Levofloxacin Hemihydrate, USP

SDS Preparation Date 06/30/2017

SAFETY DATA SHEET

Section 1 Identification of the substance/mixture and of the company/undertaking

Product Identifier:
Identification on the label/ Tradename: Levofloxacin Hemihydrate, USP
Identification of the Product:
Formula: C_{36}H_{42}F_{2}N_{6}O_{9}
Chemical Name: \((-\)-(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
(S)-(\-)-Ofloxacin

Relevant identified uses of the substance and uses advised against:
Identified Uses: Pharma active ingredients
Uses Advised Against: No information available

Name, address, and telephone number of the manufacturer:
Refer to Supplier
Name, address, and telephone number of the supplier:
Encore Scientific
801 West New Orleans Street Broken Arrow, OK, USA 74011
Supplier’s Telephone #
800-454-2304 Monday to Friday 8:00 am to 6:00 pm (Central time)
24 Hr. Emergency Tel #
INFOTRAC: (800) 535-5053 (Within Continental US and Canada); (352)323-3500 (International)

Section 2 Hazards Identification

Physical hazards: Not classified.
Health hazards: Acute toxicity, oral Category 4
Environmental hazards: Not classified.

Label elements

Hazard pictograms
GHS07.
Signal word
Warning
Hazard statements
H302 Harmful if swallowed; P301+P312 If swallowed: Call a poison center/doctor if you feel unwell; P330 Rinse mouth; P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise classified (HNOC)
Not classified
Other hazards which do not result in classification
None known
### SAFETY DATA SHEET

#### Section 2 Hazards Identification (Continued)

<table>
<thead>
<tr>
<th>Hazard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Eye Contact:</strong></td>
<td>If applied to the eyes, this material causes severe eye damage. Phototoxic agents such as sulfonamides can cause inflammation of the conjunctiva and cornea, and clouding.</td>
</tr>
<tr>
<td><strong>Inhalation:</strong></td>
<td>The material is not thought to produce respiratory irritation (as classified using animal models). Nevertheless, inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress. Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled. Clinical signs of quinoline intoxication include lethargy, respiratory distress and prostration leading to coma.</td>
</tr>
<tr>
<td><strong>Ingestion:</strong></td>
<td>Accidental ingestion of the material may be damaging to the health of the individual. Fluoroquinolones have been associated with kidney damage, effects after exposure to UV light, seizures, changes in blood sugar levels (especially in diabetics), and crystal formation in the urine. They can also cause disease in the joints.</td>
</tr>
<tr>
<td><strong>After skin contact:</strong></td>
<td>Skin contact is not thought to have harmful health effects, however the material may still produce health damage following entry through wounds, lesions or abrasions. There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons. Open cuts, abraded or irritated skin should not be exposed to this material. Entry into the bloodstream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects. Examine the skin prior to the use of the material and ensure that any external damage is suitably protected. Exposure to this product can cause sensitization of skin under sunlight. The product can reach the skin via the bloodstream either if swallowed or ingested.</td>
</tr>
</tbody>
</table>

#### CHRONIC HEALTH EFFECTS

Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems. Prolonged or repeated use of antibiotics, at therapeutic doses, may produce bacterial resistance for some types of bacteria. Prolonged use may result in the overgrowth of non-susceptible organisms (i.e. Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.)
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Section 3 Composition/information on ingredients

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS No.</th>
<th>Weight %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levofloxacin</td>
<td>138199-71-0</td>
<td>100</td>
</tr>
</tbody>
</table>

Section 4 First aid measures

Description of first aid measures

**Eye Contact:** If this product comes in contact with the eyes: · Immediately hold eyelids apart and flush the eye continuously with running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

**Inhalation:** If fumes or combustion products are inhaled remove from contaminated area. · Lay patient down. Keep warm and rested.

**Ingestion:** If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

**After skin contact:** If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

**Noted to Physician:** Treat symptomatically

Section 5 Fire-Fighting measures

**EXTINGUISHING MEDIA:** Foam; Dry chemical powder.

**FIRE FIGHTING:** Alert Emergency Responders and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves.

**GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS:** Combustible solid which burns but propagates flame with difficulty. Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited. Combustion products include: carbon monoxide (CO), carbon dioxide (CO2), hydrogen fluoride, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material. May emit poisonous fumes.

**FIRE INCOMPATIBILITY:** Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids, chlorine bleaches, pool chlorine etc. as ignition may result.
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Section 5 Fire-Fighting measures

PERSONAL PROTECTION

Glasses: Chemical goggles.
Gloves:
Respirator: Particulate

Section 6 Accidental release measures

MINOR SPILLS: Clean up waste regularly and abnormal spills immediately. Avoid breathing dust and contact with skin and eyes. Wear protective clothing, gloves, safety glasses and dust respirator. Use dry clean up procedures and avoid generating dust. Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use). Dampen with water to prevent dusting before sweeping. Place in suitable containers for disposal.

MAJOR SPILLS: Moderate hazard.
CAUTION: Advise personnel in area.
Alert Emergency Responders and tell them location and nature of hazard.

Section 7 Handling and storage

Precautions for safe handling: 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.

Conditions for safe storage, including any incompatibilities: 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

Biological limit values: No biological exposure limits noted for the ingredient(s). Exposure guidelines No exposure standards allocated.

Exposure Guidelines: No exposure standards allocated.

Appropriate engineering controls: Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.
SAFETY DATA SHEET

Section 8 Exposure Controls/Personal Protection (Continued)

Eye/face protection: Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

Skin Protection

Hand protection:
Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

Other:
For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.

Respiratory protection: Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

General hygiene considerations: Handle in accordance with good industrial hygiene and safety practice.

Section 9 Physical and chemical properties

Physical State: Solid
Appearance: Pale or bright-yellow crystalline powder.
Odor: Odorless
Odor Threshold: No information available
pH: Not applicable
Melting Point/Range: 435.2 - 444.2 °F (224 - 229 °C) (decomposes)
Boiling Point/Range: Not available
Flash Point: Not available
Evaporation Rate: No information available
Flammability (solid,gas): No information available

Flammability or explosive limits
Upper: No information available
Lower: No information available
Vapor Pressure: No information available
Vapor Density: No information available
Vapor density: Not applicable.
Evaporation rate: Not applicable.
Solubility: Freely soluble in glacial acetic acid and in chloroform; sparingly soluble in methanol; slightly soluble in ethanol; practically insoluble in ether.

Partition coefficient (n-octanol/water): No information available
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Section 9 Physical and chemical properties (Continued)

Viscosity:
- Dynamic: Not applicable.
- Kinematic: Not applicable.

Other information
No further relevant information available.

Chemical Family: Fluoroquinolone
Molecular Formula: C_{18}H_{20}FN_{3}O_{4}
Molecular Weight: 370.38 g/mol

Section 10 Stability and reactivity

Reactivity
- Chemical stability: Material is stable under normal conditions.
- Possibility of hazardous reactions: No dangerous reaction known under conditions of normal use.
- Conditions to avoid: Contact with incompatible materials.
- Incompatible materials: Oxidizing agents.
- Hazardous decomposition products: Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. F-

Section 11 Toxicological information

Information on likely routes of exposure
- Ingestion: Harmful if swallowed.
- Inhalation: Classification not possible.
- Skin contact: Classification not possible.
- Eye contact: Classification not possible.


Cross Sensitivity: Persons sensitive to one fluoroquinolone or to chemically related quinolone derivatives (cinoxacin, nalidixic acid) may be sensitive to this material also.


Acute toxicity: Harmful if swallowed.
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Section 11 Toxicological information (Continued)

<table>
<thead>
<tr>
<th>Product</th>
<th>Species</th>
<th>Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levofloxacin (CAS 138199-71-0)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Oral</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LD50</td>
<td>Mouse</td>
<td>1803 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Rat</td>
<td>1478 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Classification not possible.
Serious eye damage/eye irritation: Not classified.

Local effects

100 µL/kg Eye irritation test
Result: Non-irritant.
Species: Rabbit

Respiratory or Skin Sensitization

Respiratory sensitization: Due to lack of data the classification is not possible.
Skin sensitization: Not classified.

Skin sensitization

Guinea pig maximization test
Result: Non-sensitizing.

Germ cell mutagenicity: Not classified.

Mutagenicity

<table>
<thead>
<tr>
<th>Test</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ames test</td>
<td>Negative</td>
</tr>
<tr>
<td>Chinese hamster ovary mutation assay</td>
<td>Negative</td>
</tr>
<tr>
<td>In vitro chromosomal aberration assay</td>
<td>Positive</td>
</tr>
<tr>
<td>In vitro sister chromatid exchange assay</td>
<td>Positive</td>
</tr>
<tr>
<td>Mouse dominant lethal assay</td>
<td>Negative</td>
</tr>
<tr>
<td>Mouse micronucleus test</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Carcinogenicity: Not classified. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA

100 mg/kg/day Carcinogenicity test
Result: Not carcinogenic.
Species: Rat
Test Duration: 2 years

300 mg/kg/day Carcinogenicity test
Result: Not carcinogenic.
Species: Mouse
### Section 11 Toxicological information (Continued)

#### Reproductive Toxicity:

<table>
<thead>
<tr>
<th>Reproductivity</th>
<th>Reproductivity test</th>
<th>Result</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>360 mg/kg/day</td>
<td>Reproductivity test</td>
<td>No adverse effects on fertility</td>
<td>Rat</td>
</tr>
<tr>
<td>50 mg/kg/day</td>
<td>Reproductivity test</td>
<td>No birth defects observed</td>
<td>Rabbit</td>
</tr>
<tr>
<td>810 mg/kg/day</td>
<td>Reproductivity test</td>
<td>Fetotoxicity observed; reduction in fetal weight and delay in ossification</td>
<td>Rat</td>
</tr>
</tbody>
</table>

**Test Duration:** 2 years

**Specific target organ toxicity—single exposure:** Classification not possible

**Specific target organ toxicity—repeated exposure:** Classification not possible

**Aspiration hazard:** Not classified.

### Section 12 Ecological information

#### Ecotoxicity:

No ecotoxicity data noted for the ingredient(s).

#### Persistence and degradability:
Not available.

#### Bioaccumulative potential:
Not available.

#### Mobility in soil:
Not available.

#### Other adverse effects:
Not available.

### Section 13 Disposal considerations

#### Disposal instructions:
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.

#### Local disposal regulations:
Dispose in accordance with all applicable regulations.

#### Hazardous waste code:
The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

#### Waste from residues / unused products:
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).

#### Contaminated packaging:
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.
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Section 14 Transport information

DOT: Not regulated as dangerous goods.
IATA: Not regulated as dangerous goods.

Transport in bulk according to
Annex II of MARPOL 73/78 and
the IBC Code Not available

General information: It is the shipper’s responsibility to determine the correct transport classification at the time of shipment.

Section 15 Regulation information

US federal regulations: This product is a “Hazardous Chemical” as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200. One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories
Immediate Hazard - Yes
Delayed Hazard – No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard – No

SARA 302 Extremely hazardous substance: Not listed.
SARA 311/312 Hazardous chemical: Yes

SARA 313 (TRI reporting) Not regulated.

Other federal regulations
Safe Drinking Water Act (SDWA) Not regulated.
Food and Drug Administration (FDA) Not regulated.

US state regulations
US. California Proposition 65
California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.
Section 15 Regulation information (Continued)

International Inventories

<table>
<thead>
<tr>
<th>Country(s) or region</th>
<th>Inventory name</th>
<th>On inventory (yes/no)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>Australian Inventory of Chemical Substances (AICS)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Domestic Substances List (DSL)</td>
<td>No</td>
</tr>
<tr>
<td>Canada</td>
<td>Non-Domestic Substances List (NDSSL)</td>
<td>No</td>
</tr>
<tr>
<td>China</td>
<td>Inventory of Existing Chemical Substances in China (IECSC)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European Inventory of Existing Commercial Chemical Substances (EINECS)</td>
<td>No</td>
</tr>
<tr>
<td>Europe</td>
<td>European List of Notified Chemical Substances (ELINCS)</td>
<td>No</td>
</tr>
<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
</tr>
<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
</tr>
<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
<td>No</td>
</tr>
<tr>
<td>Philippines</td>
<td>Philippine Inventory of Chemicals and Chemical Substances (PICCS)</td>
<td>No</td>
</tr>
<tr>
<td>United States &amp; Puerto Rico</td>
<td>Toxic Substances Control Act (TSCA) Inventory</td>
<td>No</td>
</tr>
</tbody>
</table>

*A “Yes” indicates that all components of this product comply with the inventory requirements administered by the governing country(s).

A “No” indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

Section 16 Other information

Date of Preparation/Last Revision: 06/30/2017/

Further information: This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

Notice to reader: Employers should use this information only as a supplement to other information gathered by them, and should make independent judgment of suitability of this information to ensure proper use and protect the health and safety of employees. This information is furnished without warranty, and any use of the product not in conformance with this Safety Data Sheet, or in combination with any other product or process, is the responsibility of the user.