1. PRODUCT AND COMPANY IDENTIFICATION

Product name: Moxifloxacin Liquid Formulation

Manufacturer or supplier’s details
Company: MSD
Address: 50 Tuas West Drive
Singapore - Singapore 638408
Telephone: +1-908-740-4000
Emergency telephone number: 65 6697 2111 (24/7/365)
E-mail address: EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use
Recommended use: Pharmaceutical

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture: Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxifloxacin HCL</td>
<td>186826-86-8</td>
<td>&gt;= 0.1 - &lt;= 0.2</td>
</tr>
</tbody>
</table>

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.
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.

5. FIREFIGHTING MEASURES

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: 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 (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 spills 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
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.

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

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

Engineering measures : Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., dripless 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

Eye protection

Eye protection requirements: 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

Skin and body protection requirements: Work uniform or laboratory coat.

Hygiene measures

Hygiene measures requirements: 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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance

Colour

Odour

Odour Threshold

pH

Melting point/freezing point

Initial boiling point and boiling range

Flash point

Evaporation rate

Flammability (solid, gas)

Flammability (liquids)

Upper explosion limit / Upper flammability limit

Lower explosion limit / Lower flammability limit

Vapour pressure

Relative vapour density

Appearance:

Colour:
yellow

Odour:
odourless

Odour Threshold:

pH:

Melting point/freezing point:

Initial boiling point and boiling range:

Flash point:

Evaporation rate:

Flammability (solid, gas):

Flammability (liquids):

Upper explosion limit / Upper flammability limit:

Lower explosion limit / Lower flammability limit:

Vapour pressure:

Relative vapour density:
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.
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:
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)
  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.

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

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
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
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.

Special precautions for user
Not applicable

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture
### Workplace Safety and Health Act and Workplace Safety and Health (General Provisions) Regulations:
This product is subjected to the SDS, labelling, PEL and other requirements in the Act/Regulations.

| Environmental Protection and Management Act and Environmental Protection and Management (Hazardous Substances) Regulations | : Not applicable |
| Fire Safety (Petroleum and Flammable Materials) Regulations | : Not applicable |

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

| Inventory | : not determined |
| AICS | : not determined |
| DSL | : not determined |
| IECSC | : not determined |

### 16. OTHER INFORMATION

#### Further information

| Date format | : dd.mm.yyyy |

### Full text of other abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AIIC</td>
<td>Australian Inventory of Industrial Chemicals;</td>
</tr>
<tr>
<td>ANTT</td>
<td>National Agency for Transport by Land of Brazil;</td>
</tr>
<tr>
<td>ASTM</td>
<td>American Society for the Testing of Materials;</td>
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<tr>
<td>bw</td>
<td>Body weight;</td>
</tr>
<tr>
<td>CMR</td>
<td>Carcinogen, Mutagen or Reproductive Toxicant;</td>
</tr>
<tr>
<td>DIN</td>
<td>Standard of the German Institute for Standardisation;</td>
</tr>
<tr>
<td>DSL</td>
<td>Domestic Substances List (Canada);</td>
</tr>
<tr>
<td>ECx</td>
<td>Concentration associated with x% response;</td>
</tr>
<tr>
<td>ELx</td>
<td>Loading rate associated with x% response;</td>
</tr>
<tr>
<td>EmS</td>
<td>Emergency Schedule;</td>
</tr>
<tr>
<td>ENCS</td>
<td>Existing and New Chemical Substances (Japan);</td>
</tr>
<tr>
<td>ErCx</td>
<td>Concentration associated with x% growth rate response;</td>
</tr>
<tr>
<td>ERG</td>
<td>Emergency Response Guide;</td>
</tr>
<tr>
<td>GHS</td>
<td>Globally Harmonized System;</td>
</tr>
<tr>
<td>GLP</td>
<td>Good Laboratory Practice;</td>
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<tr>
<td>IARC</td>
<td>International Agency for Research on Cancer;</td>
</tr>
<tr>
<td>IATA</td>
<td>International Air Transport Association;</td>
</tr>
<tr>
<td>IBC</td>
<td>International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk;</td>
</tr>
<tr>
<td>IC50</td>
<td>Half maximal inhibitory concentration;</td>
</tr>
<tr>
<td>ICAO</td>
<td>International Civil Aviation Organization;</td>
</tr>
<tr>
<td>IECSC</td>
<td>Inventory of Existing Chemical Substances in China;</td>
</tr>
<tr>
<td>IMDG</td>
<td>International Maritime Dangerous Goods;</td>
</tr>
<tr>
<td>IMO</td>
<td>International Maritime Organization;</td>
</tr>
<tr>
<td>ISHL</td>
<td>Industrial Safety and Health Law (Japan);</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organisation for Standardisation;</td>
</tr>
<tr>
<td>KECI</td>
<td>Korea Existing Chemicals Inventory;</td>
</tr>
<tr>
<td>LC50</td>
<td>Lethal Concentration to 50% of a test population;</td>
</tr>
<tr>
<td>LD50</td>
<td>Lethal Dose to 50% of a test population (Median Lethal Dose);</td>
</tr>
<tr>
<td>MARPOL</td>
<td>International Convention for the Prevention of Pollution from Ships;</td>
</tr>
<tr>
<td>n.o.s.</td>
<td>Not Otherwise Specified;</td>
</tr>
<tr>
<td>Nch</td>
<td>Chilean Norm;</td>
</tr>
<tr>
<td>NO(A)EC</td>
<td>No Observed (Adverse) Effect Concentration;</td>
</tr>
<tr>
<td>NO(A)EL</td>
<td>No Observed (Adverse) Effect Level;</td>
</tr>
<tr>
<td>NOELR</td>
<td>No Observable Effect Loading Rate;</td>
</tr>
<tr>
<td>NOM</td>
<td>Official Mexican Norm;</td>
</tr>
<tr>
<td>NTP</td>
<td>National Toxicology Program;</td>
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<tr>
<td>NZIoC</td>
<td>New Zealand Inventory of Chemicals;</td>
</tr>
<tr>
<td>OECD</td>
<td>Organization for Economic Co-operation and Development;</td>
</tr>
<tr>
<td>OPPTS</td>
<td>Office of Chemical Safety and Pollution Prevention;</td>
</tr>
<tr>
<td>PBT</td>
<td>Persistent, Bioaccumulative and Toxic substance;</td>
</tr>
<tr>
<td>PICCS</td>
<td>Philippines Inventory of Chemicals and Chemical Substances;</td>
</tr>
<tr>
<td>(Q)SAR</td>
<td>(Quantitative) Structure Activity Relationship;</td>
</tr>
<tr>
<td>REACH</td>
<td>Regulation (EC) No</td>
</tr>
</tbody>
</table>
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.