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1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name	:	Moxifloxacin Solid Formulation
Supplier's company name, ac Company name of supplier		ess and phone number MSD
Address	:	Kumagaya, Saitama Prefecture , Xicheng 810 MSD Co., Ltd. Menuma factory
Telephone	:	048-588-8411
E-mail address	:	EHSDATASTEWARD@msd.com
Emergency telephone number	:	+1-908-423-6000

Recommended use of the chemical and restrictions on use

Recommended use	:	Pharmaceutical
Restrictions on use	:	Not applicable

2. HAZARDS IDENTIFICATION

GHS classification of chemic Acute toxicity (Oral)		product Category 4
Serious eye damage/eye irri- tation	:	Category 2B
Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure	:	Category 2 (Liver)
GHS label elements 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 (Liver) through prolonged or repeated exposure.





ersion D	Revision Date: 2024/09/28	SDS Number: 1731680-00016	Date of last issue: 2024/04/06 Date of first issue: 2017/06/05			
Preca	autionary statements	P202 Do not h and understoo P260 Do not b P264 Wash sk P270 Do not e	reathe dust/ fume/ gas/ mist/ vapours/ s n thoroughly after handling. at, drink or smoke when using this proc tective gloves/ protective clothing/ eye	spray. luct.		
		CENTER/ doc P305 + P351 + for several min easy to do. Co P308 + P313 I attention.	P330 IF SWALLOWED: Call a POISC or if you feel unwell. Rinse mouth. P338 IF IN EYES: Rinse cautiously wi utes. Remove contact lenses, if presen ntinue rinsing. F exposed or concerned: Get medical a eye irritation persists: Get medical adv	ith water at and advice/		
		Storage: P405 Store loc	ked up.			
Disposal: P501 Dispose of contents/ container to an approved waste disposal plant.						
	r hazards which do n e known.	ot result in classifica	tion			
	DSITION/INFORMATIC	DN ON INGREDIENTS : Mixture				
Com	ponents					
	nical name	CAS-No.	Concentration (% w/w) ENCS	No.		
	loxacin HCL	186826-86-8	>= 40 - <= 70			
INIOVII						

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.

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lf M ai de	In case of eye contact If swallowed Most important symptoms and effects, both acute and delayed Protection of first-aiders		: : :	Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse. In case of contact, immediately flush eyes with plenty of 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 perso Harmful if swallowed. Causes eye irritation. Suspected of damaging the unborn child. May cause damage to organs through prolonged or rep exposure. First Aid responders should pay attention to self-protec and use the recommended personal protective equipmer when the potential for exposure exists (see section 8).				
	Notes to physician 5. FIREFIGHTING MEASURES		•		cally and supportively.			
S	Suitable	e extinguishing media	:	Water spray Alcohol-resistant Carbon dioxide (C Dry chemical				
	Jnsuita nedia	ble extinguishing	:	None known.				
	Specific ghting	hazards during fire-	:	Exposure to comb	pustion products may be a hazard to health.			
	lazardo cts	ous combustion prod-	:	Carbon oxides				
	Specific ds	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			
	Special or firefi	protective equipment ghters	:		e, wear self-contained breathing apparatus. tective equipment.			

6. ACCIDENTAL RELEASE MEASURES

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

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genc	y procedures		tective equipme	ent recommendations (see section 8).			
Envir	onmental precautions	:	Prevent further Retain and disp	o the environment. leakage or spillage if safe to do so. oose of contaminated wash water. s should be advised if significant spillages ained.			
	Methods and materials for containment and cleaning up		 Sweep up or vacuum up spillage and collect in suitable container for disposal. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to detemine which regulations are applicable. Sections 13 and 15 of this SDS provide information regard certain local or national requirements. 				
7. HANDL	ING AND STORAGE						
Hand	lling						
Tech	nical measures	:		g measures under EXPOSURE			
Loca	I/Total ventilation			ERSONAL PROTECTION section. dequate ventilation.			
	ce on safe handling	:		dust, fume, gas, mist, vapours or spray.			
	dance of contact ene measures	: : : : : : : : : : : : : : : : : : : :	Do not get in ey Avoid prolonge Wash skin thor Handle in acco practice, based sessment Do not eat, drin Take care to pr environment. Oxidizing agen If exposure to o	ves. d or repeated contact with skin. oughly after handling. rdance with good industrial hygiene and safety on the results of the workplace exposure as- k or smoke when using this product. event spills, waste and minimize release to the			
			When using do Wash contamir The effective of engineering co appropriate des	not eat, drink or smoke. hated clothing before re-use. peration of a facility should include review of htrols, proper personal protective equipment, gowning and decontamination procedures, ne monitoring, medical surveillance and the rative controls.			
Stora	-	_					
Conc	litions for safe storage	:	Store locked up	y labelled containers. ance with the particular national regulations.			



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Mate	rials to avoid	:	Do not store v Strong oxidizi		g product types:		
Packa	aging material	:	Unsuitable ma	aterial: None kr	iown.		
EXPOS	URE CONTROLS/PE	RSON	IAL PROTECT	ION			
	shold limit value and ment	perm	issible expos	ure limits for e	ach component in th	e work en-	
Comp	oonents		CAS-No.	Value type (Form of exposure)	Control parame- ters / Concentra- tion standard / Permissible con- centration	Basis	
Moxif	loxacin HCL		186826-86-8	TWA	1000 µg/m3 (OEB 1)	Internal	
Cellu	lose		9004-34-6	TWA	10 mg/m3	ACGIH	
Engii	neering measures	:	compound. All engineerin design and op	g controls shou	ntrols to minimize expo Ild be implemented by rdance with GMP princ nd the environment.	facility	
Perso	onal protective equip	oment					
Fil	iratory protection	:	 If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection. Particulates type 				
	protection aterial	:	Chemical-resistant gloves				
Eye p	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.				
	and body protection	:	Work uniform	or laboratory c	oat.		
PHYSIC	CAL AND CHEMICAL	PRO	PERTIES				
Physi	ical state	:	solid				
Colou	ır	:	pink				

Odour	:	odourless
Odour Threshold	:	No data available
Melting point/freezing point	:	No data available





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		oint, initial boiling d boiling range	:	No data available	
	Flammal	bility (solid, gas)	:	Not classified as	a flammability hazard
	Flammal	bility (liquids)	:	No data available	
	Uppe	xplosion limit and uppo r explosion limit / Up- ammability limit			
		er explosion limit / er flammability limit	:	No data available	
	Flash po	int	:	Not applicable	
	Decomp	osition temperature	:	No data available	
	рН		:	No data available	
	Evapora	tion rate	:	No data available	
	Auto-ign	ition temperature	:	No data available	•
	Viscosity Visco	/ sity, kinematic	:	No data available	
	Solubility Wate	/(ies) r solubility	:	No data available	
	Partition octanol/v	coefficient: n- water	:	No data available	
	Vapour p	oressure	:	No data available	
		and / or relative densit ive density	y :	No data available	•
	Dens	ity	:	No data available	•
	Relative	vapour density	:	No data available	
	Explosiv	e properties	:	Not explosive	
	Oxidizin	g properties	:	The substance or	mixture is not classified as oxidizing.
	Molecula	ar weight	:	Not applicable	
		characteristics cle size	:	No data available	



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10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions Conditions to avoid Incompatible materials Hazardous decomposition products	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents. None known. Oxidizing agents No hazardous decomposition products are known.
11. TOXICOLOGICAL INFORMAT	101	N
Information on likely routes of exposure	:	Skin contact Ingestion Eye contact
Acute toxicity Harmful if swallowed.		
Product: Acute oral toxicity	:	Acute toxicity estimate: 1,886 mg/kg Method: Calculation method
Components:		
Moxifloxacin HCL:		
Acute oral toxicity	:	LD50 (Rat): 1,320 mg/kg
		LD50 (Mouse): > 435 mg/kg
		LD50 (Monkey): 1,500 mg/kg
Cellulose:		
Acute oral toxicity	:	LD50 (Rat): > 5,000 mg/kg
Acute inhalation toxicity	:	LC50 (Rat): > 5.8 mg/l Exposure time: 4 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Moxifloxacin HCL:





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Speci Resu		: Rabbit : No skin irritation	
	us eye damage/eye	ritation	
	es eye irritation. conents:		
	loxacin HCL:		
Speci Resu	es	: Rabbit : Moderate eye irritation	
Resp	iratory or skin sens	sation	
	sensitisation lassified based on av	able information.	
-	iratory sensitisation	able information.	
	a cell mutagenicity assified based on av	able information.	
Com	oonents:		
	floxacin HCL: toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AM Result: positive	/IES)
		Test Type: Chromosome aberration test in vitro Result: negative	
		Test Type: In vitro mammalian cell gene mutatio Result: negative	n test
		Test Type: in vitro micronucleus test Result: negative	
Geno	toxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus cytogenetic assay) Application Route: Oral Result: negative	s test (in vivo
Cellu	lose:		
	toxicity in vitro	: Test Type: Bacterial reverse mutation assay (AN Result: negative	/IES)
		Test Type: In vitro mammalian cell gene mutatio Result: negative	n test
Geno	toxicity in vivo	: Test Type: Mammalian erythrocyte micronucleus cytogenetic assay)	s test (in vivo

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ersion)	Revision Date: 2024/09/28	SDS Number: 1731680-00016	Date of last issue: 2024/04/06 Date of first issue: 2017/06/05
		Species: Mo Application I Result: nega	Route: Ingestion
Carci	nogenicity		
	lassified based on avai	lable information.	
	ponents:		
Cellu		. Det	
Speci Applie	cation Route	: Rat : Ingestion	
Expo	sure time	: 72 weeks	
Resu	IT	: negative	
Susp	oductive toxicity ected of damaging the ponents:	unborn child.	
	floxacin HCL:		
	ts on fertility	Species: Ra Application I Fertility: LO	
Effect ment	ts on foetal develop-	Species: Mc Application I	Route: Oral htal Toxicity: NOAEL: 10 mg/kg body weight
		Species: Ra Application I Developmer	Embryo-foetal development bbit Route: Intravenous injection Ital Toxicity: LOAEL: 20 mg/kg body weight Skeletal malformations
Repro sessr	oductive toxicity - As- nent	: Some evide animal expe	nce of adverse effects on development, based o riments.
II Cellu	lose:		
	ts on fertility	Species: Ra	Route: Ingestion
Effect ment	ts on foetal develop-	Species: Ra	ertility/early embryonic development t Route: Ingestion



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II		Result: negative	e
II STOT	- single exposure		
	assified based on av	ailable information.	
	- repeated exposur		onged or repeated exposure.
-	oonents:		
	loxacin HCL:		
	et Organs ssment	: Liver : May cause dan exposure.	nage to organs through prolonged or repeated
Repe	ated dose toxicity		
Com	oonents:		
Moxi	floxacin HCL:		
Speci		: Rat	
LOAE Applie	:L cation Route	: 100 mg/kg : Oral	
	sure time	: 4 Weeks	
Speci		: Rat	
NOAE		: 100 mg/kg	
	cation Route	: Oral	
	sure time et Organs	: 13 Weeks	
Symp		: Liver : Liver disorders	
Speci	es	: Rat	
NOAE		: 20 mg/kg	
	cation Route	: Oral	
Expos	sure time et Organs	: 6 Months : Liver	
Symp	toms	: Liver disorders	
Speci	es	: Monkey	
NOAE	EL	: 50 mg/kg	
	cation Route	: Oral	
Expos Symp	sure time toms	: 4 Weeks : No adverse effe	ects
Speci	es	: Monkey	
NOA	EL	: 15 mg/kg	
	cation Route	: Oral	
Expo	sure time	: 13 Weeks	l troot
rarge	et Organs otoms	: Gastrointestina : Vomiting	

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Specie	S	:	Monkey	
	ation Route	:	Oral	
Exposi	ure time Organs	÷	26 Weeks Liver	
Sympt		:	Liver disorders	
O ympt		•		
Cellulo	ose:			
Specie		:	Rat	
NOAE		:	>= 9,000 mg/kg	
	ation Route ure time	÷	Ingestion 90 Days	
		•	50 Days	
Aspira	ation toxicity			
Not cla	assified based on availa	able	information.	
Experi	ience with human exp	osi	ure	
Comp	onents:			
Moxifl	oxacin HCL:			
Ingesti		:	Symptoms: Naus	ea, Abdominal pain, Headache, Dizziness,
9				ystem effects, joint pain
12. ECOLO	GICAL INFORMATIO	N		
Ecoto	xicity			
	onents:			
-				
Cellulo		_		
Toxicit	y to fish	:	Exposure time: 48	ipes (Japanese medaka)): > 100 mg/l
				on data from similar materials
Persis	tence and degradabil	ity		
Comp	onents:			
Cellulo	ose:			
Biodeg	gradability	:	Result: Readily bi	odegradable.
Bioaco	cumulative potential			
	a available			
Mobili	ty in soil			
	a available			
Hazard	dous to the ozone lay	er		
	plicable			
···· ••				



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Othe	r adverse effects				
No da	ata available				
3. DISPC	SAL CONSIDERATIO	NS			
Dispo	osal methods				
Wast	e from residues	:		ccordance with local regulations. of waste into sewer.	
Conta	aminated packaging	:	 Empty containers should be taken to an approved waste dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product 		
4. TRAN	SPORT INFORMATION	1			
Intor	actional Poquiations				
	national Regulations				
	umber		Not applicable		
	er shipping name	:	Not applicable		
Class		÷	Not applicable		
	diary risk	:	Not applicable		
	ng group	:	Not applicable		
Label		:	Not applicable		
Envir	onmentally hazardous	:	no		
ΙΑΤΑ	-DGR				
UN/IE		:	Not applicable		
•	er shipping name	:	Not applicable		
Class		:	Not applicable		
	diary risk	:	Not applicable		
	ng group	:	Not applicable		
Label		:	Not applicable		
aircra	ng instruction (cargo	•	Not applicable		
Packi	ng instruction (passen- ircraft)	:	Not applicable		
•	-Code				
	umber		Not applicable		
	er shipping name	:	Not applicable		
Class		•	Not applicable		
	diary risk	÷	Not applicable		
	ng group	÷	Not applicable		
Label		:	Not applicable		
Emg			Not applicable		

Not applicable Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Not applicable for product as supplied.

National Regulations

EmS Code

Marine pollutant

Refer to section 15 for specific national regulation.

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Special precautions for user

Not applicable

15. REGULATORY INFORMATION

Related Regulations

Fire Service Law

Not applicable to dangerous materials / designated flammables.

Chemical Substance Control Law

Not applicable for Specified Chemical Substance, Monitoring Chemical Substance and Priority Assessment Chemical Substance.

Industrial Safety and Health Law

Harmful Substances Prohibited from Manufacture

Not applicable

Harmful Substances Required Permission for Manufacture

Not applicable

Substances Prevented From Impairment of Health

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 2: Information on Existing Chemicals having Mutagenicity

Not applicable

Circular concerning Information on Chemicals having Mutagenicity - Annex 1: Information on Notified Substances having Mutagenicity

Chemical name

1-Cyclopropyl-6-fluoro-8-methoxy-7-[(4aS,7aS)-octahydropyrrolo[3,4b]pyridine-6-yl]-4-oxo-1,4-dihydroquinoline-3-carboxylic acid monohydrochloride

Substances Subject to be Notified Names

Not applicable

Substances Subject to be Indicated Names

Not applicable

Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2) Not applicable

Carcinogenic Substances (Article 577-2 of the Occupational Health and Safety Regulations)

Not applicable

Ordinance on Prevention of Hazards Due to Specified Chemical Substances Not applicable

Ordinance on Prevention of Lead Poisoning Not applicable





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	nance on Prevention	of Tetraalkyl Lead Po	bisoning
	nance on Prevention	of Organic Solvent P	oisoning
Subs	rcement Order of the tances)	e Industrial Safety and	I Health Law - Attached table 1 (Dangerou
	onous and Deleterio	us Substances Contro	bi Law
viron	-		of Specific Chemical Substances in the E the Management Thereof
-	Pressure Gas Safet	y Act	
•	pplicable		
	el Safety Law	ous good	
	ion Law egulated as a danger	ous good	
Marir	ne Pollution and Sea	Disaster Prevention	etc Law
Bulk t	transportation	: Not classified a	s noxious liquid substance
Pack	transportation	: Not classified a	s marine pollutant
Narco	otics and Psychotro	pics Control Act	
Not a Speci	pplicable	aw Material (Export / In otropic Raw Material (E	nport Permission) xport / Import permission)
	e Disposal and Pub trial waste	lic Cleansing Law	
The c	components of this	product are reported i	n the following inventories:
AICS		: not determined	
DSL		: not determined	
IECS	с	: not determined	
OTHE	R INFORMATION		

Further information



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	ces of key data used to ile the Safety Data t		nical data, data from raw material SDSs, OECD I search results and European Chemicals Agen- a.europa.eu/
	where changes have to ment by two vertical line		evious version are highlighted in the body of this
Date	format	: yyyy/mm/dd	

: 8-hour, time-weighted average

Full text of other abbreviations

ACGIH	:	USA. ACGIH Threshold Limit Values (TLV)

ACGIH / TWA

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

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





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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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