according to GB/T 16483 and GB/T 17519



# **Moxifloxacin Solid Formulation**

Version Revision Date: SDS Number: Date of last issue: 2024/04/06 2024/09/28 1731665-00016 Date of first issue: 2017/06/05 2.0

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Moxifloxacin Solid Formulation Product name

Manufacturer or supplier's details

Company MSD

Address 199 Wenhai North Road

HEDA, Hangzhou - Zhejiang Province - CHINA 310018

Telephone 908-740-4000

Emergency telephone number: 86-571-87268110

E-mail address EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use Pharmaceutical Restrictions on use Not applicable

#### 2. HAZARDS IDENTIFICATION

### **Emergency Overview**

**Appearance** solid Colour pink Odour odourless

Harmful if swallowed. Causes eye irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

**GHS Classification** 

Acute toxicity (Oral) Category 4

Serious eye damage/eye irri-

tation

Category 2B

Reproductive toxicity Category 2

Specific target organ toxicity - : Category 2

repeated exposure

#### **GHS** label elements

according to GB/T 16483 and GB/T 17519



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Hazard pictograms :





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 through prolonged or re-

peated 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.

P264 Wash skin thoroughly after handling.

P270 Do not eat, drink or smoke when using this product. P280 Wear protective gloves/ protective clothing/ eye protec-

tion/ 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/ at-

tention.

### Storage:

P405 Store locked up.

### Disposal:

P501 Dispose of contents/ container to an approved waste

disposal plant.

#### Physical and chemical hazards

Not classified based on available information.

### **Health hazards**

Harmful if swallowed. Causes eye irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure.

#### **Environmental hazards**

Not classified based on available information.

according to GB/T 16483 and GB/T 17519



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#### 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)
Moxifloxacin HCL	186826-86-8	>= 40 -<= 70
Cellulose	9004-34-6	>= 10 -<= 30

#### 4. FIRST AID MEASURES

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice 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, 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

and effects, 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

according to GB/T 16483 and GB/T 17519



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Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances 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, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective 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 con-

tainer 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 deter-

mine 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 : Do not breathe dust, fume, gas, mist, vapours or spray.

Do not swallow.

according to GB/T 16483 and GB/T 17519



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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 as-

sessment

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

**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

### Components with workplace control parameters

Components	CAS-No.	Value type	Control parame-	Basis
		(Form of	ters / Permissible	
		exposure)	concentration	
Moxifloxacin HCL	186826-86-8	TWA	1000 μg/m3 (OEB	Internal
			1)	
Cellulose	9004-34-6	PC-TWA	10 mg/m3	CN OEL
		TWA	10 mg/m3	ACGIH

**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 expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection.

Filter type : Particulates type

Eye/face 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

Hand protection

Work uniform or laboratory coat.

according to GB/T 16483 and GB/T 17519



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Material : Chemical-resistant gloves

Hygiene measures : If exposure to chemical is likely during typical use, provide

eye flushing systems and safety showers close to the work-

ing 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 : solid

Colour : pink

Odour : odourless

Odour Threshold : No data available

pH : No data available

Melting point/freezing point : No data available

Initial boiling point and boiling

range

No data available

Flash point : Not applicable

Evaporation rate : No data available

Flammability (solid, gas) : Not classified as a flammability hazard

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 : No data available

according to GB/T 16483 and GB/T 17519



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Solubility(ies)

Water solubility No data available

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 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. Can react with strong oxidizing agents.

Possibility of hazardous reac- :

tions

Conditions to avoid None known.

Incompatible materials Oxidizing agents

Hazardous decomposition

products

No hazardous decomposition products are known.

### 11. TOXICOLOGICAL INFORMATION

Exposure routes Skin contact

Ingestion Eye contact

**Acute toxicity** 

Harmful if swallowed.

**Product:** 

Acute toxicity estimate: 1,886 mg/kg Acute oral toxicity

Method: Calculation method

**Components:** 

**Moxifloxacin HCL:** 

Acute oral toxicity LD50 (Rat): 1,320 mg/kg

according to GB/T 16483 and GB/T 17519



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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

according to GB/T 16483 and GB/T 17519



# **Moxifloxacin Solid Formulation**

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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

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 develop-

ment

Test Type: Embryo-foetal development

Species: Monkey

according to GB/T 16483 and GB/T 17519



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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 - As-

sessment

: 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 develop-

ment

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 through prolonged or repeated exposure.

#### **Components:**

#### **Moxifloxacin HCL:**

Target Organs : Liver

Assessment : May cause damage to organs through prolonged or repeated

exposure.

### Repeated dose toxicity

### **Components:**

### **Moxifloxacin HCL:**

Species: RatLOAEL: 100 mg/kgApplication Route: OralExposure time: 4 Weeks

Species : Rat

NOAEL : 100 mg/kg Application Route : Oral

according to GB/T 16483 and GB/T 17519



# **Moxifloxacin Solid Formulation**

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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

Cellulose:

Species : Rat

NOAEL : >= 9,000 mg/kg
Application Route : Ingestion
Exposure time : 90 Days

**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

according to GB/T 16483 and GB/T 17519



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#### 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

### Other adverse effects

No data available

### 13. DISPOSAL CONSIDERATIONS

### **Disposal methods**

Waste from residues : Do not dispose of waste into sewer.

Dispose of in accordance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste han-

dling 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

Environmentally hazardous : no

**IATA-DGR** 

according to GB/T 16483 and GB/T 17519



### **Moxifloxacin Solid Formulation**

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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 : Not applicable

aircraft)

Packing instruction (passen- : Not applicable

ger aircraft)

**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 : no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

#### **National Regulations**

GB 6944/12268

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

Marine pollutant : no

Special precautions for user

Not applicable

### 15. REGULATORY INFORMATION

#### **National regulatory information**

Law on the Prevention and Control of Occupational Diseases

### Regulations on Safety Management of Hazardous Chemicals

Catalogue of Hazardous Chemicals : This product is not listed in the cata-

logue of hazardous chemicals, but it meets the definition of hazardous chemicals and its principles of de-

termination.

Identification of Major Hazard Installations for Hazardous Chemicals (GB : Not listed

18218)

according to GB/T 16483 and GB/T 17519



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Hazardous Chemicals for Priority Management under : Not listed

SAWS

Regulations on Labour Protection in Workplaces where Toxic Substances are Used

Catalogue of Highly Toxic Chemicals : Not listed

Regulation of Environmental Management on the First Import of Chemicals and the Import and Export of Toxic Chemicals

China Severely Restricted Toxic Chemicals for Import : Not listed

and Export

**Regulation on the Administration of Precursor Chemicals** 

Catalogue and Classification of Precursor Chemicals : Not listed

Yangtze River Protection Law

This product does not contain any dangerous chemicals prohibited for inland river transport.

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

**AICS** not determined

DSL not determined

**IECSC** not determined

**16. OTHER INFORMATION** 

**Revision Date** 2024/09/28

**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 Agen-

cy, http://echa.europa.eu/

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)

**CN OEL** Occupational exposure limits for hazardous agents in the

workplace - Chemical hazardous agents.

ACGIH / TWA 8-hour, time-weighted average

CN OEL / PC-TWA Permissible concentration - time weighted average

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AIIC - 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

#### **Disclaimer**

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.

CN / EN