

**Moxifloxacin Liquid Formulation**

Version 1.6      Revision Date: 12.10.2021      SDS Number: 1731701-00007      Date of last issue: 13.09.2019  
Date of first issue: 05.06.2017

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**SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Moxifloxacin Liquid Formulation

**Manufacturer or supplier's details**

Company : MSD

Address : Building A - Level 1/26 Talavera Rd  
Macquarie Park NSW, Australia 2113

Telephone : +1-908-740-4000

Emergency telephone number : 1 800 033 461

E-mail address : EHSDATASTEWARD@msd.com

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

Recommended use : Pharmaceutical

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Not a hazardous substance or mixture.

**GHS label elements**

Not a hazardous substance or mixture.

**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	$\geq 0.1$ - $\leq 0.2$

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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 of water.  
Remove contaminated clothing and shoes.

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	Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	: 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. FIREFIGHTING 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 firefighters	: 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). 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 dyking or other appropriate containment to keep material from spreading. If dyked material can

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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 vapour 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.
- 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.
- Conditions for safe storage : Keep in properly labelled containers.  
 Store in accordance with the particular national regulations.
- Materials to avoid : Do not store with the following product types:  
 Strong oxidizing agents

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Moxifloxacin HCL	186826-86-8	TWA	1000 µg/m <sup>3</sup> (OEB 2)	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

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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  
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.
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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- Appearance : liquid
- Colour : yellow
- Odour : odourless
- Odour 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
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapour pressure : No data available
- Relative vapour density : No data available

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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

Auto-ignition 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 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**

Exposure routes : Inhalation  
Skin contact  
Ingestion  
Eye contact

**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

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**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 sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Chronic toxicity****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

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

**Carcinogenicity**

Not classified based on available information.

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**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 foetal development : Test Type: Embryo-foetal development  
Species: Monkey  
Application Route: Oral  
Developmental Toxicity: NOAEL: 10 mg/kg body weight  
Result: negative
- Test Type: Embryo-foetal 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 : Liver  
Assessment : May cause damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Moxifloxacin HCL:**

- Species : Rat  
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

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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

**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 : 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.

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

##### UNRTDG

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable

##### IATA-DGR

UN/ID No. : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 Packing instruction (cargo aircraft) : Not applicable  
 Packing instruction (passenger aircraft) : Not applicable

##### IMDG-Code

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 EmS Code : Not applicable  
 Marine pollutant : Not applicable

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

Not applicable for product as supplied.

#### National Regulations

##### ADG

UN number : Not applicable  
 Proper shipping name : Not applicable  
 Class : Not applicable  
 Subsidiary risk : Not applicable  
 Packing group : Not applicable  
 Labels : Not applicable  
 Hazchem Code : Not applicable

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**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**

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

**The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

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**SECTION 16. OTHER INFORMATION****Further information**

Revision Date : 12.10.2021  
Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>  
Date format : dd.mm.yyyy

**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; KECI - 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

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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; TECl - 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 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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