SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Moxifloxacin Liquid Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier
Trade name : Moxifloxacin Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against
Use of the Substance/Mixture : Pharmaceutical

1.3 Details of the supplier of the safety data sheet
Company : MSD
Shotton Lane
NE23 3JU Cramlington NU - Great Britain

Telephone : 44 1 670 59 30 00
Telefax : 908-735-1496
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number
1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture
Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements
Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

Additional Labelling
EUH210 Safety data sheet available on request.

2.3 Other hazards
None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Classification</th>
<th>Concentration</th>
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</table>
## SECTION 4: First aid measures

### 4.1 Description of 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.

**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).

**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. 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.

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

None known.

### 4.3 Indication of any immediate medical attention and special treatment needed

**Treatment**

Treat symptomatically and supportively.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

**Suitable extinguishing media**

- Water spray
- Alcohol-resistant foam
- Carbon dioxide (CO2)
- Dry chemical
5.2 Special hazards arising from the substance or mixture
Specific hazards during firefighting
Exposure to combustion products may be a hazard to health.
Hazardous combustion products
No hazardous combustion products are known

5.3 Advice for firefighters
Special protective equipment for firefighters
In the event of fire, wear self-contained breathing apparatus.
Use personal protective equipment.
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.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures
Personal precautions
Use personal protective equipment.
Follow safe handling advice and personal protective equipment recommendations.

6.2 Environmental precautions
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.

6.3 Methods and material for containment and cleaning up
Methods for 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 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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Moxifloxacin Liquid Formulation

Version 1.5  Revision Date: 09/13/2019  SDS Number: 1732581-00006  Date of last issue: 24.04.2019
Date of first issue: 05.06.2017

certain local or national requirements.

6.4 Reference to other sections
See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe 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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers:
Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage:
Do not store with the following product types:
Strong oxidizing agents

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Occupational Exposure Limits</th>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
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<tbody>
<tr>
<td></td>
<td>Moxifloxacin HCL</td>
<td>186826-86-8</td>
<td>TWA</td>
<td>1000 µg/m3 (OEB 2)</td>
<td>Internal</td>
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</tbody>
</table>
8.2 Exposure controls

**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**

**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.

**Hand protection**
- Material: Chemical-resistant gloves

**Skin and body protection**
- Work uniform or laboratory coat.

**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 (P)

**SECTION 9: Physical and chemical properties**

**9.1 Information on basic 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
- **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
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Moxifloxacin Liquid Formulation

Relative density : No data available
Density : 1.0044 g/cm³ (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.

9.2 Other information
Flammability (liquids) : No data available
Molecular weight : No data available
Particle size : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity
Not classified as a reactivity hazard.

10.2 Chemical stability
Stable under normal conditions.

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

10.4 Conditions to avoid
Conditions to avoid : None known.

10.5 Incompatible materials
Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
No hazardous decomposition products are known.
SECTION 11: Toxicological information

11.1 Information on toxicological effects
Information on likely routes of exposure:
- 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

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.

Germ cell mutagenicity
Not classified based on available information.

Components:

Moxifloxacin HCL:
Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Moxifloxacin Liquid Formulation

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
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<td>1.5</td>
<td>09/13/2019</td>
<td>1732581-00006</td>
<td>24.04.2019</td>
<td>05.06.2017</td>
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</tbody>
</table>

- **Result:** positive
  - Test Type: Chromosome aberration test in vitro
  - Result: negative
- **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.

**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
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

SECTION 12: Ecological information

12.1 Toxicity
No data available

12.2 Persistence and degradability
No data available

12.3 Bioaccumulative potential
No data available

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant

12.6 Other adverse effects
No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

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

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good
SAFETY DATA SHEET
according to Regulation (EC) No. 1907/2006

Moxifloxacin Liquid Formulation

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks : Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Not applicable
REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable
REACH - List of substances subject to authorisation (Annex XIV) : Not applicable
Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable
Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable
Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

The components of this product are reported in the following inventories:
AICS : not determined
DSL : not determined
IECSC : not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.

SECTION 16: Other information

Other information : 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 H-Statements
H302 : Harmful if swallowed.
H319 : Causes serious eye irritation.
H361d : Suspected of damaging the unborn child.
H373 : May cause damage to organs through prolonged or repeated
Moxifloxacin Liquid Formulation

Version: 1.5
Revision Date: 09/13/2019
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Full text of other abbreviations

- ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road
- AICS - Australian Inventory of Chemical Substances
- ASTM - American Society for the Testing of Materials
- bw - Body weight
- CLP - Classification Labelling Packaging Regulation
- CMR - Carcinogen, Mutagen or Reproductive Toxicant
- DIN - Standard of the German Institute for Standardisation
- DSL - Domestic Substances List (Canada)
- EC - European Union number
- ECx - Concentration associated with x% response
- ENCS - Existing and New Chemical Substances (Japan)
- FDR - Accelerating Decomposition Temperature
- GHS - Globally Harmonized System
- GLP - Good Laboratory Practice
- IARC - International Agency for Research on Cancer
- IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk
- ICAO - International Civil Aviation Organization
- IDMS - Inventory of Domestic Substances (Japan)
- IECSC - Inventory of Existing Chemical Substances (China)
- IMDG - International Maritime Dangerous Goods
- ISHL - Industrial Safety and Health Law (Japan)
- ISO - International Organisation for Standardization
- KECI - Korea Existing Chemicals Inventory
- LC50 - Lethal Concentration
- MARPOL - International Convention for the Prevention of Pollution from Ships
- MSDS - Material Safety Data Sheet
- NO(A)EC - No Carcinogen, Mutagen or Reproductive Toxicant
- NO(A)EL - No Observed (Adverse) Effect Concentration
- NOELR - No Observable Effect Loading Rate
- NZIoC - New Zealand Inventory of Chemicals
- PBT - Persistent, Bioaccumulative and Toxic substance
- PICCS - Philippines Inventory of Chemicals and Chemical Substances
- PMI - Phases of Material Impact
- PNSG - Persistent, Not Bioaccumulative
- PNSG/STOT RE - Persistent, Not Bioaccumulative/Repeated Exposure
- Repr. - Reproductive toxicity
- Rd. - Date of review
- SADT - Self-Accelerating Decomposition Temperature
- SDS - Safety Data Sheet
- SVHC - Substance of very high concern
- TCSI - Toxic Substances Control Act (United States)
- TS - Taiwan Chemical Substance Inventory
- UN - United Nations
- UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods
- vPvB - Very Persistent and Very Bioaccumulative

Further information

Sources of key data used to compile the Safety Data Sheet:

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 exposure.
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.

NO / EN