

Levofloxacin in Dextrose Injection

Safety Data Sheet

SECTION 1: Identification

1.1. Identification

Product name : Levofloxacin in Dextrose Injection
Other means of identification : (250 mg/50 mL) NDC 55150-243-46, (500 mg/100 mL) NDC 55150-244-47, (750 mg/150 mL) NDC 55150-245-52

1.2. Relevant identified uses of the substance or mixture and uses advised against

Use of the substance/mixture : Pharmaceutical

1.3. Details of the supplier of the safety data sheet

AuroMedics
6 Wheelling Road
Dayton, NJ 08810
T 609-642-1136

1.4. Emergency telephone number

Emergency number : 888-238-7880, option 2

SECTION 2: Hazard(s) identification

2.1. Classification of the substance or mixture

Classification (GHS-US)

Skin Irrit. 2 H315
Eye Irrit. 2A H319
Resp. Sens. 1 H334
Skin Sens. 1 H317
Repr. 2 H361
Lact. H362

Full text of classification categories and H statements : see section 16

2.2. Label elements

GHS-US labeling

Hazard pictograms (GHS-US) :



GHS08

Signal word (GHS-US) :

Danger

Hazard statements (GHS-US) :

H315 - Causes skin irritation
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H361 - Suspected of damaging fertility or the unborn child
H362 - May cause harm to breast-fed children

Precautionary statements (GHS-US) :

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P272 - Contaminated work clothing must not be allowed out of the workplace
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P284 - [In case of inadequate ventilation] wear respiratory protection
P302+P352 - If on skin: Wash with plenty of water
P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing
P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P308+P313 - If exposed or concerned: Get medical advice/attention
P333+P313 - If skin irritation or rash occurs: Get medical advice/attention
P337+P313 - If eye irritation persists: Get medical advice/attention
P342+P311 - If experiencing respiratory symptoms: Call a poison center/doctor/...
P362+P364 - Take off contaminated clothing and wash it before reuse

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P363 - Wash contaminated clothing before reuse
P405 - Store locked up
P501 - Dispose of contents/container in accordance with local/regional/national/international regulations.

2.3. Other hazards

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/information on ingredients

3.1. Substance

Not applicable

3.2. Mixture

Name	Product identifier	%	Classification (GHS-US)
Water	(CAS No) 7732-18-5	> 90	Not classified
.alpha.-D-Glucopyranose, monohydrate	(CAS No) 14431-43-7	5	Not classified
Hydrochloric acid	(CAS No) 7647-01-0	< 1	Acute Tox. 3 (Inhalation:gas), H331 Skin Corr. 1A, H314
Sodium hydroxide	(CAS No) 1310-73-2	< 1	Met. Corr. 1, H290 Skin Corr. 1A, H314 Eye Dam. 1, H318
Levofloxacin	(CAS No) 100986-85-4	0.5	Acute Tox. 4 (Oral), H302 Resp. Sens. 1, H334 Skin Sens. 1, H317 Lact., H362 Repr. 2, H361

Full text of classification categories and H statements : see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to non-contaminated area. If not breathing, give artificial respiration.
First-aid measures after skin contact : Wash contact areas with soap and water.
First-aid measures after eye contact : Rinse with water. Get medical attention if irritation develops and persists.
First-aid measures after ingestion : Rinse mouth thoroughly. No harmful effects expected in amounts likely to be ingested by accident.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/injuries after inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Symptoms/injuries after skin contact : Causes skin irritation.
Symptoms/injuries after eye contact : Direct contact with eyes causes serious irritation.
Symptoms/injuries after ingestion : May cause discomfort if swallowed.

4.3. Indication of any immediate medical attention and special treatment needed

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Use extinguishing media appropriate for surrounding fire.
Unsuitable extinguishing media : None.

5.2. Special hazards arising from the substance or mixture

Fire hazard : None known.

5.3. Advice for firefighters

Protection during firefighting : Use standard firefighting procedures and consider the hazards of other involved materials.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : No special measures required.

6.1.1. For non-emergency personnel

No additional information available

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6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent entry to sewers and public waters.

6.3. Methods and material for containment and cleaning up

For containment : Stop the flow of material, if this is without risk.
Methods for cleaning up : Absorb spillage with suitable absorbent material. Place in a suitable container and dispose according to local, state and federal regulations.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Avoid prolonged and repeated contact. Wear appropriate personal protective equipment. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep container tightly closed.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Levofloxacin (100986-85-4)		
Not applicable		
.alpha.-D-Glucopyranose, monohydrate (14431-43-7)		
Not applicable		
Hydrochloric acid (7647-01-0)		
ACGIH	ACGIH Ceiling (ppm)	2 ppm
OSHA	OSHA PEL (Ceiling) (mg/m ³)	7 mg/m ³
OSHA	OSHA PEL (Ceiling) (ppm)	5 ppm
IDLH	US IDLH (ppm)	50 ppm
NIOSH	NIOSH REL (ceiling) (mg/m ³)	7 mg/m ³
NIOSH	NIOSH REL (ceiling) (ppm)	5 ppm
Sodium hydroxide (1310-73-2)		
ACGIH	ACGIH Ceiling (mg/m ³)	2 mg/m ³
OSHA	OSHA PEL (TWA) (mg/m ³)	2 mg/m ³
IDLH	US IDLH (mg/m ³)	10 mg/m ³
NIOSH	NIOSH REL (ceiling) (mg/m ³)	2 mg/m ³
Water (7732-18-5)		
Not applicable		

8.2. Exposure controls

Appropriate engineering controls : Local exhaust and general ventilation must be adequate to meet exposure standards.
Hand protection : Use neoprene or rubber gloves.
Eye protection : In case of dust production: protective goggles.
Skin and body protection : Wear suitable working clothes.
Respiratory protection : Wear NIOSH approved respirator when handling.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear.

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Color	: Yellow or Greenish yellow
Odor	: Odorless
Odor threshold	: 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
Relative evaporation rate (butyl acetate=1)	: No data available
Flammability (solid, gas)	: No data available
Explosion limits	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Vapor pressure	: No data available
Relative density	: No data available
Relative vapor density at 20 °C	: No data available
Solubility	: No data available
Log Pow	: No data available
Log Kow	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

The product is stable at normal handling and storage conditions.

10.3. Possibility of hazardous reactions

Will not occur.

10.4. Conditions to avoid

Excessive heat. Freezing.

10.5. Incompatible materials

None known.

10.6. Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Levofloxacin (100986-85-4)	
LD50 oral rat	1478 mg/kg
ATE US (oral)	500.000 mg/kg body weight

Hydrochloric acid (7647-01-0)	
LD50 oral rat	238 - 277 mg/kg
LD50 dermal rabbit	> 5010 mg/kg
LC50 inhalation rat (mg/l)	1.68 mg/l (Exposure time: 1 h)

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Hydrochloric acid (7647-01-0)	
ATE US (gases)	781.000 ppmV/4h
Sodium hydroxide (1310-73-2)	
LD50 dermal rabbit	1350 mg/kg
ATE US (dermal)	1350.000 mg/kg
Water (7732-18-5)	
LD50 oral rat	> 90 ml/kg

Skin corrosion/irritation	: Causes skin irritation. pH: 3.8 - 5.8
Serious eye damage/irritation	: Causes serious eye irritation. 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 - Not classifiable

Reproductive toxicity	: Suspected of damaging fertility or the unborn child. May cause harm to breast-fed children.
Specific target organ toxicity (single exposure)	: Not classified
Specific target organ toxicity (repeated exposure)	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Sodium hydroxide (1310-73-2)	
LC50 fish 1	45.4 mg/l (Exposure time: 96 h - Species: Oncorhynchus mykiss [static])

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Other adverse effects

Effect on the global warming : No known effects from this product.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste disposal recommendations : Dispose of contents/container in accordance with local/regional/national/international regulations.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Not applicable

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SECTION 15: Regulatory information

15.1. US Federal regulations

Hydrochloric acid (7647-01-0)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory Listed on the United States SARA Section 302 Subject to reporting requirements of United States SARA Section 313	
SARA Section 302 Threshold Planning Quantity (TPQ)	500 lb (gas only)
SARA Section 313 - Emission Reporting	1.0 % (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	
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State regulations

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

SECTION 16: Other information

Full text of H-phrases:

Acute Tox. 3 (Inhalation:gas)	Acute toxicity (inhalation:gas) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Lact.	Reproductive toxicity (Lact.)
Met. Corr. 1	Corrosive to metals Category 1
Repr. 2	Reproductive toxicity Category 2
Resp. Sens. 1	Respiratory sensitisation Category 1
Skin Corr. 1A	Skin corrosion/irritation Category 1A
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization Category 1
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H318	Causes serious eye damage
H319	Causes serious eye irritation
H331	Toxic if inhaled
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H361	Suspected of damaging fertility or the unborn child
H362	May cause harm to breast-fed children

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