire conditions, may generate oxides of carbon, nitrogen, and sodium, fluorinated compounds, and chlorine compounds.

10.5. Incompatible Materials

Strong acids, strong bases, strong oxidizers.

10.6. Hazardous Decomposition Products

Thermal decomposition may produce: Oxides of carbon, nitrogen, and sodium, fluorinated compounds, and chlorine compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Likely Routes of Exposure: Dermal, Ingestion, Inhalation, Eye contact

Acute Toxicity (Oral): Not classified.

Acute Toxicity (Dermal): Not classified.

Acute Toxicity (Inhalation): Not classified.

Levofloxacin (100986-85-4)	
LD50 Oral Rat	1478 mg/kg
Hydrochloric acid (7647-01-0)	
LD50 Oral Rat	238 – 277 mg/kg (Source: JAPAN_GHS)
LD50 Dermal Rabbit	> 5010 mg/kg (Source: JAPAN_GHS)
LC50 Inhalation Rat	1.68 mg/l (Exposure time: 1 h Source: JAPAN_GHS)
Sodium hydroxide (1310-73-2)	
LD50 Oral Rat	325 mg/kg
LD50 Dermal Rabbit	1350 mg/kg (Source: NLM_HSDB)
Water (7732-18-5)	
LD50 Oral Rat	> 90 ml/kg (Source: FOOD_JOURN)

Skin Corrosion/Irritation: Not classified.

pH: 3.8 – 5.8

Serious Eye Damage/Irritation: Not classified.

pH: 3.8 – 5.8

Respiratory or Skin Sensitization: May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ Cell Mutagenicity: Not classified.

Carcinogenicity: Not classified.

Hydrochloric acid (7647-01-0)	
IARC group	3

Reproductive Toxicity: Not classified.

Specific Target Organ Toxicity (Single Exposure): Not classified.

Specific Target Organ Toxicity (Repeated Exposure): Not classified.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

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Chronic Symptoms: Inhalation may cause allergic respiratory reaction with asthma-like symptoms and difficulty breathing. Repeated and prolonged exposure may cause an allergic skin reaction.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity	
Hydrochloric acid (7647-01-0)	
LC50 Fish 1	7.45 mg/l (Species: Oncorhynchus mykiss - Exposure time: 96h)
Sodium hydroxide (1310-73-2)	
LC50 Fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])
EC50 - Crustacea [1]	40 mg/l
12.2. Persistence and Degradability	
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Persistence and Degradability	Expected to be biodegradable.
12.3. Bioaccumulative Potential	
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Bioaccumulative Potential	Not expected to bioaccumulate.
12.4. Mobility in Soil	
Levofloxacin Injection in 5% Dextrose	
Ecology - Soil	Adsorbs into the soil. Product partially leaches if exposed to water.
12.5. Other Adverse Effects	
Other Adverse Effects	: None known.
Other Information	: Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods	
Waste Treatment Methods: Incineration is the preferred method for disposal of waste product.	
Sewage Disposal Recommendations: Do not dispose of waste into sewer. Do not empty into drains.	
Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.	
Additional Information: Biologically contaminated materials should be incinerated.	
Ecology - Waste Materials: Avoid unnecessary release into the environment.	

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.	
14.1. In Accordance with DOT	
Not regulated for transport	
14.2. In Accordance with IMDG	
Not regulated for transport	
14.3. In Accordance with IATA	
Not regulated for transport	

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations	
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SARA Section 311/312 Hazard Classes	Health hazard - Respiratory or skin sensitization
Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
Listed on the United States SARA Section 302	
Subject to reporting requirements of United States SARA Section 313	
CERCLA RQ	5000 lb
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1 % (acid aerosols including mists, vapors, gas, fog, and other airborne forms of any particle size)
Sodium hydroxide (1310-73-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active	
CERCLA RQ	1000 lb

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Water (7732-18-5)
Listed on the United States TSCA (Toxic Substances Control Act) inventory - Status: Active

15.2. US State Regulations

Hydrochloric acid (7647-01-0)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List
Sodium hydroxide (1310-73-2)
U.S. - New Jersey - Right to Know Hazardous Substance List
U.S. - Pennsylvania - RTK (Right to Know) List
U.S. - Massachusetts - Right To Know List
U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision	: 06/16/2025
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

H290	May be corrosive to metals
H302	Harmful if swallowed
H312	Harmful in contact with skin
H314	Causes severe skin burns and eye damage
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335	May cause respiratory irritation
H401	Toxic to aquatic life
H402	Harmful to aquatic life

Glossary of Data Source Abbreviations

ATSDR: Agency for Toxic Substances and Disease Registry (U.S. Department of Health and Human Services)	FOOD_JOURN: Food Research Journal (1956)
AU_WES: Australia WES	IARC: The International Agency for Research on Cancer
CHEMVIEW: ChemView (U.S. Environmental Protection Agency)	IDLH: National Institute for Occupational Health and Safety Immediately Dangerous to Life or Health Value Profiles
EC_RAR: European Commission Renewal Assessment Report	IUCIID: International Uniform Chemical Information Database
EC_SCOEL: European Commission Scientific Committee on Occupational Exposure Limits	JAPAN_GHS: Japan GHS Basis for Classification Data
ECETOC: European Centre for Ecotoxicology and Toxicology of Chemicals Reports	JP_J-CHECK: Japan J-Check
ECHA_API: European Chemicals Agency API	KR_NIER: South Korea National Institute of Environmental Research Evaluations
ECHA_RAC: ECHA Committee for Risk Assessment	NICNAS: Australia National Industrial Chemicals Notification and Assessment Scheme
EFSA: European Food Safety Authority	NIOSH: National Institute for Occupational Health and Safety (U.S. Department of Health and Human Services)
EPA: U.S. Environmental Protection Agency	NLM_CIP: National Library of Medicine ChemID plus database
EPA_AEGL: Acute Exposure Guideline Levels (U.S. Environmental Protection Agency)	NLM_HSDB: National Library of Medicine Hazardous Substance Data Bank
EPA_FIFRA: Federal Insecticide, Fungicide, and Rodenticide Act Reregistration Eligibility Decision (U.S. Environmental Protection Agency)	NLM_PUBMED: National Library of Medicine PubMed database
EPA_HPV: High Production Volume Chemicals (U.S. Environmental Protection Agency)	NTP: National Toxicology Program
EPA_TRED: Risk Assessment for Tolerance Reassessment Eligibility Decision (U.S. Environmental Protection Agency)	NZ_CCID: New Zealand Chemical Classification and Information Database
EU_CLH: European Union Harmonised Classification and Labelling Proposal	OECD_EHSP: Environment, Health, and Safety Publication (Organisation for Economic Co-operation and Development)
EU_RAR: European Union Risk Assessment Report	OECD_SIDS: Screening Information Data Sets (Organisation for Economic Co-operation and Development)
	WHO: World Health Organization

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.