SAFETY DATA SHEET

1. Identification

Product identifier Levofloxacin Related Compound F

Other means of identification

- Catalog number: 1362169
- CAS number: 117620-85-6
- Synonyms: 9-Desfluoro levofloxacin
- Chemical name: (S)-2,3-Dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic acid

Recommended use Specified quality tests and assay use only.

Recommended restrictions Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

- Company name: U. S. Pharmacopeia
- Address: 12601 Twinbrook Parkway
- Rockville
- MD
- 20852-1790
- United States
- Telephone: RS Technical Services 301-816-8129
- Website: www.usp.org
- E-mail: RSTECH@usp.org
- Emergency phone number: CHEMTREC within US & Canada 1-800-424-9300
- CHEMTREC outside US & Canada +1 703-527-3887

2. Hazard(s) identification

Physical hazards Not classified.
Health hazards Not classified.
Environmental hazards Not classified.
OSHA defined hazards Not classified.

Label elements

- Hazard symbol: None.
- Signal word: None.
- Hazard statement: Not available.
- Precautionary statement:
  - Prevention: Not available.
  - Response: Not available.
  - Storage: Not available.
  - Disposal: Not available.
- Hazard(s) not otherwise classified (HNOC): None known.
- Supplemental information: Pharmaceutical related compound of unknown potency.

3. Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance</th>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Levofloxacin Related Compound F</td>
<td>9-Desfluoro levofloxacin</td>
<td>117620-85-6</td>
<td>100</td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.
Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact Rinse with water. Get medical attention if irritation develops and persists.
Ingestion
Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important symptoms/effects, acute and delayed
Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.

Indication of immediate medical attention and special treatment needed
Provide general supportive measures and treat symptomatically.

General information
Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media
Water, Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters
Wear suitable protective equipment.

Fire fighting equipment/instructions
Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods
Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards
No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures
Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up
For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Environmental precautions
Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling
As a general rule, when handling USP Reference Standards, 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. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential. Cover all containers for solutions and slurries while being transferred. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.

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.

8. Exposure controls/personal protection

Occupational exposure limits
No exposure limits noted for ingredient(s).

Biological limit values
No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls
Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). No open handling.

Individual protection measures, such as personal protective equipment

Eye/face protection
Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection
Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Consider double gloves.

Hand protection
Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent. Consider double gloves.
9. Physical and chemical properties

Appearance descriptions are general information and not specific to any USP lot.

### Appearance
- **Physical state**: Solid.
- **Form**: Powder.
- **Color**: Off-white. Yellow.

### Odor
- **Odor**: Not available.
- **Odor threshold**: Not available.
- **pH**: Not available.

### Melting point/freezing point
- **Melting point**: 415.4 - 426.2 °F (213 - 219 °C) (decomposes)

### Initial boiling point and boiling range
- **Initial boiling point and boiling range**: Not available.

### Flash point
- **Flash point**: Not available.

### Evaporation rate
- **Evaporation rate**: Not available.

### Flammability (solid, gas)
- **Flammability limit - lower (%)**: Not available.
- **Flammability limit - upper (%)**: Not available.

### Upper/lower flammability or explosive limits
- **Explosive limit - lower (%)**: Not available.
- **Explosive limit - upper (%)**: Not available.

### Vapor pressure
- **Vapor pressure**: Not available.

### Vapor density
- **Vapor density**: Not available.

### Relative density
- **Relative density**: Not available.

### Solubility(ies)
- **Solubility (water)**: Not available.

### Auto-ignition temperature
- **Auto-ignition temperature**: Not available.

### Decomposition temperature
- **Decomposition temperature**: Not available.

### Viscosity
- **Viscosity**: Not available.

### Other information
- **Molecular formula**: C18H21N3O4
- **Molecular weight**: 343.38

10. Stability and reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport.

- **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**: Strong oxidizing agents.
- **Hazardous decomposition products**: NOx. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

### Information on likely routes of exposure
- **Inhalation**: Knowledge about health hazard is incomplete.
Skin contact  Knowledge about health hazard is incomplete.
Eye contact  Knowledge about health hazard is incomplete.
Ingestion  Knowledge about health hazard is incomplete.
Symptoms related to the physical, chemical, and toxicological characteristics  Not available.

Information on toxicological effects

Acute toxicity  Not known.
Skin corrosion/irritation  Knowledge about health hazard is incomplete.
Serious eye damage/eye irritation  Knowledge about health hazard is incomplete.

Respiratory or skin sensitization
  Respiratory sensitization  Knowledge about health hazard is incomplete.
  Skin sensitization  Knowledge about health hazard is incomplete.
  Germ cell mutagenicity  Knowledge about mutagenicity is incomplete.
  Carcinogenicity  Knowledge about carcinogenicity is incomplete.

IARC Monographs. Overall Evaluation of Carcinogenicity
  Not listed.
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
  Not regulated.
US. National Toxicology Program (NTP) Report on Carcinogens
  Not listed.
Reproductive toxicity  Knowledge about health hazard is incomplete.
Specific target organ toxicity - single exposure  Knowledge about health hazard is incomplete.
Specific target organ toxicity - repeated exposure  Knowledge about health hazard is incomplete.
Aspiration hazard  Based on available data, the classification criteria are not met.
Further information  Pharmaceutical related compound of unknown potency. It is not known if occupational exposure may cause physiological effects.

12. Ecological information
Ecotoxicity  The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability  No data is available on the degradability of this product.
Bioaccumulative potential  No data available.
Mobility in soil  No data available.
Other adverse effects  No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

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.

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

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations

One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.
This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)
Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)
Not listed.

SARA 304 Emergency release notification
Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)
Not regulated.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

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

SARA 302 Extremely hazardous substance
Not listed.

SARA 311/312 Hazardous chemical
No

SARA 313 (TRI reporting)
Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List
Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)
Not regulated.

Safe Drinking Water Act (SDWA)
Not regulated.

US state regulations

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.

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 (NDSEL)</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>
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<tr>
<td>Japan</td>
<td>Inventory of Existing and New Chemical Substances (ENCS)</td>
<td>No</td>
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<tr>
<td>Korea</td>
<td>Existing Chemicals List (ECL)</td>
<td>No</td>
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<tr>
<td>New Zealand</td>
<td>New Zealand Inventory</td>
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</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).
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