

# Scientific Documentation

## Moxifloxacin HCl, USP, bioCERTIFIED (TM)

Not appropriate for regulatory submission.

Please visit [www.spectrumchemical.com](http://www.spectrumchemical.com) or contact Tech Services for the most up-to-date information contained in this information package.

Spectrum Chemical Mfg Corp  
769 Jersey Avenue  
New Brunswick, NJ 08901  
Phone 732.214.1300



## **Table of Contents**

Product Specification  
Certificate of Analysis  
Safety Data Sheet (SDS)  
Certification of Current Good Manufacturing Practices (cGMP)  
Technical Statements  
Elemental Impurities Statement  
Residual Solvents Statement  
General Label Information – Sample Label

# Specification for Moxifloxacin HCl, USP, bioCERTIFIED (TM) (MO902)

Item Number	MO902
Item	Moxifloxacin HCl, USP, bioCERTIFIED (TM)
CAS Number	186826-86-8
Molecular Formula	C <sub>21</sub> H <sub>25</sub> ClFN <sub>3</sub> O <sub>4</sub>
Molecular Weight	437.9
MDL Number	
Synonyms	

Test	Specification	
	Min	Max
ASSAY (ANHYDROUS BASIS)	98.0	102.0%
IDENTIFICATION (IR)	TO PASS TEST	
IDENTIFICATION (HPLC)	TO PASS TEST	
IDENTIFICATION (CHLORIDE)	TO PASS TEST	
pH	3.9	4.6
WATER		4.5%
RESIDUE ON IGNITION		0.5%
SULFATE		0.04%
RELATED SUBSTANCES:		
MOXIFLOXACIN RELATED COMPOUND A		0.1%
MOXIFLOXACIN RELATED COMPOUND B		0.1%
MOXIFLOXACIN RELATED COMPOUND C		0.1%
MOXIFLOXACIN RELATED COMPOUND D		0.1%
MOXIFLOXACIN RELATED COMPOUND E		0.1%
ANY OTHER INDIVIDUAL IMPURITY		0.10%
TOTAL IMPURITIES		0.3%
ELEMENTAL IMPURITIES	AS REPORTED	
ENANTIOMERIC PURITY (MOXIFLOXACIN RELATED COMPOUND G)		0.10%
MICROBIAL LIMITS:		

Test	Specification	
	Min	Max
TOTAL AEROBIC MICROBIAL COUNT (TAMC)		1000 CFU/g
TOTAL YEAST AND MOLD COUNT (TYMC)		100 CFU/g
IDENTIFICATION	TO PASS TEST	
APPEARANCE		
EXPIRATION DATE		
MANUFACTURE DATE		
RESIDUAL SOLVENTS	AS REPORTED	

***Spectrum Chemical Mfg Corp***

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<b>Corporate Headquarters:</b>	<b>West Coast Facility:</b>
769 Jersey Ave.	14422 S. San Pedro St.
New Brunswick, NJ 08901	Gardena, CA 90248
732.214.1300	310.516.8000

## Certificate Of Analysis

Item Number	MO902	Lot Number	4KA0020
Item	Moxifloxacin HCl, USP, bioCERTIFIED (TM)	Manufacturer Lot	MH 018 K 20
CAS Number	186826-86-8	Manufacturer Code	15063
Molecular Formula	C <sub>21</sub> H <sub>25</sub> ClFN <sub>3</sub> O <sub>4</sub>	Molecular Weight	437.9

TEST	SPECIFICATION		RESULT
	MIN	MAX	
ASSAY (ANHYDROUS BASIS)	98.0	102.0%	100.7 %
IDENTIFICATION (IR)	TO PASS TEST		PASSES TEST
IDENTIFICATION (HPLC)	TO PASS TEST		PASSES TEST
IDENTIFICATION (CHLORIDE)	TO PASS TEST		PASSES TEST
pH	3.9	4.6	4.50
WATER		4.5%	4.3 %
RESIDUE ON IGNITION		0.5%	0.1 %
SULFATE		0.04%	< 0.04 %
RELATED SUBSTANCES:			.
MOXIFLOXACIN RELATED COMPOUND A		0.1%	0.0 %
MOXIFLOXACIN RELATED COMPOUND B		0.1%	0.0 %
MOXIFLOXACIN RELATED COMPOUND C		0.1%	0.0 %
MOXIFLOXACIN RELATED COMPOUND D		0.1%	0.0 %
MOXIFLOXACIN RELATED COMPOUND E		0.1%	0.0 %
ANY OTHER INDIVIDUAL IMPURITY		0.10%	0.0 %
TOTAL IMPURITIES		0.3%	0.0 %
ELEMENTAL IMPURITIES	AS REPORTED		COMPLIES WITH STANDARD
ENANTIOMERIC PURITY (MOXIFLOXACIN RELATED COMPOUND G)		0.10%	0.09 %
MICROBIAL LIMITS:			.
TOTAL AEROBIC MICROBIAL COUNT (TAMC)		1000 CFU/g	< 1000 CFU/g
TOTAL YEAST AND MOLD COUNT (TYMC)		100 CFU/g	< 100 CFU/g
IDENTIFICATION	TO PASS TEST		PASSES TEST

TEST	SPECIFICATION		RESULT
	MIN	MAX	
APPEARANCE			YELLOW POWDER
EXPIRATION DATE			31-OCT-2025
MANUFACTURE DATE			01-NOV-2020
RESIDUAL SOLVENTS	AS REPORTED		PASSES SCREENING
MONOGRAPH EDITION			(USP) 43
CLASS 2 (solvent) / HEXANE			< 290 ppm
CLASS 2 (SOLVENT) / METHANOL			< 3000 ppm
CLASS 3 (solvent) / 2-PROPANOL			< 5000 ppm
CLASS 2 (solvent) / ACETONITRILE			< 410 ppm
CLASS 2 (solvent) TOLUENE			< 890 ppm

Certificate of Analysis Results Entered By:

AJABLONSKI  
Andrew Jablonski  
21-APR-21 04:51:30

Spectrum Chemical Mfg Corp  
777 Jersey Avenue  
New Brunswick 08901 NJ



Certificate of Analysis Results Approved By:

AJABLONSKI  
Andrew Jablonski  
21-APR-21 04:51:35

**All pharmaceutical ingredients are tested using current edition of applicable pharmacopeia.**

**Read and understand label and SDS before handling any chemicals. All Spectrum's chemicals are for manufacturing, processing, repacking or research purposes by experienced personnel only. It is the customer's responsibility to provide adequate hazardous material training and ensure that appropriate Personal Protective Equipment (PPE) is used before handling any chemical.**

Spectrum Chemical Mfg. Corp. repackages Active Pharmaceutical Ingredient chemicals provided by other manufacturers and suppliers. For traceability purposes, Spectrum's Certificate of Analysis contains an identifier code unique to each manufacturer or supplier, as well as the chemical's lot number provided on the original manufacturer Certificate of Analysis. This material is manufactured by Chromo Laboratories India Private Limited at Plot No: 43 & 44 Phase II, IDA, Pashamylaram, Sangareddy District, Telangana 502307, India (IND). Copies of the original Certificate of Analysis are available upon request from your Spectrum Sales Representative or by calling Spectrum's Quality Department at 1-800-772-8786.

# SAFETY DATA SHEET

# spectrum®



Revision date 22-October-2020

Revision Number 1

## 1. Identification

### Product identifier

**Product Name** Moxifloxacin HCl, USP

### Other means of identification

**Product Code(s)** MO902

**Synonyms** None

### Recommended use of the chemical and restrictions on use

**Recommended use** No information available

**Restrictions on use** No information available

### Details of the supplier of the safety data sheet

#### Supplier Address

Spectrum Chemical Mfg. Corp.  
14422 South San Pedro St.  
Gardena, CA 90248  
(310) 516-8000

### Emergency telephone number

**Emergency Telephone** Chemtrec 1-800-424-9300

## 2. Hazard(s) identification

### Classification

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 2A

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

#### **Warning**

#### Hazard statements

Harmful if swallowed  
Causes serious eye irritation



**Appearance** Crystalline powder or Powder

**Physical state** Solid

**Odor** Odorless

#### **Precautionary Statements - Prevention**

Wash face, hands and any exposed skin thoroughly after handling  
Do not eat, drink or smoke when using this product  
Wear eye protection/ face protection

#### **Precautionary Statements - Response**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
If eye irritation persists: Get medical advice/attention  
IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell  
Rinse mouth

#### **Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

#### **Unknown acute toxicity**

#### **Other information**

No information available.

### **3. Composition/information on ingredients**

#### **Substance**

Chemical name	CAS No	Weight-%	Trade secret
Moxifloxacin HCl	186826-86-8	100	*

\*The exact percentage (concentration) of composition has been withheld as a trade secret.

### **4. First-aid measures**

#### **Description of first aid measures**

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and persists.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.
<b>Self-protection of the first aider</b>	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

#### **Most important symptoms and effects, both acute and delayed**



**Symptoms** May cause redness and tearing of the eyes. Burning sensation.

**Indication of any immediate medical attention and special treatment needed**

**Note to physicians** Treat symptomatically.

## **5. Fire-fighting measures**

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Large Fire** CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

**Specific hazards arising from the chemical** No information available.

**Explosion data**

**Sensitivity to mechanical impact** none.

**Sensitivity to static discharge** none.

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## **6. Accidental release measures**

**Personal precautions, protective equipment and emergency procedures**

**Personal precautions** Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

**Other information** Refer to protective measures listed in Sections 7 and 8.

**Methods and material for containment and cleaning up**

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up** Pick up and transfer to properly labeled containers.

## **7. Handling and storage**

**Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product.

**Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

## **8. Exposure controls/personal protection**

**Control parameters**

**Exposure Limits** The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure

limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

### **Appropriate engineering controls**

<b>Engineering controls</b>	Showers
	Eyewash stations
	Ventilation systems.

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

<b>Eye/face protection</b>	If splashes are likely to occur, wear safety glasses with side-shields.
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<b>Hand protection</b>	Wear suitable gloves.
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<b>Skin and body protection</b>	Wear suitable protective clothing.
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<b>Respiratory protection</b>	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
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**General hygiene considerations** Avoid contact with skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

## 9. Physical and chemical properties

### Information on basic physical and chemical properties

<b>Physical state</b>	Solid
<b>Appearance</b>	Crystalline powder or Powder
<b>Color</b>	Yellow; white
<b>Odor</b>	Odorless
<b>Odor threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	no data available	None known
Melting point / freezing point	615 °C / 1139 °F	None known
Boiling point / boiling range	no data available	None known
Flash point	no data available	None known
Evaporation rate	no data available	None known
Flammability (solid, gas)	no data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	
Vapor pressure	No data available	None known
Vapor density	no data available	None known
Relative density	no data available	None known
Water solubility	No data available	None known
Solubility(ies)	no data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	no data available	None known
Decomposition temperature		None known
Kinematic viscosity	no data available	None known
Dynamic viscosity	No data available	None known

## Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	437.9
VOC Content (%)	No information available

Liquid Density	No information available
Bulk density	No information available

## 10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

## 11. Toxicological information

### Information on likely routes of exposure

#### Product Information

Inhalation	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
Eye contact	Specific test data for the substance or mixture is not available. Causes serious eye irritation. (based on components). May cause redness, itching, and pain.
Skin contact	Specific test data for the substance or mixture is not available. May cause irritation. Prolonged contact may cause redness and irritation.
Ingestion	Specific test data for the substance or mixture is not available. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Harmful if swallowed. (based on components).

### Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	May cause redness and tearing of the eyes.
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### Acute toxicity

**Numerical measures of toxicity**  
No information available

### Unknown acute toxicity

### Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	May cause skin irritation.
Serious eye damage/eye irritation	Classification based on data available for ingredients. Causes serious eye irritation.
Respiratory or skin sensitization	No information available.
Germ cell mutagenicity	No information available.
Reproductive toxicity	No information available.
STOT - single exposure	No information available.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.

Interactive effects	No information available.
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## 12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability Bioaccumulation	No information available. Inherently biodegradable.
Other adverse effects	No information available.

## 13. Disposal considerations

### Waste treatment methods

Waste from residues/unused products	Dispose of in accordance with local regulations. Dispose of waste in accordance with environmental legislation.
Contaminated packaging	Do not reuse empty containers.

## 14. Transport information

<u>DOT</u>	not regulated
<u>TDG</u>	not regulated
<u>MEX</u>	not regulated
<u>ICAO (air)</u>	not regulated
<u>IATA</u>	not regulated
<u>IMDG</u>	not regulated
<u>RID</u>	not regulated
<u>ADR</u>	not regulated
<u>ADN</u>	not regulated

## 15. Regulatory information

### International Inventories

TSCA	Not listed
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Note	*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements
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DSL/NDSL	Does not Comply
EINECS/ELINCS	Does not Comply
ENCS	This product complies with ENCS:
IECSC	This product does not comply with china:
KECL	Does not Comply
PICCS	Does not Comply
AICS	This product does not comply with AICS

**Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**US Federal Regulations****SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

**CWA (Clean Water Act)**

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

**CERCLA**

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

**US State Regulations****California Proposition 65**

This product does not contain any Proposition 65 chemicals.

**U.S. State Right-to-Know Regulations**

This product does not contain any substances regulated under applicable state right-to-know regulations

**U.S. EPA Label Information**

**EPA Pesticide Registration Number** Not applicable

**16. Other information****NFPA**

**Health hazards** 2

**Flammability** 0

**Instability** 0

**Physical and chemical properties** -

**HMIS**

**Health hazards** 2

**Flammability** 0

**Physical hazards** 0

**Personal protection** X

**Key or legend to abbreviations and acronyms used in the safety data sheet**

**Legend** Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA Ceiling	TWA (time-weighted average) Maximum limit value	STEL	STEL (Short Term Exposure Limit)
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#### **Key literature references and sources for data used to compile the SDS**

Agency for Toxic Substances and Disease Registry (ATSDR)  
 U.S. Environmental Protection Agency ChemView Database  
 European Food Safety Authority (EFSA)  
 EPA (Environmental Protection Agency)  
 Acute Exposure Guideline Level(s) (AEGL(s))  
 U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act  
 U.S. Environmental Protection Agency High Production Volume Chemicals  
 Food Research Journal  
 Hazardous Substance Database  
 International Uniform Chemical Information Database (IUCLID)  
 Japan GHS Classification  
 Australia National Industrial Chemicals Notification and Assessment Scheme (NICNAS)  
 NIOSH (National Institute for Occupational Safety and Health)  
 National Library of Medicine's ChemID Plus (NLM CIP)  
 National Library of Medicine's PubMed database (NLM PUBMED)  
 National Toxicology Program (NTP)  
 New Zealand's Chemical Classification and Information Database (CCID)  
 Organization for Economic Co-operation and Development Environment, Health, and Safety Publications  
 Organization for Economic Co-operation and Development High Production Volume Chemicals Program  
 Organization for Economic Co-operation and Development Screening Information Data Set  
 World Health Organization

<b>Revision date</b>	22-October-2020
<b>Revision Note</b>	No information available.

#### **Disclaimer**

**The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.**

**End of Safety Data Sheet**



**Certification of Compliance with current Good Manufacturing Practices**

Dear Valued Customer:

Spectrum Chemical Mfg Corp certifies that the following product(s) is produced, processed, packaged and held in compliance with current Good Manufacturing Practices (cGMP) in accordance with the applicable parts of 21 CFR, parts 210 and 211 of the Code of Federal Regulations.

Catalog Number	Product Name
MO902	Moxifloxacin HCl, USP

Spectrum is an FDA registered and inspected Drug Establishment. Our United States Food and Drug Administration (USFDA) Registration numbers are as follows:

Spectrum-Gardena, CA: 2020632

Spectrum-New Brunswick, NJ: 2246824

Thank you for your interest in Spectrum products. If we may be of further assistance, please feel free to contact the Quality Assurance department at 310-516-8000 or via email at [qualityassurance@spectrumchemical.com](mailto:qualityassurance@spectrumchemical.com)

Sincerely,

A handwritten signature in black ink, appearing to read "Oralia Chavez", written in a cursive style.

Oralia Chavez  
Quality Assurance Specialist

## MO902, Moxifloxacin HCl, USP

### Source Statement

The above mentioned catalog item is manufactured by chemical synthesis. No animal or plant derived products are used in the manufacturing process.

### BSE/TSE Statement

The above mentioned catalog item does not contain nor is manufactured using any animal derived products and is therefore, BSE/TSE free.

### Allergen Statement

The above mentioned catalog item does not contain any of the following:

- Milk
- Egg
- Fish
- Shellfish
- Tree Nuts
- Wheat
- Peanuts
- Soy
- Cereals containing Gluten
- Celery
- Mustard
- Sesame Seed
- Corn
- Latex
- Sulfites > 10 ppm

### EU Fragrance Allergen Statement

The above mentioned catalog item does not contain any of the 26 EU fragrance allergens listed in Annex III lines 67-92. These substances are not intentionally added to the following chemical and therefore are not expected to be present.

### GMO Statement

The above mentioned catalog item is manufactured without the use of genetically modified organisms and is therefore GMO free.

### Melamine Statement

The above mentioned catalog does not use or add melamine to the manufacturing process and is considered melamine-free.



## **Nitrosamine Statement**

Based on knowledge of the manufacturing process, nitrosamine impurities are not known or suspected to be present in this material.

## **Organic Compliance Statement**

The above mentioned catalog item has not been produced using GMOs, irradiation, ethylene oxide (EtO) or sewage sludge.

## **Shelf Life Statement**

The above mentioned catalog item is typically assigned a shelf life of 60 months from the date of manufacture. The actual assigned shelf life for any specific lot should be referenced on the Certificate of Analysis.

## **Other Chemicals Statement**

Spectrum does not have any reason to suspect the above mentioned catalog item contains any of the following chemicals. This product does not come into contact with these chemicals during packaging or storage:

- |                     |                 |
|---------------------|-----------------|
| • Aflatoxins        | • Parabens      |
| • Antibiotics       | • Pesticides    |
| • Bisphenol A (BPA) | • Phthalates    |
| • CMR Substances    | • Preservatives |



**RE: Elemental Impurities - Moxifloxacin HCl, USP (Cat# MO902)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned material complies with the USP<232>, <233> Elemental Impurities and the ICH Q3D Elemental Impurities Guideline. No Class 1, Class 2A, Class 2B or Class 3 elemental impurities are likely to be present. These substances are not used in the production process, are not intentionally added or known to be present in the above mentioned material.

This information is subject to change and is intended for risk assessment only. It is responsibility of the end user to evaluate suitability of any chemical for the intended use as well as to assess compound-specific limits of daily intake of metal impurities. For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

CORPORATE HEADQUARTERS

769 Jersey Avenue  
New Brunswick, NJ 08901  
PHONE 732.214.1300  
FAX 732.246.7132

WEST COAST FACILITY

14422 South San Pedro Street  
Gardena, California 90248  
PHONE 310.516.8000  
FAX 310.516.9843



**RE: Residual Solvents - Moxifloxacin HCl, USP (Cat# MO902)**

To Whom It May Concern:

Thank you for your interest in Spectrum high quality chemicals.

The above mentioned catalog item complies with the requirements of USP <467> Residual Solvents and ICH Q3C Residual Solvents Guideline. The following solvents are likely to be present:

Residual Solvent	Class	Expected Concentration
Acetonitrile	2	< 410 ppm
Hexane	2	< 290 ppm
Methanol	2	< 3000 ppm
Toluene	2	< 890 ppm
2-Propanol	3	< 5000 ppm

No Class 1 or other solvents are used or produced in the manufacturing process of this material.

For lot-specific information, please refer to the respective Certificate of Analysis.

If you have any further questions, please contact us by telephone at 1(800)772-8786 Option 2, or by email at [TechServices@spectrumchemical.com](mailto:TechServices@spectrumchemical.com).

Sincerely,

Technical Services  
Spectrum Chemical Mfg. Corp.

This document has been produced electronically and is valid without a signature.

**CORPORATE HEADQUARTERS**

769 Jersey Avenue

New Brunswick, NJ 08901

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FAX 732.246.7132

**WEST COAST FACILITY**

14422 South San Pedro Street


Gardena, California 90248

PHONE 310.516.8000

FAX 310.516.9843


## Label Information

The Spectrum label presents technical and safety information in an easily understood format. Our technical specialists stay abreast of the latest requirements of the Globally Harmonized System for Classification and Labelling of Chemicals (GHS), as well as the Occupational Safety and Health Administration (OSHA), the Food and Drug Administration (FDA) and other government regulatory agencies in order to ensure compliance, accuracy and concise hazard communication.

**A**  \*4 9 4 5 2 M 0 2 0 6 2 2 3 3 B E A \*

**C** **WARNING**  
 • Harmful if swallowed • Causes serious eye irritation.  
 • Do not eat, drink or smoke when using this product • Wear eye protection, face protection • Wash face, hands and any exposed skin thoroughly after handling.  
**FIRST AID:** IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention. IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth.

**L** **KEEP FROM CHILDREN**

**B** 

**spectrum®**  
CHEMICAL MFG CORP

**D** **M0902** **F** **5 KG**

**E** **USP**

**H** **G** **CAS 186826-86-8**

**J** **CAUTION:** For manufacturing, processing, repacking, or for prescription compounding. Rx only. **Read and understand the label and Safety Data Sheet (SDS) prior to use.**

**Chemical Emergency: (800)424-9300**  
www.SpectrumChemical.com

**K** **C<sub>21</sub>H<sub>25</sub>ClFN<sub>3</sub>O<sub>4</sub>** **F.W. 437.9**

Manufacturer/Supplier Code .....?  
 Manufacturer Lot Number .....?

Assay (Anhydrous Basis) ..... 98.0-102.0%  
 Identification (IR) ..... To pass test  
 Identification (HPLC) ..... To pass test  
 Identification (Chloride) ..... To pass test  
 pH ..... 3.9-4.6

**MAXIMUM LIMITS**

Water ..... 4.5%  
 Residue on Ignition ..... 0.5%  
 Sulfate ..... 0.04 %

**Related Substances:**

Moxifloxacin Related Compound A ..... 0.1%  
 Moxifloxacin Related Compound B ..... 0.1%  
 Moxifloxacin Related Compound C ..... 0.1%  
 Moxifloxacin Related Compound D ..... 0.1%  
 Moxifloxacin Related Compound E ..... 0.1%  
 Any Other Individual Impurity ..... 0.10%  
 Total Impurities ..... 0.3%

Elemental Impurities ..... As reported  
 Enantiomeric Purity (Moxifloxacin Related Compound G) ..... 0.10%  
 Total Aerobic Microbial Count ..... 1000 CFU/g  
 Total Yeast and Mold Count ..... 100 CFU/g  
 Residual Solvents ..... To pass test

**M** **Repackaged by Spectrum as:**  
**Lot No. 062233**

**O** **G 2/J9GHS-A A**

**SPECTRUM CHEMICAL MFG. CORP. Gardena, CA 90248 • New Brunswick, NJ 08901**

- |  |   |   |
|--|---|---|
| <p><b>A</b> Bar Code</p> <p><b>B</b> GHS Hazard Pictograms</p> <p><b>C</b> Warning, Safety Data and Precautionary Information</p> <p><b>D</b> Product Catalog Number</p> <p><b>E</b> Item Name, Form, Grade</p> <p><b>O</b> Storage Color Band</p> | <p><b>F</b> Size/Quantity</p> <p><b>G</b> Chemical Abstracts Service (CAS) Registry Number</p> <p><b>H</b> Caution Information</p> <p><b>I</b> DOT Shipping Information</p> <p><b>J</b> Toll-Free 24-Hour Chemical Emergency Telephone Number</p> | <p><b>K</b> Empirical Formula, Formula Weight and Technical Specifications Panel</p> <p><b>L</b> Expiration Information</p> <p><b>M</b> Lot Number</p> <p><b>N</b> Kosher Certified by Kosher Supervision of America (KSA).</p> |
|--|---|---|

This color-coded band indicates the hazard most likely to be posed by that material under storage conditions. The criteria used to assign band colors have been established by the Storage Code working group of the Society for Chemical Hazard Communication (SCHC). It is recommended that like colors be stored together, unless otherwise stated, based on the color codes indicated to the right. However, it is the responsibility of the customer to check with their local fire department for possible conflicts with our recommendations when storing hazardous chemicals.

- YELLOW:** Oxidizer
- RED:** Flammable
- GREEN:** General Storage
- BLUE:** Health Hazard
- WHITE:** Corrosive

### Spectrum Chemical Mfg Corp

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