



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Gatifloxacin</b>
<b>Other means of identification</b>	
<b>Catalog number</b>	1288408
<b>CAS number</b>	112811-59-3
<b>Chemical name</b>	(±)-1-Cyclopropyl-6-fluoro-8-methoxy-7-(3-methyl-1-piperazinyl)-4-oxo-1,4-dihydroquinoline-3-carboxylic acid
<b>Recommended use</b>	Specified quality tests and assay use only.
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.

### Manufacturer/Importer/Supplier/Distributor information

#### Manufacturer

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

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.
<b>Health hazards</b>	Not classified.
<b>Environmental hazards</b>	Not classified.
<b>OSHA defined hazards</b>	Not classified.

#### Label elements

<b>Hazard symbol</b>	None.
<b>Signal word</b>	None.
<b>Hazard statement</b>	Not available.
<b>Precautionary statement</b>	
<b>Prevention</b>	Not available.
<b>Response</b>	Not available.
<b>Storage</b>	Not available.
<b>Disposal</b>	Not available.

**Hazard(s) not otherwise classified (HNOC)** This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

**Supplemental information** Pharmacologically active material.

## 3. Composition/information on ingredients

#### Substance

<b>Chemical name</b>	<b>Common name and synonyms</b>	<b>CAS number</b>	<b>%</b>
Gatifloxacin		112811-59-3	100

## 4. First-aid measures

<b>Inhalation</b>	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.
<b>Skin contact</b>	Wash off with soap and water. Get medical attention if irritation develops and persists.
<b>Eye contact</b>	Rinse with water. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Rinse mouth. Get medical attention if symptoms occur.
<b>Most important symptoms/effects, acute and delayed</b>	Gastrointestinal disturbances. Endocrine system effects. Cardiovascular effects. Pharmacologically active material.. Occupational exposure may cause physiological effects.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. Fluoroquinolones: Administer activated charcoal for large ingestions. Monitor cardiac function. Monitor for hypotension, dysrhythmias, hypoglycemia, hyperglycemia, and seizures.
<b>General information</b>	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

<b>Suitable extinguishing media</b>	Water. Foam. Dry chemical or CO <sub>2</sub> . Use fire-extinguishing media appropriate for surrounding materials.
<b>Unsuitable extinguishing media</b>	None known.
<b>Specific hazards arising from the chemical</b>	Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.
<b>Special protective equipment and precautions for firefighters</b>	Wear suitable protective equipment.
<b>Fire fighting equipment/instructions</b>	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.
<b>Specific methods</b>	Use standard firefighting procedures and consider the hazards of other involved materials.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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.
<b>Methods and materials for containment and cleaning up</b>	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.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	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. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust).
<b>Conditions for safe storage, including any incompatibilities</b>	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

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

**Exposure limit values****Industrial Use  
Material****Type****Value**

Industrial Use Material	Type	Value
Gatifloxacin (CAS 112811-59-3)	TWA	0.4 mg/m3

**Biological limit values**

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

**Appropriate engineering controls**

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. 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.

**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****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.

**Other**

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

**Respiratory protection**

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

**Thermal hazards**

Wear appropriate thermal protective clothing, when necessary.

**General hygiene considerations**

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

**9. Physical and chemical properties****Appearance**

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

**Physical state**

Solid.

**Form**

Powder.

**Color**

White. Light yellow.

**Odor**

Not available.

**Odor threshold**

Not available.

**pH**

Not available.

**Melting point/freezing point**

363.2 °F (184 °C)

**Initial boiling point and boiling range**

Not available.

**Flash point**

Not available.

**Evaporation rate**

Not available.

**Flammability (solid, gas)**

Not available.

**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**

> 1

**Relative density**

Not available.

**Solubility(ies)****Solubility (water)**

Partially soluble.

<b>Partition coefficient (n-octanol/water)</b>	0.9
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Fluoroquinolone.
<b>Dust explosion properties</b>	
<b>Kst</b>	172 bar.m/s
<b>Minimum ignition energy (MIE) - dust cloud</b>	> 10 mJ
<b>Molecular formula</b>	C19H22FN3O4
<b>Molecular weight</b>	375.4

## 10. Stability and reactivity

<b>Reactivity</b>	The product is stable and non-reactive under normal conditions of use, storage and transport.
<b>Chemical stability</b>	Material is stable under normal conditions.
<b>Possibility of hazardous reactions</b>	No dangerous reaction known under conditions of normal use.
<b>Conditions to avoid</b>	Contact with incompatible materials.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx. F-.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Knowledge about health hazard is incomplete.
<b>Eye contact</b>	Knowledge about health hazard is incomplete.
<b>Ingestion</b>	Based on information from therapeutic use, this material may cause: Cardiovascular effects. Endocrine effects.
<b>Symptoms related to the physical, chemical, and toxicological characteristics</b>	Fluoroquinolones: Gastrointestinal disturbances. Altered taste. Dizziness. Drowsiness. Headache. Sleep disturbances. Slurred speech. Tremors. Restlessness. Convulsions. Skin rash. Joint tenderness or swelling. Numbness or tingling of hands or feet.

### Information on toxicological effects

#### Acute toxicity

Product	Species	Test Results
Gatifloxacin (CAS 112811-59-3)		
<b>Oral</b> LD50	Rat	> 825 mg/kg
<b>Acute</b>		
<b>Oral</b> LD50	Rat	> 2000 mg/kg

**Skin corrosion/irritation** Knowledge about health hazard is incomplete.

**Serious eye damage/eye irritation** Knowledge about health hazard is incomplete.

#### Local effects

Eye irritation, (0.5%-1.0% solution)  
Result: Negative.  
Species: Rabbit

#### 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.  
**Mutagenicity**  
Ames test  
Result: Equivocal.  
In vivo mouse micronucleus test  
Result: Negative.  
Mutagenicity, In vitro cytogenetics assay (Chinese hamster CHL/IU cells)  
Result: Positive.  
Mutagenicity, In vitro unscheduled DNA synthesis (rat hepatocytes)  
Result: Positive.

**Carcinogenicity** Knowledge about carcinogenicity is incomplete.  
47 - 139 mg/kg/day Carcinogenicity  
Result: No increase in neoplasms.  
Species: Rat  
Test Duration: 24 months  
81 - 90 mg/kg/day Carcinogenicity  
Result: No increase in neoplasms.  
Species: Mouse  
Test Duration: 18 months

#### **IARC Monographs. Overall Evaluation of Carcinogenicity**

Not listed.

#### **OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)**

Not regulated.

#### **US. National Toxicology Program (NTP) Report on Carcinogens**

Not listed.

**Reproductive toxicity** Knowledge about health hazard is incomplete.

#### **Reproductivity**

150 mg/kg/day Developmental Effects  
Result: Skeletal malformations, delayed bone development, heart defects, and reduced fetal weight.  
Species: Rat  
50 mg/kg/day Teratogenicity  
Result: No birth defects.  
Species: Rabbit

**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** Pharmacologically active material. 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 substance.

#### **Bioaccumulative potential**

**Octanol/water partition coefficient log Kow**  
0.9

**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.

<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
<b>Waste from residues / unused products</b>	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).
<b>Contaminated packaging</b>	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** Not applicable.

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

## 15. Regulatory information

**US federal regulations** 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 1910.1001-1052)

Not regulated.

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

#### SARA 302 Extremely hazardous substance

Not listed.

**SARA 311/312 Hazardous chemical** Yes

**Classified hazard categories** Combustible dust

#### 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 Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 2016 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

### International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

\*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).

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

<b>Issue date</b>	06-17-2010
<b>Revision date</b>	01-07-2020
<b>Version #</b>	04
<b>Further information</b>	Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.
<b>Disclaimer</b>	USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.