	<b>Sagent Pharmaceuticals, Inc.</b>				
	<b>Levofloxacin Injection</b>			<b>Material Safety Data Sheet (MSDS)</b>	
	Issue Date: <b>Jan 16, 2012</b>	MSDS No.: <b>MSDS 050</b>	Version No.: <b>1.0</b>	Form Number: <b>R-SOP-009-F001</b>	Page: <b>1 of 8</b>

### Section 1 - Chemical Product and Company

**Distributor:**


Sagent Pharmaceuticals, Inc.  
1901 N. Roselle Rd, Suite 700  
Schaumburg, IL 60195  
847-908-1600

**Emergency Telephone:** 866-625-1618

<b>Product Identifier:</b>	Levofloxacin
<b>Product Code:</b>	25021-130
<b>Common/Trade Name:</b>	Levaquin
<b>Chemical Name:</b>	(-)-(S)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-benzoxazine-6-carboxylic acid hemihydrate
<b>Chemical Family:</b>	Fluoroquinolone
<b>Product Use:</b>	Pharmaceutical
<b>Product Type:</b>	Regulated Prescription Drug
<b>Container Information:</b>	Vial

### Section 2 - Composition / Information on Ingredients

Ingredient	mg/mL	CAS No.
Levofloxacin	25	100986-85-4
Hydrochloric Acid	q.s. to pH	7647-01-0
Sodium Hydroxide	q.s. to pH	1310-73-2
Water for Injection	q.s. to 1 mL	7732-18-5


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### Section 3 - Hazards Identification

<b>Primary Physical and Health Hazards:</b>	Levofloxacin may be irritating to mucous membranes and respiratory tract.
<b>Routes of Entry:</b>	Ingestion, inhalation, skin and eyes.
<b>Signs &amp; Symptoms of Exposure:</b>	Abnormal taste, headache, allergic reactions, diarrhea and gastrointestinal disturbances.
<b>Chemical Listed as Carcinogen:</b>	<b>NTP: No IARC: No OSHA: No</b>
<b>Medical Conditions Generally Aggravated by Exposure:</b>	Conditions affected by Levofloxacin are severe allergic reaction to an antibiotic known as a fluoroquinolone, or if you are allergic to any of the ingredients in LEVOFLOXACIN

### Section 4 - First Aid Measures

<b>Eye Exposure:</b>	Wash immediate with large amounts of water or normal saline. Keep eyelids open with the finger. Get medical attention and be sure to show the label.
<b>Skin Exposure:</b>	Remove contaminated clothes and shoes immediately. Wash affected area with soap or mild detergent and large amount of water until no evidence of substance remains (15-20 minutes). Get medical attention immediately.
<b>Ingestion:</b>	If swallowed, wash mouth with water, provided person is conscious. Get medical attention immediately.
<b>Injection:</b>	See patient package insert in shipping carton for complete information.
<b>Inhalation:</b>	Avoid breathing dusts that may be generated by handling of the product. Remove the person from the exposed area to fresh air immediately. Get medical advice if adverse symptoms appear.
<b>Notes to Physician:</b>	See patient package insert in shipping carton for complete information.

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**Section 5 - Fire Fighting Measures**

**Flash Point:** Not established

**Auto-ignition Temperature:** Not established

**Flammable Limits in Air:** Lower %: Not established  
Upper %: Not established

**Flammable Limits:** Not established

**Extinguishing Media:** Nebulised water, chemical powder, foam, CO<sub>2</sub>. Use any means suitable for extinguishing surrounding fire.  
Small Fire: carbon dioxide, foam  
Large Fire: fog, foam

**Special Fire Fighting Procedures:** Wear boots, overalls, gloves, eye and face protection and breathing apparatus. Equipment must be conformed with EN criteria and used in highest condition of protection on the basis of the information reported in the previous sub-sections.

**Unusual Fire/Explosion Hazards:** Unsuitable extinguishing media are not known. Adding water to caustic solution generates large amounts of heat.


**Section 6 - Accidental Release Measures**

**Spill:** Collect all of the material scattered on the ground with protective equipment adapted and put it in a clean and dry container. Keep unnecessary and unprotected people away from area of spill. Wear appropriate personal equipment as specified in Section 8.

Spillage to be vacuum cleaned or swept. It should be placed in appropriate container for waste disposal. Avoid raising dust. Area should be ventilated and spill site washed after material pick up is complete.

**Release to Air:** Ventilate area of leak or spill.

**Release to Water:** Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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## Section 7 - Handling and Storage

**General Handling:** Handle away from flames and sources of ignition. Handle in a well ventilated place. Avoid contact with incompatible materials. Store in tight containers in a cool dry place. Wear suitable personal protection equipment (see section 8). Keep the mixture away from drains, surface or ground waters. Do not eat, drink or smoke in the working areas. Wash hands after handling this mixture. Remove contaminated clothing and protective equipment before entering eating areas.

This material should be handled and stored as per label and other instructions to ensure product integrity.

**Waste Disposal Method:** Dispose of in accordance with all applicable Federal, State and local environmental regulations

**Storage Conditions:** Stored at or below 25°C (77°F); however, brief exposure up to 40°C (104°F) does not adversely affect the product. Avoid excessive heat and protect from freezing and light. Follow instructions provided in packaging.

## Section 8 - Exposure Controls / Personal Protection

**Respiratory Protection:** Adequate masks and NIOSH/MSHA approved respirator to be provided in case of powder being blown.


**Eye Protection:** Safety goggles

**Ventilation:** Use a powder filter like P1, P2 and P3. Use only devices approved by NIOSH / MSHA.

**Skin Protection:** Appropriate laboratory apparel to be used to protect exposed skin. Use only in a chemical fume hood.

**Other Protective Equipment:** Select the suitable protective equipment based on the activity of use and possible exposure.

**Additional Exposure Precautions:** Not applicable

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### Exposure Limits


<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Levofloxacin	OSHA	PEL	NE
	ACGIH	TLV	NE
	-----	STEL	NE

### Section 9 - Physical and Chemical Properties

<b>Physical State:</b>	Liquid	<b>Specific Gravity:</b>	Not available
<b>Appearance and Odor:</b>	Clear yellow to clear greenish – yellow solution odorless	<b>Evaporation</b>	Not available
<b>Boiling Point:</b>	Not available	<b>Melting Point:</b>	Not applicable
<b>Vapor Pressure:</b>	Not available	<b>Solubility in Water:</b>	Not applicable
<b>Vapor Density:</b>	Not available	<b>pH:</b>	3.8 - 5.8
		<b>Molecular Weight:</b>	370.38

### Section 10 - Stability and Reactivity

<b>Stability:</b>	Stable under normal condition of temperature and pressure and if stored per package insert.
<b>Incompatibility (Materials to avoid):</b>	Strong oxidizing agents
<b>Hazardous Decomposition:</b>	If heated at high temperatures, decomposes releasing fumes and toxic gases of CO <sub>x</sub> , NO <sub>x</sub> and HF.
<b>Hazardous Polymerization:</b>	Will not occur
<b>Conditions to Avoid:</b>	Heat, moisture, incompatibles.

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### Section 11 - Toxicological Information

**Signs & Symptoms of Exposure:**

Abnormal taste, headache, allergic reactions, diarrhea and gastrointestinal disturbances.

**Acute Toxicity**

Component	Type	Route	Species	Dosage
Levofloxacin	LD <sub>50</sub>	Oral	Rat	503 mg/kg
Levofloxacin	LD <sub>50</sub>	Oral	Mouse	285 mg/kg

### Section 12 - Ecological Information

No applicable ecological information found.

### Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

### Section 14 - Transport Information

**Regulatory Organizations:**

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

### Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.


**U.S. Regulations**

TSCA - *No*

CERCLA - *Not on this list*

SARA 302 - *Not on this list*

OSHA Substance Specific - *No*


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**Section 16 - Other Information**

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. **THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE).** In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.  
 1901 N. Roselle Rd, Suite 700  
 Schaumburg, IL 60195  
 847-908-1600

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**Glossary:** This glossary contains definitions of general terms used in MSDSs. Not all of these Glossary Terms will apply to this MSDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AIHA	American Industrial Hygiene Association
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
EPA	Environmental Protection Agency
HEPA	High Efficiency Particulate Air (Filter)
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NIOSH	National Institute for Occupational Safety and Health
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)