SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Levofloxacin 5 mg/mL in 5% Dextrose**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	July 08, 2013
SDS Revision Date:	June 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Skin Sensitization. Category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May cause an allergic skin reaction.
May cause harm to breast-fed children.

Precautionary Statements:
Obtain special instructions before use.
Do not breathe dust/fume/gas/mist/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/spray.
Avoid contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves/protective clothing/eye protection/face protection.
In case of inadequate ventilation wear respiratory protection.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
Specific treatment (see ... on this label).
If skin irritation or rash occurs: Get medical advice/attention.
If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.
Take off contaminated clothing and wash it before reuse.
Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.

Emergency Overview:
This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Irritant. Potential Sensitizer Reproductive effects.

Route of Exposure:
Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

- Eye: Contact with eyes may cause irritation.
- Skin: May cause skin irritation.
  May cause skin sensitization, an allergic reaction, which becomes evident on reexposure to this material.
- Inhalation: Harmful by inhalation. May cause irritation of respiratory tract.
  May cause respiratory sensitization with asthma-like symptoms in susceptible individuals.
- Ingestion: Harmful if swallowed. Ingestion can cause nausea, vomiting, diarrhea and gastrointestinal irritation.

Target Organs: Central nervous system (CNS), Kidney, Eyes

Aggravation of Pre-Existing Conditions:
May aggravate pre-existing respiratory disorders, allergy, eczema, or skin conditions.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Glucose Monohydrate	14431-43-7	5 %	
Levofloxacin	100986-85-4	0.5 %	

Hydrochloric Acid	7674-01-0	As needed to adjust pH
Sodium Hydroxide	1310-73-2	As needed to adjust pH
Water for Injection	7732-18-5	

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	This material will settle out of the air.
Methods for cleanup:	Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. However, brief exposure up to 40°C (104°F) does not adversely affect the product. Avoid excessive heat and protect from freezing and light.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.

Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

Hydrochloric Acid :

Guideline ACGIH:	TLV-STEL: 2 ppm(ceiling)

Sodium Hydroxide :

Guideline ACGIH:	TLV-STEL: C 2 mg/m3
Guideline OSHA:	OSHA-TWA: 2 mg/m3

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	Not established.
Molecular Formula:	$C_{18}H_{20}FN_3O_4$ * ½-H_20
Molecular Weight:	361.4
Flash Point:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Levofloxacin :

RTECS Number:	UU8815550
Ingestion:	Oral - Rat LD50: 1478 mg/kg [Sense Organs and Special Senses (Eye) - Ptosis Behavioral - Somnolence (general depressed activity) Lungs, Thorax, or Respiration - Respiratory depression] Oral - Mouse LD50: 1803 mg/kg [Sense Organs and Special Senses (Eye) - Ptosis Behavioral - Somnolence (general depressed activity) Lungs, Thorax, or Respiration - Respiratory depression]
Other Toxicological Information:	Intravenous. - Rat TDLo: 100 mg/kg [Endocrine - Hypoglycemia] Oral - Rat TDLo: 8910 mg/kg [Reproductive - Effects on Newborn - growth statistics (e.g.,%, reduced weight gain)]

Hydrochloric Acid :

RTECS Number:	WC4500000
Eye:	Eye - Rabbit Total particulate/dust (T): 5 mg/30S (RTECS)
Skin:	Administration onto the skin - Human Standard Draize test.: 4 %/24H (RTECS)
Inhalation:	Inhalation - Rat LC50: 3124 ppm/1H [Sense Organs and Special Senses (Olfaction) - effect, not Otherwise specified Sense Organs and Special Senses (Eye) - Iritis] Inhalation - Mouse LC50: 1108 ppm/1H [Sense Organs and Special Senses (Eye) - effect, not Otherwise specified Lungs, Thorax, or Respiration - Respiratory stimulation Skin and Appendages - Dermatitis, other (After systemic exposure)] Inhalation - Rat LC50: 45000 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 8300 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 8300 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - LC50: 0.1 gm/m3 [Details of toxic effects not reported other than lethal dose value] Inhalation - Rat LC50: 60938 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 20487 mg/m3/5M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 7004 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Mouse LC50: 3940 mg/m3/30M [Lungs, Thorax, or Respiration - Acute pulmonary edema] Inhalation - Rat LC50: 3700 ppm/30M [Details of toxic effects not reported other than lethal dose value] Inhalation - Mouse LC50: 2644 ppm/30M [Details of toxic effects not reported other than lethal dose value] (RTECS)

Ingestion:	Oral - Rabbit LD50: 900 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Sodium Hydroxide :

RTECS Number:	WB4900000
Eye:	Eye - Standard Draize test.: 1 %/24H Eye - Rabbit Standard Draize test.: 400 ug Eye - Rabbit Standard Draize test.: 1 % Eye - Rabbit Standard Draize test.: 50 ug/24H Eye - Rabbit Standard Draize test.: 1 mg/24H Eye - Rabbit Total particulate/dust (T): 1 mg/30S (RTECS)
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H Administration onto the skin - Human Standard Draize test.: 2 %/24H (RTECS)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.
IATA Shipping Name:	Non regulated.
IATA UN Number:	Non regulated.
IMDG UN NUmber :	Non regulated.
IMDG Shipping Name :	Non regulated.

SECTION 15 : REGULATORY INFORMATION

Levofloxacin :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

Hydrochloric Acid :

TSCA Inventory Status:	Listed
SARA:	EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical.
Section 302 EHS:	EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 500 Lbs.
Section 304 RQ:	EPCRA (SARA Title III) Section 304 Extremely Hazardous Substances (EHS) Reportable Quantities (RQ) in pounds.: 5,000 Lbs.
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.845(502)

Sodium Hydroxide :

TSCA Inventory Status:	Listed
State Regulations:	Listed in the New Jersey State Right to Know List. Listed in the Pennsylvania State Hazardous Substances List.
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	2
HMIS Fire Hazard:	0
HMIS Reactivity:	1
HMIS Personal Protection:	X

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Disclaimer:

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