1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name : Moxifloxacin Solid Formulation

Supplier’s company name, address and phone number
Company name of supplier : MSD
Address : Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma 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 of chemical product
Acute toxicity (Oral) : Category 4
Serious eye damage/eye irritation : Category 2B
Reproductive toxicity : Category 2
Specific target organ toxicity - repeated exposure : Category 2 (Liver)

GHS label elements
Hazard pictograms : ![Warning symbol]
Signal word : Warning
Hazard statements : H302 Harmful if swallowed.
H320 Causes eye irritation.
H361d Suspected of damaging the unborn child.
H373 May cause damage to organs (Liver) through prolonged or repeated exposure.

Precautionary statements : Prevention:
P201 Obtain special instructions before use.
P202 Do not handle until all safety precautions have been read and understood.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
SAFETY DATA SHEET

Moxifloxacin Solid Formulation

P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.
P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

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>
<th>ENCS No.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxifloxacin HCL</td>
<td>186826-86-8</td>
<td>&gt;= 40 - &lt;= 70</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>&gt;= 10 - &lt;= 30</td>
<td></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 : In case of contact, immediately flush eyes with plenty of water for at least 15 minutes.
If easy to do, remove contact lens, if worn.
Get medical attention.
If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: Harmful if swallowed. Causes eye irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

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: Carbon oxides

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. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. 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
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**: Do not breathe dust, fume, gas, mist, vapours or spray.
  - Do not swallow.
  - Do not get in eyes.
  - Avoid prolonged or repeated contact with skin.
  - Wash skin thoroughly after handling.
  - Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
  - Do not eat, drink or smoke when using this product.
  - 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 locked up.
  - 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

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Reference concentration / 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>
<tr>
<td>Cellulose</td>
<td>9004-34-6</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>
Engineering measures

Use feasible engineering controls to minimize exposure to compound. All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

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

Physical state

solid

Colour

pink

Odour

odourless

Odour Threshold

No data available

Melting point/freezing point

No data available

Boiling point, initial boiling point and boiling range

No data available

Flammability (solid, gas)

Not classified as a flammability hazard

Flammability (liquids)

No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Upper flammability limit

No data available

Lower explosion limit / Lower flammability limit

No data available

Flash point

Not applicable

Decomposition temperature

No data available

pH

No data available

Evaporation rate

No data available
Auto-ignition temperature : No data available

Viscosity
   Viscosity, kinematic : No data available

Solubility(ies)
   Water solubility : No data available

Partition coefficient: n-octanol/water

Vapour pressure : No data available

Density and / or relative density
   Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : Not applicable

Particle characteristics
   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 : Skin contact
   Ingestion
   Eye contact

Acute toxicity
   Harmful if swallowed.

Product:
   Acute oral toxicity : Acute toxicity estimate: 1,886 mg/kg
   Method: Calculation method
Components:

Moxifloxacin HCL:

- **Acute oral toxicity**
  - LD50 (Rat): 1,320 mg/kg
  - LD50 (Mouse): > 435 mg/kg
  - LD50 (Monkey): 1,500 mg/kg

- **Cellulose**
  - **Acute oral toxicity**
    - LD50 (Rat): > 5,000 mg/kg
  - **Acute inhalation toxicity**
    - LC50 (Rat): > 5.8 mg/l
      - Exposure time: 4 h
      - Test atmosphere: dust/mist
  - **Acute dermal toxicity**
    - LD50 (Rabbit): > 2,000 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

Causes eye irritation.

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 vivo micronucleus test  
Result: negative

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

Cellulose:  
Genotoxicity in vitro  
Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Result: negative

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

Carcinogenicity  
Not classified based on available information.

Components:  
Cellulose:  
Species: Rat  
Application Route: Ingestion  
Exposure time: 72 weeks  
Result: negative

Reproductive toxicity  
Suspected of damaging the unborn child.

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.

Cellulose:

Effects on fertility

Test Type: One-generation reproduction toxicity study
Species: Rat
Application Route: Ingestion
Result: negative

Effects on foetal development

Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs (Liver) through prolonged or repeated exposure.

Components:

Moxifloxacin HCL:

Target Organs
Assessment

Liver
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
<table>
<thead>
<tr>
<th>Component</th>
<th>Species</th>
<th>NOAEL</th>
<th>Application Route</th>
<th>Exposure time</th>
<th>Target Organs</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moxifloxacin HCL</td>
<td>Monkey</td>
<td>20 mg/kg</td>
<td>Oral</td>
<td>6 Months</td>
<td>Liver</td>
<td>Liver disorders</td>
</tr>
<tr>
<td></td>
<td>Monkey</td>
<td>50 mg/kg</td>
<td>Oral</td>
<td>4 Weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Monkey</td>
<td>15 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Gastrointestinal tract</td>
<td>No adverse effects</td>
</tr>
<tr>
<td></td>
<td>Monkey</td>
<td>15 mg/kg</td>
<td>Oral</td>
<td>13 Weeks</td>
<td>Gastrointestinal tract</td>
<td>No adverse effects</td>
</tr>
<tr>
<td></td>
<td>Monkey</td>
<td>15 mg/kg</td>
<td>Oral</td>
<td>26 Weeks</td>
<td>Liver</td>
<td></td>
</tr>
<tr>
<td>Cellulose</td>
<td>Rat</td>
<td>&gt;= 9,000 mg/kg</td>
<td>Ingestion</td>
<td>90 Days</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Experience with human exposure**

**Components:**

**Moxifloxacin HCL:**

- **Ingestion:** Symptoms: Nausea, Abdominal pain, Headache, Dizziness, central nervous system effects, joint pain

---

12. ECOLOGICAL INFORMATION

**Ecotoxicity**

**Components:**

**Cellulose:**

- **Toxicity to fish:**
  - **LC50 (Oryzias latipes (Japanese medaka)):** > 100 mg/l
  - **Exposure time:** 48 h
  - **Remarks:** Based on data from similar materials
Persistence and degradability

Components:

Cellulose:

Biodegradability: Result: Readily biodegradable.

Bioaccumulative potential
No data available

Mobility in soil
No data available

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
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
SAFETY DATA SHEET

Moxifloxacin Solid Formulation

### Version
4.0

### Revision Date
2021/10/13

### SDS Number
1731680-00008

### Date of last issue
2020/03/23

### Date of first issue
2017/06/05

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
Refer to section 15 for specific national regulation.

**Special precautions for user**
Not applicable

### 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

**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**

<table>
<thead>
<tr>
<th>Chemical name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-Cyclopropyl-6-fluoro-8-methoxy-7-[(4aS,7aS)-octahydropyrrolo[3,4-b]pyridine-6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid monohydrochloride</td>
</tr>
</tbody>
</table>

**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
Ordnance 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)
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
SAFETY DATA SHEET

Moxifloxacin Solid Formulation

Version: 4.0
Revision Date: 2021/10/13
SDS Number: 1731680-00008
Date of last issue: 2020/03/23
Date of first issue: 2017/06/05

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

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Date format: yyyy/mm/dd

Full text of other abbreviations:
- ACGIH: USA. ACGIH Threshold Limit Values (TLV)
- ACGIH / TWA: 8-hour, time-weighted average
- ALIC: 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 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; TECI: 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.