

# SAFETY DATA SHEET

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures".



## Moxifloxacin Solid Formulation

Version 2.1      Revision Date: 04/24/2019      SDS Number: 2437922-00004      Date of last issue: 15.10.2018  
Date of first issue: 09.02.2018

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

#### 1.1 Product identifier

Trade name : Moxifloxacin Solid 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 T.R. SEA No 28848

Acute toxicity, Category 4	H302: Harmful if swallowed.
Eye irritation, Category 2	H319: Causes serious eye irritation.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 2	H373: May cause damage to organs through prolonged or repeated exposure.

#### 2.2 Label elements

##### Labelling T.R. SEA No 28848

Hazard pictograms :



Signal word : Warning

Hazard statements : H302 Harmful if swallowed.  
H319 Causes serious eye irritation.  
H361d Suspected of damaging the unborn child.

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H373    May cause damage to organs through prolonged or repeated exposure.

Precautionary statements :

### Prevention:

P201    Obtain special instructions before use.

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 or doctor/ physician if you feel unwell. Rinse mouth.  
P308 + P313    IF exposed or concerned: Get medical advice/ attention.  
P337 + P313    If eye irritation persists: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Moxifloxacin HCL

### 2.3 Other hazards

None known.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Moxifloxacin HCL	186826-86-8	Acute Tox.4; H302 Eye Irrit.2; H319 Repr.2; H361d STOT RE2; H373	>= 40 - <= 70

For explanation of abbreviations see section 16.

## 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.

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- 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.

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

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

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

- Treatment : Treat symptomatically and supportively.
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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

### 5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Exposure to combustion products may be a hazard to health.
- Hazardous combustion products : Carbon oxides

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### 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.
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## 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. 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 : 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 certain local or national requirements.

### 6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

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## 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 : Do not swallow. Do not get in eyes. Avoid prolonged or repeated contact with skin.
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Hygiene measures : 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.  
: Ensure that eye flushing systems and safety showers are located 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 locked up. 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

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Moxifloxacin HCL	186826-86-8	TWA	1000 µg/m <sup>3</sup> (OEB 2)	Internal

### 8.2 Exposure controls

#### 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

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

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Skin and body protection	:	Work uniform or laboratory coat.
Respiratory protection	:	Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.
Filter type	:	Particulates type (P)

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### SECTION 9: Physical and chemical properties

#### 9.1 Information on basic 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
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
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

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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 : Not applicable  
Particle size : No data available

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## 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.

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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

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

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### 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**

Causes serious 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 vitro micronucleus test  
Result: negative



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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**

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.

### **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.

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### 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,

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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

#### 14.5 Environmental hazards

Not regulated as a dangerous good

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### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to IMO instruments

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

KKDIK (30105 (Bis)) - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex 17) : Not applicable

#### Other regulations:

According to 13 December 2014, No:29204, "Ministry of Environment and Urbanization; Regulation on Safety data sheets regarding hazardous substances and mixtures".  
Regulation on Classification, Labelling and Packaging of Substances and Mixtures. Dated 11 December 2013, Numbered 28848 (Bis) Ministry of Environment and Forestry.  
Regulation on Health and Safety Measures Of Working with Chemicals Substances Dated 12.08.13, numbered 28733 Ministry of Labour and Social Security.

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

AICS	: not determined
DSL	: not determined
IECSC	: not determined

## 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 exposure.

#### Full text of other abbreviations

Acute Tox.	: Acute toxicity
Eye Irrit.	: Eye irritation
Repr.	: Reproductive toxicity
STOT RE	: Specific target organ toxicity - repeated exposure

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

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for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of very high concern; TCSI - Taiwan Chemical Substance 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

### 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 Agency, <http://echa.europa.eu/>

### Classification of the mixture:

Acute Tox. 4	H302
Eye Irrit. 2	H319
Repr. 2	H361d
STOT RE 2	H373

### Classification procedure:

Calculation method
Calculation method
Calculation method
Calculation method

**The Turkish SDS has been prepared according to the Regulation on Safety Data Sheets for Hazardous Substances and Mixtures No. 29204.**

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

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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.

TR / EN