1. Identification

Product identifier  R-Ofloxacin

Other means of identification

Catalog number  1478083

Chemical name  (R)-9-Fluoro-2,3-dihydro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-7H-pyrido[1,2,3-de]-1,4-benz-oxazine-6-carboxylic acid

Synonym(s)  D-Levofloxacin * D-Ofloxacin

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

Company name  U. S. Pharmacopeia

Address  12601 Twinbrook Parkway

Rockville

MD  20852-1790

US

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

Note  Information on the chemical, physical and toxicological properties of this material is not readily available. Individuals working with this chemical should consider it to be potentially hazardous even if its actual hazards may be uncharacterized or unknown.

Physical hazards  Not classified.

Health hazards  Not classified.

OSHA hazard(s)  Not classified.

Label elements

Hazard symbol  No symbol.

Signal word  Not available.

Hazard statement  Not available.

Precautionary statement

Prevention  Not available.

Response  Not available.

Storage  Not available.

Disposal  Not available.

Hazard(s) not otherwise classified (HNOC)  Not classified.

3. Composition/information on ingredients

Substance

Non-hazardous components

<table>
<thead>
<tr>
<th>Common name and synonyms</th>
<th>CAS number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>D-Levofloxacin</td>
<td>100986-86-5</td>
<td>100</td>
</tr>
<tr>
<td>D-Ofloxacin</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. First-aid measures

Inhalation  If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
**Skin contact**
Wash off with soap and water. Get medical attention if irritation develops and persists.

**Eye contact**
Flush eyes with water as a precaution. 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**
Not available.

**Indication of immediate medical attention and special treatment needed**
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 spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and 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**
As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

**Specific methods**
Cool containers exposed to flames with water until well after the fire is out.

6. **Accidental release measures**

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

**Methods and materials for containment and cleaning up**
Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Wash spill site.

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. 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.

8. **Exposure controls/personal protection**

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

**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. Local exhaust ventilation such as a laboratory fume hood or other vented enclosure is recommended, particularly for grinding, crushing, weighing, or other dust-generating procedures.

**Individual protection measures, such as personal protective equipment**

**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.

9. Physical and chemical properties

Appearance
Pale yellow to yellow crystalline powder.

Physical state
Solid.

Form
Powder.

Odor
Not available.

Odor threshold
Not available.

pH
Not available.

Melting point/freezing point
437 - 440.6 °F (225 - 227 °C)

Initial boiling point and boiling range
Not available.

Flash point
Not available.

Evaporation rate
Not available.

Flammability (solid, gas)
Not applicable.

Upper/lower flammability or explosive limits
Flammability limit - lower (%)
Not available.

Flammability limit - upper (%)
Not available.

Explosive limit - lower (%)
Not available.

Explosive limit - upper (%)
Not available.

Vapor pressure
Not available.

Vapor density
Not available.

Relative density
Not available.

Solubility in water
Not available.

Partition coefficient (n-octanol/water)
Not available.

Auto-ignition temperature
Not available.

Decomposition temperature
Not available.

Viscosity
Not available.

Other information
Chemical family
Fluorinated quinolone.

Molecular formula
C18H20FN3O4

Molecular weight
361.37

10. Stability and reactivity

Reactivity
No reactivity hazards known.

Chemical stability
Material is stable under normal conditions.

Possibility of hazardous reactions
No dangerous reaction known under conditions of normal use.

Conditions to avoid
None known.

Incompatible materials
None known.

Hazardous decomposition products
NOx, HF. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.
11. Toxicological information

Information on likely routes of exposure

<table>
<thead>
<tr>
<th>Route</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ingestion</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Inhalation</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Skin contact</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Eye contact</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
</tbody>
</table>

Symptoms related to the physical, chemical, and toxicological characteristics

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Due to lack of data the classification is not possible.</td>
</tr>
<tr>
<td>Mutagenicity Ames Salmonella typhimurium assays</td>
<td>Result: Negative</td>
</tr>
</tbody>
</table>

Carcinogenicity

Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.

Reproductive toxicity

Due to lack of data the classification is not possible.

Specific target organ toxicity - single exposure

Due to lack of data the classification is not possible.

Specific target organ toxicity - repeated exposure

Due to lack of data the classification is not possible.

Aspiration hazard

Based on available data, the classification criteria are not met.

12. Ecological information

Ecotoxicity

There are no data on the ecotoxicity of this product.

Persistence and degradability

No data is available on the degradability of this product.

Bioaccumulative potential

Not available.

Mobility in soil

Not available.

Other adverse effects

Not available.

13. Disposal considerations

Disposal instructions

This product, in its present state, when discarded or disposed of, is not a hazardous waste according to Federal regulations (40 CFR 261.4 (b)(4)). 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. Dispose in accordance with all applicable regulations.

Local disposal regulations

Not available.

Hazardous waste code

Not regulated.

Waste from residues / unused products

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

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No information available.
15. Regulatory information

US federal regulations
One or more components are not listed on TSCA.

CERCLA/SARA Hazardous Substances - Not applicable.

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
No

SARA 311/312 Hazardous chemical
No

Other federal regulations
Safe Drinking Water Act (SDWA)
Not regulated.

Food and Drug Administration (FDA)
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 (NDSL)</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)

16. Other information, including date of preparation or last revision

Issue date
01-17-2013

Version #
01

Further information
Not available.

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