



Versic 3.8	on	Revision Date: 28.09.2024		S Number: 31699-00015	Date of last issue: 30.09.2023 Date of first issue: 05.06.2017
SECT	ION 1	. IDENTIFICATION			
P	Produc	t identifier	:	Moxifloxacin Liqu	uid Formulation
	/lanufa Compa	acturer or supplier's o	deta :	ils MSD	
Address		:	Avenue Comendador Antônio Loureiro Ramos, nº 1500 – Distrito Industrial Montes Claros – MG, Brazil 39404-620		
Т	eleph	one	:	+55 (38) 3229 70	000
Emergency telephone		:	+55 (38) 3201 56	370	
E	-mail	address	:	EHSDATASTEW	/ARD@msd.com
R	Recom	mended use of the c mended use tions on use		ical and restriction Pharmaceutical Not applicable	ons on use

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification in accordance with ABNT NBR 14725 Standard

Not classified as hazardous in accordance with ABNT NBR 14725

GHS label elements in accordance with ABNT NBR 14725 Standard

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

:

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Classification	Concentration (% w/w)
Moxifloxacin HCL	186826-86-8	Acute Tox. (Oral), 4 Eye Irrit., 2B Repr., 2 STOT RE, (Liver) , 2	>= 0,1 -<= 0,2

SECTION 4. FIRST AID MEASURES

General advice

In the case of accident or if you feel unwell, seek medical advice immediately.



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If	f inhale	ed	:	When symptoms advice. If inhaled, remove	persist or in all cases of doubt seek medical e to fresh air.
Ir	n case	of skin contact	:	of water. Remove contamir Get medical atten Wash clothing bet	, immediately flush skin with soap and plenty nated clothing and shoes. tion.
Ir	n case	of eye contact	:	Flush eyes with w	rater as a precaution. tion if irritation develops and persists.
lf	f swallo	owed	:		NOT induce vomiting. tion.
а		portant symptoms ects, both acute and	:	None known.	
		on of first-aiders	:	and use the recor	ers should pay attention to self-protection, nmended personal protective equipment Il for exposure exists (see section 8).
Ν	Notes to	o physician	:		cally and supportively.
SECT	ION 5.	FIRE-FIGHTING ME	ASU	IRES	
S	Suitable	e extinguishing media	:	Water spray Alcohol-resistant t Carbon dioxide (C Dry chemical	
	Jnsuita nedia	ble extinguishing	:	None known.	
	Specific ighting	hazards during fire	:	Exposure to comb	oustion products may be a hazard to health.
	Hazardo ucts	ous combustion prod-	:	No hazardous cor	mbustion products are known
	Specific ods	extinguishing meth-	:	cumstances and t Use water spray t	measures that are appropriate to local cir- he surrounding environment. o cool unopened containers. ged containers from fire area if it is safe to do
		protective equipment fighters	:		e, wear self-contained breathing apparatus. tective equipment.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protec-	:	Use personal protective equipment.
tive equipment and emer-		Follow safe handling advice (see section 7) and personal
gency procedures		protective equipment recommendations (see section 8).

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Er	nvironm	nental precautions	:	Prevent spreading oil barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g., by containment or be of contaminated wash water. should be advised if significant spillages
		and materials for ent and cleaning up	:	For large spills, pr containment to ke can be pumped, s container. Clean up remainin absorbent. Local or national r disposal of this ma employed in the c determine which r Sections 13 and 1	absorbent material. ovide diking or other appropriate ep material from spreading. If diked material tore recovered material in appropriate ng materials from spill with suitable egulations may apply to releases and aterial, as well as those materials and items leanup of releases. You will need to egulations are applicable. 5 of this SDS provide information regarding tional requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures	See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.	
Local/Total ventilation Advice on safe handling	 Use only with adequate ventilation. Avoid inhalation of vapor or mist. Do not swallow. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment 	
	Take care to prevent spills, waste and minimize release to the environment.	1
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. 	3
Conditions for safe storage	Keep in properly labeled containers.	
Materials to avoid	Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents Gases	



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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

		.					
Components	CAS-No.	Value type (Form of	Control parame- ters / Permissible	Basis			
		exposure)	concentration				
Moxifloxacin HCL	186826-86-8	TWA	1000 µg/m3 (OEB 1)	Internal			
Engineering measures :	technologies t less quick con All engineerin design and op protect produc	o control airborn nections). g controls should erated in accord ts, workers, and	controls and manufactie concentrations (e.g d be implemented by lance with GMP prince the environment. require special contai	ı., drip- facility iples to			
Personal protective equipmen	t						
Respiratory protection :	exposure asse	If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.					
Filter type : Hand protection	: Particulates type						
Material :	Chemical-resi	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 co	at				

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	:	liquid
Color	:	yellow
Odor	:	odorless
Odor Threshold	:	No data available
рН	:	4,1 - 4,6
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available

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	Flamma	ability (solid, gas)	:	Not applicable	
	Flamma	ability (liquids)	:	No data available	
		explosion limit / Upper bility limit	:	No data available	
	Lower of flamma	explosion limit / Lower bility limit	:	No data available	
	Vapor p	pressure	:	No data available)
	Relative	e vapor density	:	No data available	
	Relative	e density	:	No data available	9
	Density	1	:	1,0044 g/cm ³ (20	°C)
	Solubili Wat	ty(ies) er solubility	:	slightly soluble	
	Partitio octanol	n coefficient: n-	:	No data available	9
		nition temperature	:	No data available	9
	Decom	position temperature	:	No data available	
	Viscosi Visc	ty cosity, kinematic	:	No data available)
	Explosi	ve properties	:	Not explosive	
	Oxidizii	ng properties	:	The substance o	r mixture is not classified as oxidizing.
	Molecu	lar weight	:	No data available)
	Particle Particle	e characteristics e size	:	No data available	9

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	Not classified as a reactivity hazard.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reac-	:	Can react with strong oxidizing agents.
tions		
Conditions to avoid	:	None known.
Incompatible materials	:	Oxidizing agents
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

Information on likely routes of : Inhalation



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exposi	ure		Skin contact Ingestion Eye contact	
	toxicity			
	assified based on ava	ailable	information.	
	onents:			
-	oxacin HCL: oral toxicity	:	LD50 (Rat): 1.3	20 ma/ka
	0.0. (0)		. ,	
			LD50 (Mouse): : LD50 (Monkey):	
	orrosion/irritation	ailable	information.	
Comp	onents:	-		
Moxifl	oxacin HCL:			
Specie Result		:	Rabbit No skin irritatior	1
Not cla	us eye damage/eye assified based on ava onents:			
Moxifl	oxacin HCL:			
Specie Result		:	Rabbit Moderate eye ir	ritation
Respir	ratory or skin sensi	tizatio	n	
	ensitization assified based on ava	ailabla	information	
	ratory sensitization			
•	assified based on ava		information.	
	cell mutagenicity assified based on ava	ailable	information.	
	onents:	-		
Moxifl	oxacin HCL:			
Genote	oxicity in vitro	:	Test Type: Bact Result: positive	erial reverse mutation assay (AMES)
			Test Type: Chro Result: negative	omosome aberration test in vitro
			Test Turney In with	tro mammalian cell gene mutation test



ersion 3	Revision Date: 28.09.2024	-	9S Number: 31699-00015	Date of last issue: 30.09.2023 Date of first issue: 05.06.2017	
			Result: negative		
			Test Type: in vitro Result: negative	o micronucleus test	
Genotoxicity in vivo		:	Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay) Application Route: Oral Result: negative		
	nogenicity assified based on availa	ble	information.		
-	oductive toxicity assified based on availa	ıble	information.		
Comp	oonents:				
Moxif	loxacin HCL:				
Effect	s on fertility	:	Species: Rat Application Route	500 mg/kg body weight	
Effects on fetal development		:	Test Type: Embryo-fetal development Species: Monkey Application Route: Oral Developmental Toxicity: NOAEL: 10 mg/kg body weight Result: negative		
			Species: Rabbit Application Route Developmental To	vo-fetal development :: Intravenous injection oxicity: LOAEL: 20 mg/kg body weight tal malformations.	
Repro sessn	oductive toxicity - As- nent	:	Some evidence of adverse effects on development, based or animal experiments.		
	-single exposure assified based on availa	ble	information.		
sтот	-repeated exposure				
	assified based on availa	ble	information.		

Components:

Moxifloxacin HCL:

Target Organs	:	Liver
Assessment	:	May cause damage to organs through prolonged or repeated
		exposure.



ersion 8	Revision Date: 28.09.2024	SDS Number: 1731699-00015	Date of last issue: 30.09.2023 Date of first issue: 05.06.2017
Repe	ated dose toxicity		
<u>Com</u>	oonents:		
Moxif	floxacin HCL:		
		: Rat : 100 mg/kg : Oral : 4 Weeks	
Expos	EL cation Route sure time et Organs	: Rat : 100 mg/kg : Oral : 13 Weeks : Liver : Liver disorders	
Expos	EL cation Route sure time et Organs	: Rat : 20 mg/kg : Oral : 6 Months : Liver : Liver disorders	
	EL cation Route sure time	: Monkey : 50 mg/kg : Oral : 4 Weeks : No adverse effe	cts.
Expos	EL cation Route sure time et Organs	: Monkey : 15 mg/kg : Oral : 13 Weeks : Gastrointestinal : Vomiting	tract
Expos	cation Route sure time et Organs	: Monkey : Oral : 26 Weeks : Liver : Liver disorders	
Aspir Not cl	ations ration toxicity lassified based on ava rience with human e	ailable information.	

Components:

Moxifloxacin HCL:

Ingestion

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

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SECTION	12. ECOLOGICAL II	NFORMATION	
	oxicity ata available		
	istence and degrada ata available	bility	
	ccumulative potenti a ata available	al	
	i lity in soil ata available		
Othe	r adverse effects		

No data available

SECTION 13. DISPOSAL CONSIDERATIONS

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 handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

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

Not applicable for product as supplied.

Domestic regulation

ANTT

Not regulated as a dangerous good

Special precautions for user

Not applicable

SECTION 15. REGULATORY INFORMATION

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

National List of Carcinogenic Agents for Humans - : Not applicable



raw material SDSs, OECD European Chemicals Agen-

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(LINA	CH)		
Brazil Police		trolled by the Federal	: Not applicable
The i AICS	ngredients of this pro	oduct are reported in : not determined	the following inventories:
DSL		: not determined	
IECS	C	: not determined	

SECTION 16. OTHER INFORMATION

Revision Date	:	28.09.2024
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Further information

Sources of key data used to	:	Internal technical data, data from
compile the Material Safety		eChem Portal search results and
Data Sheet		cy, http://echa.europa.eu/

Full text of other abbreviations

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 Svstem; 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 Sub-



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stances 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 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.

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