

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
9839712-00011

Date of last issue: 14.04.2025  
Date of first issue: 13.10.2021

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### 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 Sub-  
stance/Mixture : Pharmaceutical

Recommended restrictions  
on use : Not applicable

#### 1.3 Details of the supplier of the safety data sheet

Company : MSD  
120 Moorgate  
EC2M 6UR London, United Kingdom

Telephone : +44 (0) 2081548000

E-mail address of person  
responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK  
SI 2019/720, and UK SI 2020/1567)

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 pro- longed or repeated exposure.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version 5.0	Revision Date: 17.06.2025	SDS Number: 9839712-00011	Date of last issue: 14.04.2025 Date of first issue: 13.10.2021
----------------	------------------------------	------------------------------	---

### 2.2 Label elements

**Labelling (REGULATION (EC) No 1272/2008) as amended by GB-CLP Regulation, UK SI 2019/720, and UK SI 2020/1567)**

Hazard pictograms	:	
Signal word	:	Warning
Hazard 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.
Precautionary statements	:	<b>Prevention:</b> 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.  <b>Response:</b> P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/ doctor 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

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

## 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	>= 70 - < 90

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
9839712-00011

Date of last issue: 14.04.2025  
Date of first issue: 13.10.2021

		Eye Irrit. 2; H319 Repr. 2; H361d STOT RE 2; H373 (Liver)	
Substances with a workplace exposure limit :			
Cellulose	9004-34-6 232-674-9		>= 30 - < 50

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 (see section 8).

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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version 5.0	Revision Date: 17.06.2025	SDS Number: 9839712-00011	Date of last issue: 14.04.2025 Date of first issue: 13.10.2021
----------------	------------------------------	------------------------------	---

Treatment : Treat symptomatically and supportively.

## 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

### 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.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

### 6.2 Environmental precautions

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
If spillage enters rivers or watercourses, inform the Environment Agency (emergency telephone number 0800 807060).

### 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.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
9839712-00011

Date of last issue: 14.04.2025  
Date of first issue: 13.10.2021

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.

## 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. 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.
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.

### 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
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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version 5.0 Revision Date: 17.06.2025 SDS Number: 9839712-00011 Date of last issue: 14.04.2025  
Date of first issue: 13.10.2021

### 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/m3 (OEB 1)	Internal
Cellulose	9004-34-6	TWA (inhalable dust)	10 mg/m3	GB EH40
		TWA (Respirable dust)	4 mg/m3	GB EH40
		STEL (inhalable dust)	20 mg/m3	GB EH40

#### 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/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.
Hand protection	
Material	: Chemical-resistant gloves
Skin and body protection	: Work uniform or laboratory coat.
Respiratory protection	: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Equipment should conform to BS EN 143
Filter type	: Particulates type (P)

### 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version 5.0	Revision Date: 17.06.2025	SDS Number: 9839712-00011	Date of last issue: 14.04.2025 Date of first issue: 13.10.2021
----------------	------------------------------	------------------------------	---

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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

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.

### 9.2 Other information

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.

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version 5.0      Revision Date: 17.06.2025      SDS Number: 9839712-00011      Date of last issue: 14.04.2025  
Date of first issue: 13.10.2021

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### 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

#### 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version 5.0      Revision Date: 17.06.2025      SDS Number: 9839712-00011      Date of last issue: 14.04.2025  
Date of first issue: 13.10.2021

---

### **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
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
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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version  
5.0

Revision Date:  
17.06.2025

SDS Number:  
9839712-00011

Date of last issue: 14.04.2025  
Date of first issue: 13.10.2021

		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
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# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version 5.0      Revision Date: 17.06.2025      SDS Number: 9839712-00011      Date of last issue: 14.04.2025  
Date of first issue: 13.10.2021

---

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 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 : 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

## SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by UK REACH Regulations SI 2019/758



## **Moxifloxacin Solid Formulation**

Version	Revision Date:	SDS Number:	Date of last issue: 14.04.2025
5.0	17.06.2025	9839712-00011	Date of first issue: 13.10.2021

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

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## SECTION 12: Ecological information

## 12.1 Toxicity

## Components:

## Cellulose-

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

## 12.2 Persistence and degradability

## Components:

## Cellulose-

Biodegradability : Result: Readily biodegradable.

### 12.3 Bioaccumulative potential

No data available

## 12.4 Mobility in soil

No data available

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version 5.0      Revision Date: 17.06.2025      SDS Number: 9839712-00011      Date of last issue: 14.04.2025  
Date of first issue: 13.10.2021

---

### 12.5 Results of PBT and vPvB assessment

#### Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

### 12.6 Other adverse effects

#### Product:

Endocrine disrupting potential : This substance/mixture does not contain components considered to have endocrine disrupting properties for environment according to UK REACH Article 57(f).

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## 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.  
Do not dispose of waste into sewer.

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.

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## SECTION 14: Transport information

### 14.1 UN number

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
**IATA** : Not regulated as a dangerous good

### 14.2 UN proper shipping name

**ADN** : Not regulated as a dangerous good  
**ADR** : Not regulated as a dangerous good  
**RID** : Not regulated as a dangerous good  
**IMDG** : Not regulated as a dangerous good  
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### 14.3 Transport hazard class(es)

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version 5.0	Revision Date: 17.06.2025	SDS Number: 9839712-00011	Date of last issue: 14.04.2025 Date of first issue: 13.10.2021
----------------	------------------------------	------------------------------	---

---

<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA</b>	:	Not regulated as a dangerous good

### 14.4 Packing group

<b>ADN</b>	:	Not regulated as a dangerous good
<b>ADR</b>	:	Not regulated as a dangerous good
<b>RID</b>	:	Not regulated as a dangerous good
<b>IMDG</b>	:	Not regulated as a dangerous good
<b>IATA (Cargo)</b>	:	Not regulated as a dangerous good
<b>IATA (Passenger)</b>	:	Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks	:	Not applicable for product as supplied.
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## SECTION 15: Regulatory information

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

Relevant EU provisions transposed through retained EU law

UK REACH List of restrictions (Annex 17)	:	Not applicable
UK REACH Candidate list of substances of very high concern (SVHC) for Authorisation	:	Not applicable
The Persistent Organic Pollutants Regulations (retained Regulation (EU) 2019/1021 as amended for Great Britain)	:	Not applicable
Regulation (EU) No 2024/590 on substances that deplete the ozone layer	:	Not applicable
UK REACH List of substances subject to authorisation (Annex XIV)	:	Not applicable
GB Export and import of hazardous chemicals - Prior Informed Consent (PIC) Regulation	:	Not applicable
Control of Major Accident Hazards Regulations 2015 (COMAH)		
		Not applicable

### Other regulations:

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements

# SAFETY DATA SHEET

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UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

Version  
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Revision Date:  
17.06.2025

SDS Number:  
9839712-00011

Date of last issue: 14.04.2025  
Date of first issue: 13.10.2021

---

relating to new and expectant mothers at work contained in Regulation 16 to 18) and of the Pregnant Workers Directive 92/85/EEC.

Take note of The Management of Health and Safety at Work Regulations 1999 (requirements relating to protection of young people at work contained in Regulation 19) and of Directive 94/33/EC on the protection of young people at work.

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

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

### **15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

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## **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  
GB EH40 : UK. EH40 WEL - Workplace Exposure Limits  
GB EH40 / TWA : Long-term exposure limit (8-hour TWA reference period)  
GB EH40 / STEL : Short-term exposure limit (15-minute reference period)

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society 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

# SAFETY DATA SHEET

According to REACH Regulation (EC) No 1907/2006, as amended by  
UK REACH Regulations SI 2019/758



## Moxifloxacin Solid Formulation

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Revision Date:  
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- 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; 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

### 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

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

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