

# SAFETY DATA SHEET



## Moxifloxacin Liquid Formulation

Version 3.0 Revision Date: 17.06.2025 SDS Number: 1732577-00016 Date of last issue: 14.04.2025  
Date of first issue: 05.06.2017

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### SECTION 1. IDENTIFICATION

Product name : Moxifloxacin Liquid Formulation

#### Manufacturer or supplier's details

Company : MSD

Address : 855 Leandro N. Alem St., 8 Floor  
Buenos Aires, Argentina C1001AFB

Telephone : 908-740-4000

Emergency telephone : 1-908-423-6000

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

Restrictions on use : Not applicable

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Not a hazardous substance or mixture.

#### GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

#### Other hazards which do not result in classification

None known.

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### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Moxifloxacin HCL	186826-86-8	>= 0,1 - < 1

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### SECTION 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.

When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air.

Get medical attention.

In case of skin contact : In case of contact, immediately flush skin with soap and plenty

# SAFETY DATA SHEET



## Moxifloxacin Liquid Formulation

Version 3.0

Revision Date: 17.06.2025

SDS Number: 1732577-00016

Date of last issue: 14.04.2025  
Date of first issue: 05.06.2017

---

In case of eye contact	of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
If swallowed	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists. : If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed	: None known.
Protection of first-aiders	: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
Notes to physician	: Treat symptomatically and supportively.

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## SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	: Water spray Alcohol-resistant foam Carbon dioxide (CO <sub>2</sub> ) Dry chemical
Unsuitable extinguishing media	: None known.
Specific hazards during fire fighting	: Exposure to combustion products may be a hazard to health.
Hazardous combustion products	: No hazardous combustion products are known
Specific extinguishing methods	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.
Special protective equipment for fire-fighters	: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

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## SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	: Use personal protective equipment. Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).
Environmental precautions	: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g., by containment or oil barriers).

# SAFETY DATA SHEET



## Moxifloxacin Liquid Formulation

Version  
3.0

Revision Date:  
17.06.2025

SDS Number:  
1732577-00016

Date of last issue: 14.04.2025  
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Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up

: Soak up with inert absorbent material.  
For large spills, provide diking or other appropriate containment to keep material from spreading. If diked material can be pumped, store recovered material in appropriate container.  
Clean up remaining materials from spill with suitable absorbent.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

## SECTION 7. HANDLING AND STORAGE

Technical measures

: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation

: Use only with adequate ventilation.

Advice on safe handling

: Avoid inhalation of vapor or mist.

Do not swallow.

Avoid contact with eyes.

Avoid prolonged or repeated contact with skin.

Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment

Take care to prevent spills, waste and minimize release to the environment.

Conditions for safe storage

: Keep in properly labeled containers.

Store in accordance with the particular national regulations.

Materials to avoid

: Do not store with the following product types:

Strong oxidizing agents

Gases

## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Ingredients with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Moxifloxacin HCL	186826-86-8	TWA	1000 µg/m <sup>3</sup> (OEB 1)	Internal

### Engineering measures

: Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).  
All engineering controls should be implemented by facility

# SAFETY DATA SHEET



## Moxifloxacin Liquid Formulation

Version 3.0	Revision Date: 17.06.2025	SDS Number: 1732577-00016	Date of last issue: 14.04.2025 Date of first issue: 05.06.2017
----------------	------------------------------	------------------------------	---

design and operated in accordance with GMP principles to protect products, workers, and the environment.  
Laboratory operations do not require special containment.

### Personal protective equipment

Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

Filter type : Particulates type

Hand protection : Chemical-resistant gloves

Material : Chemical-resistant gloves

Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

Skin and body protection : Work uniform or laboratory coat.

Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place.  
When using do not eat, drink or smoke.  
Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Color : yellow

Odor : odorless

Odor Threshold : No data available

pH : 4,1 - 4,6

Melting point/freezing point : No data available

Initial boiling point and boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : Not applicable

Flammability (liquids) : No data available

# SAFETY DATA SHEET



## Moxifloxacin Liquid Formulation

Version 3.0      Revision Date: 17.06.2025      SDS Number: 1732577-00016      Date of last issue: 14.04.2025  
Date of first issue: 05.06.2017

---

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Density : 1,0044 g/cm<sup>3</sup> (20 °C)

Solubility(ies)  
Water solubility : slightly soluble

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics  
Particle size : No data available

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## SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions : Can react with strong oxidizing agents.

Conditions to avoid : None known.

Incompatible materials : Oxidizing agents

Hazardous decomposition products : No hazardous decomposition products are known.

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## SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Moxifloxacin Liquid Formulation**

Version 3.0      Revision Date: 17.06.2025      SDS Number: 1732577-00016      Date of last issue: 14.04.2025  
Date of first issue: 05.06.2017

---

**Acute toxicity**

Not classified based on available information.

**Components:****Moxifloxacin HCL:**

Acute oral toxicity	:	LD50 (Rat): 1.320 mg/kg
		LD50 (Mouse): > 435 mg/kg
		LD50 (Monkey): 1.500 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Moxifloxacin HCL:**

Species	:	Rabbit
Result	:	No skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Moxifloxacin HCL:**

Species	:	Rabbit
Result	:	Moderate eye irritation

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Moxifloxacin HCL:**

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: positive
		Test Type: Chromosome aberration test in vitro Result: negative
		Test Type: In vitro mammalian cell gene mutation test Result: negative
		Test Type: in vitro micronucleus test Result: negative

**Moxifloxacin Liquid Formulation**

Version 3.0	Revision Date: 17.06.2025	SDS Number: 1732577-00016	Date of last issue: 14.04.2025 Date of first issue: 05.06.2017
----------------	------------------------------	------------------------------	---

Genotoxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Application Route: Oral Result: negative
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**Carcinogenicity**

Not classified based on available information.

**Reproductive toxicity**

Not classified based on available information.

**Components:****Moxifloxacin HCL:**

Effects on fertility	: Test Type: Fertility/early embryonic development Species: Rat Application Route: Oral Fertility: LOAEL: 500 mg/kg body weight Result: Effects on fertility.
Effects on fetal development	: Test Type: Embryo-fetal development Species: Monkey Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: negative
	Test Type: Embryo-fetal development Species: Rabbit Application Route: Intravenous injection Developmental Toxicity: LOAEL: 20 mg/kg body weight Symptoms: Skeletal malformations.
Reproductive toxicity - Assessment	: Some evidence of adverse effects on development, based on animal experiments.

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Components:****Moxifloxacin HCL:**

Target Organs Assessment	: Liver : May cause damage to organs through prolonged or repeated exposure.
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**Repeated dose toxicity****Components:****Moxifloxacin HCL:**

Species	: Rat
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# SAFETY DATA SHEET



## Moxifloxacin Liquid Formulation

Version 3.0 Revision Date: 17.06.2025 SDS Number: 1732577-00016 Date of last issue: 14.04.2025 Date of first issue: 05.06.2017

---

LOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	4 Weeks
Species	:	Rat
NOAEL	:	100 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Target Organs	:	Liver
Symptoms	:	Liver disorders
Species	:	Rat
NOAEL	:	20 mg/kg
Application Route	:	Oral
Exposure time	:	6 Months
Target Organs	:	Liver
Symptoms	:	Liver disorders
Species	:	Monkey
NOAEL	:	50 mg/kg
Application Route	:	Oral
Exposure time	:	4 Weeks
Symptoms	:	No adverse effects.
Species	:	Monkey
NOAEL	:	15 mg/kg
Application Route	:	Oral
Exposure time	:	13 Weeks
Target Organs	:	Gastrointestinal tract
Symptoms	:	Vomiting
Species	:	Monkey
Application Route	:	Oral
Exposure time	:	26 Weeks
Target Organs	:	Liver
Symptoms	:	Liver disorders

### Aspiration toxicity

Not classified based on available information.

### Experience with human exposure

#### Components:

#### Moxifloxacin HCL:

Ingestion	:	Symptoms: Nausea, Abdominal pain, Headache, Dizziness, central nervous system effects, joint pain
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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

No data available

### Persistence and degradability

No data available

# SAFETY DATA SHEET



## Moxifloxacin Liquid Formulation

Version 3.0      Revision Date: 17.06.2025      SDS Number: 1732577-00016      Date of last issue: 14.04.2025  
Date of first issue: 05.06.2017

---

### Bioaccumulative potential

No data available

### Mobility in soil

No data available

### Other adverse effects

No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : Do not dispose of waste into sewer.  
Dispose of in accordance with local regulations.  
Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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## SECTION 14. TRANSPORT INFORMATION

### International Regulations

#### UNRTDG

Not regulated as a dangerous good

#### IATA-DGR

Not regulated as a dangerous good

#### IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

### Special precautions for user

Not applicable

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## SECTION 15. REGULATORY INFORMATION

### Safety, health and environmental regulations/legislation specific for the substance or mixture

Argentina. Carcinogenic Substances and Agents Registry. : Not applicable

Control of precursors and essential chemicals for the preparation of drugs. : Not applicable

### The ingredients of this product are reported in the following inventories:

AICS : not determined

DSL : not determined

IECSC : not determined

**Moxifloxacin Liquid Formulation**

Version 3.0	Revision Date: 17.06.2025	SDS Number: 1732577-00016	Date of last issue: 14.04.2025 Date of first issue: 05.06.2017
----------------	------------------------------	------------------------------	---

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**SECTION 16. OTHER INFORMATION**

Revision Date : 17.06.2025  
Date format : dd.mm.yyyy

**Further information**

Sources of key data used to compile the Material Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECL - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOM - Official Mexican Norm; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified

# SAFETY DATA SHEET



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Version  
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17.06.2025

SDS Number:  
1732577-00016

Date of last issue: 14.04.2025  
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---

in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

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