

**Moxifloxacin Liquid Formulation**

Version 1.5      Revision Date: 09/13/2019      SDS Number: 1731720-00006      Date of last issue: 2019/04/24  
Date of first issue: 2017/06/05

---

**1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Moxifloxacin Liquid Formulation

**Manufacturer or supplier's details**

Company name of supplier : MSD

Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd.  
Menuuma factory

Telephone : 048-588-8411

E-mail address : EHSDATASTEWARD@msd.com

Emergency telephone number : 1-908-423-6000

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

Recommended use : Pharmaceutical

---

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

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

**GHS label elements**

Not a hazardous substance or mixture according to the Globally Harmonised System (GHS).

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

None known.

---

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Moxifloxacin HCL	186826-86-8	>= 0.1 - <= 0.2	

---

**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.

---

## Moxifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/04/24
1.5	09/13/2019	1731720-00006	Date of first issue: 2017/06/05

---

In case of eye contact	:	Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. Flush eyes with water as a precaution.
If swallowed	:	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.

---

### 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.

---

### 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.
Environmental precautions	:	Discharge into the environment must be avoided. 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

## Moxifloxacin Liquid Formulation

Version 1.5      Revision Date: 09/13/2019      SDS Number: 1731720-00006      Date of last issue: 2019/04/24  
 Date of first issue: 2017/06/05

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.

### 7. HANDLING AND STORAGE

#### Handling

- 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.
- Avoidance of contact : Oxidizing agents
- 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.

#### Storage

- 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
- Packaging material : Unsuitable material: None known.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Threshold limit value and permissible exposure limits for each component in the work environment

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)	Internal

## Moxifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/04/24
1.5	09/13/2019	1731720-00006	Date of first issue: 2017/06/05

			2)	
--	--	--	----	--

**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 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.

## 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	: No data available

**Moxifloxacin Liquid Formulation**

Version 1.5      Revision Date: 09/13/2019      SDS Number: 1731720-00006      Date of last issue: 2019/04/24  
Date of first issue: 2017/06/05

---

flammability limit

Vapour pressure : No data available

Relative vapour 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

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

---

**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.

---

**11. TOXICOLOGICAL INFORMATION**

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

**Acute toxicity**

Not classified based on available information.

**Components:**

**Moxifloxacin HCL:**



## Moxifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/04/24
1.5	09/13/2019	1731720-00006	Date of first issue: 2017/06/05

---

### **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 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

**Moxifloxacin Liquid Formulation**

Version 1.5      Revision Date: 09/13/2019      SDS Number: 1731720-00006      Date of last issue: 2019/04/24  
Date of first issue: 2017/06/05

---

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

---

**12. ECOLOGICAL INFORMATION****Ecotoxicity**

No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available



**Moxifloxacin Liquid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 2019/04/24
1.5	09/13/2019	1731720-00006	Date of first issue: 2017/06/05

---

**Hazardous to the ozone layer**

Not applicable

**Other adverse effects**

No data available

---

**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.

---

**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.

**National Regulations**

Refer to section 15 for specific national regulation.

---

**15. REGULATORY INFORMATION****Related Regulations****Fire Service Law**

Not applicable to dangerous materials / designated flammables.

**Chemical Substance Control Law**

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

**Industrial Safety and Health Law****Harmful Substances Prohibited from Manufacture**

Not applicable

**Harmful Substances Required Permission for Manufacture**

Not applicable

**Substances Prevented From Impairment of Health**

Not applicable

**Moxifloxacin Liquid Formulation**

Version            Revision Date:            SDS Number:            Date of last issue: 2019/04/24  
1.5                09/13/2019              1731720-00006        Date of first issue: 2017/06/05

---

**Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity**

Not applicable

**Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity**

Not applicable

**Substances Subject to be Notified Names**

Not applicable

**Substances Subject to be Indicated Names**

Not applicable

**Ordinance on Prevention of Hazards Due to Specified Chemical Substances**

Not applicable

**Ordinance on Prevention of Lead Poisoning**

Not applicable

**Ordinance on Prevention of Tetraalkyl Lead Poisoning**

Not applicable

**Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

**Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)**

Not applicable

**Poisonous and Deleterious Substances Control Law**

Not applicable

**Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof**

Not applicable

**High Pressure Gas Safety Act**

Not applicable

**Explosive Control Law**

Not applicable

**Vessel Safety Law**

Not regulated as a dangerous good

**Aviation Law**

Not regulated as a dangerous good

**Marine Pollution and Sea Disaster Prevention etc Law**

Bulk transportation                    : Not classified as noxious liquid substance

Pack transportation                    : Not classified as marine pollutant

**Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

## Moxifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/04/24
1.5	09/13/2019	1731720-00006	Date of first issue: 2017/06/05

---

Not applicable

**Waste Disposal and Public Cleansing Law**

Industrial waste

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

AICS	:	not determined
DSL	:	not determined
IECSC	:	not determined

---

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

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 : yyyy/mm/dd

**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; 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 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; 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

## Moxifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 2019/04/24
1.5	09/13/2019	1731720-00006	Date of first issue: 2017/06/05

---

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.

JP / EN