1. PRODUCT AND COMPANY IDENTIFICATION

Product name : Moxifloxacin Liquid Formulation

Manufacturer or supplier’s details
Company : MSD
Address : Briahnager - Off Pune Nagar Road
Wagholi - Pune - India 412 207
Telephone : 908-740-4000
Emergency telephone number : 1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com
Telefax : 908-735-1496

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

2. HAZARDS IDENTIFICATION

Manufacture, Storage and Import of Hazardous Chemicals Rules 1989

Classification
Not classified as hazardous according to criteria laid down in Part I of Schedule-1.

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 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 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

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., 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: 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.

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
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
**SAFETY DATA SHEET**

**Moxifloxacin Liquid Formulation**

<table>
<thead>
<tr>
<th>Application Route</th>
<th>Oral</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exposure time</td>
<td>13 Weeks</td>
</tr>
<tr>
<td>Target Organs</td>
<td>Liver</td>
</tr>
<tr>
<td>Symptoms</td>
<td>Liver disorders</td>
</tr>
</tbody>
</table>

**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
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 IMO instruments: Not applicable for product as supplied.

15. REGULATORY INFORMATION

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

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
- Date format: dd.mm.yyyy

Full text of other abbreviations
SAFETY DATA SHEET

Moxifloxacin Liquid Formulation

Version 1.5  Revision Date: 09/13/2019  SDS Number: 1732584-00006  Date of last issue: 24.04.2019

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.

IN / EN