



Version 3.5	Revision Date: 06.04.2024		S Number: 5421-00018	Date of last issue: 30.09.2023 Date of first issue: 28.06.2016
	1: IDENTIFICATION uct name	:	Orbifloxacin L	iquid Formulation
Manu	afacturer or supplier's	deta	ils	
Comp	bany	:	Intervet Austr	alia Pty Limited (trading as MSD Animal Health)
Addre	ess	:	91-105 Harpi Bendigo 355	n Street 0, Victoria Austrailia
Telep	hone	:	1 800 033 46	1
Emer	gency telephone numb	er :	Poisons Infor	mation Centre: Phone 13 11 26
E-ma	il address	:	EHSDATAST	EWARD@msd.com
Recommended use of the chemical and restrictions on use				ictions on use
	mmended use ictions on use	:	Veterinary pro Not applicable	

### **SECTION 2. HAZARDS IDENTIFICATION**

GHS Classification Reproductive toxicity	:	Category 2
Specific target organ toxicity - repeated exposure (Oral)	:	Category 2 (Eye)
GHS label elements Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H361d Suspected of damaging the unborn child. H373 May cause damage to organs (Eye) through prolonged or repeated exposure if swallowed.
Precautionary statements	:	<ul> <li>Prevention:</li> <li>P201 Obtain special instructions before use.</li> <li>P202 Do not handle until all safety precautions have been read and understood.</li> <li>P260 Do not breathe mist or vapours.</li> <li>P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.</li> </ul>





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#### **Response:**

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

#### Storage:

P405 Store locked up.

#### Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

#### Other hazards which do not result in classification

None known.

#### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

#### Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)
Propylene glycol	57-55-6	>= 10 -< 30
Orbifloxacin	113617-63-3	>= 3 -< 10
Silicon dioxide	7631-86-9	< 10
Lactic acid	50-21-5	>= 1 -< 3
Sodium hydroxide	1310-73-2	>= 1 -< 2

#### **SECTION 4. FIRST AID MEASURES**

General advice	:	In the case of accident or if you feel unwell, seek medical ad- vice immediately. When symptoms persist or in all cases of doubt seek medical advice.
If inhaled	:	If inhaled, remove to fresh air. Get medical attention.
In case of skin contact	:	In case of contact, immediately flush skin with soap and plenty of water. Remove contaminated clothing and shoes. Get medical attention. Wash clothing before reuse. Thoroughly clean shoes before reuse.
In case of eye contact	:	Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.
If swallowed	:	If swallowed, DO NOT induce vomiting. Get medical attention. Rinse mouth thoroughly with water.
Most important symptoms and effects, both acute and delayed Protection of first-aiders	:	Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure if swallowed.





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			when the potentia	I for exposure exists (see section 8).		
Note	es to physician	:		cally and supportively.		
SECTIO	N 5. FIREFIGHTING MEA	SU	RES			
Suit	Suitable extinguishing media		: Water spray Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical			
Uns med	uitable extinguishing lia	:	None known.			
Spe figh	cific hazards during fire-	:	Exposure to comb	pustion products may be a hazard to health.		
•	ardous combustion prod-	:	Carbon oxides Metal oxides			
Spe ods	Specific extinguishing meth- ods		Use extinguishing measures that are appropriate to local cumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe so.			
	cial protective equipment irefighters	:		e, wear self-contained breathing apparatus. tective equipment.		
SECTIO	N 6. ACCIDENTAL RELE	AS	E MEASURES			
tive	sonal precautions, protec- equipment and emer- cy procedures	:	Follow safe handl	tective equipment. ing advice (see section 7) and personal pro- t recommendations (see section 8).		
Env	ironmental precautions	:	Prevent spreading barriers). Retain and dispos	akage or spillage if safe to do so. g over a wide area (e.g. by containment or oil se of contaminated wash water. should be advised if significant spillages		
	hods and materials for tainment and cleaning up	:	For large spills, pur ment to keep mat be pumped, store Clean up remaining bent. Local or national up posal of this mate employed in the comine which regular Sections 13 and 1	t absorbent material. rovide dyking or other appropriate contain- erial from spreading. If dyked material can recovered material in appropriate container. In materials from spill with suitable absor- regulations may apply to releases and dis- erial, as well as those materials and items cleanup of releases. You will need to deter- ations are applicable. Its of this SDS provide information regarding ational requirements.		



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#### **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. Do not breathe mist or vapours. 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 as- sessment
		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.
Conditions for safe storage	:	Keep in properly labelled containers. Store locked up.
Materials to avoid	:	Store in accordance with the particular national regulations. Do not store with the following product types: Strong oxidizing agents

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components	CAS-No.	Value type (Form of exposure)	Control parame- ters / Permissible concentration	Basis
Propylene glycol	57-55-6	TWA (partic- ulate)	10 mg/m3	AU OEL
		TWA (Total (vapour and particles))	150 ppm 474 mg/m3	AU OEL
Orbifloxacin	113617-63-3	TWA	0.2 mg/m3 (OEB 2)	Internal
Silicon dioxide	7631-86-9	TWA (Res- pirable dust)	2 mg/m3	AU OEL
Sodium hydroxide	1310-73-2	Peak limit	2 mg/m3	AU OEL
		С	2 mg/m3	ACGIH

#### Components with workplace control parameters

Engineering measures : Use appropriate engineering controls and manufacturing





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			less quick connect All engineering co design and opera protect products,	ontrol airborne concentrations (e.g., drip- ctions). ontrols should be implemented by facility ted in accordance with GMP principles to workers, and the environment. tions do not require special containment.
	sonal protective equipme	ent		
	spiratory protection Filter type nd protection	:	sure assessment ommended guide	exhaust ventilation is not available or expo- demonstrates exposures outside the rec- lines, use respiratory protection. lates and organic vapour type
	Material	:	Chemical-resista	nt gloves
Eye	e protection	: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditi mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is potential for direct contact to the face with dusts, mists, aerosols.		nment or activity involves dusty conditions, , wear the appropriate goggles. d or other full face protection if there is a
Ski	n and body protection	:	Work uniform or I	aboratory coat.
SECTIO	N 9. PHYSICAL AND CH	EMI	CAL PROPERTIE	S
Арр	pearance	:	suspension	
Col	our	:	light brown	
Ode	our	: odourless		
Ode	our Threshold	:	No data available	e
рН		:	No data available	e
Me	ting point/freezing point	:	No data available	e
Initi ran	al boiling point and boiling ge	:	No data available	e
Flas	sh point	:	No data available	e
Eva	poration rate	:	No data available	e
Fla	mmability (solid, gas)	:	Not applicable	
Fla	mmability (liquids)	:	No data available	e
	per explosion limit / Upper nmability limit	:	No data availabl	e
Lov	ver explosion limit / Lower	:	No data available	e

### SAFETY DATA SHEET



### Orbifloxacin Liquid Formulation

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flar	nmability limit			
Va	pour pressure	:	No data available	9
Re	lative vapour density	:	No data available	9
Re	lative density	:	No data available	9
De	nsity	:	No data available	9
So	lubility(ies) Water solubility	:	No data available	9
	rtition coefficient: n- anol/water	:	No data available	9
	to-ignition temperature	:	No data available	9
De	composition temperature	:	No data available	9
Vis	cosity Viscosity, kinematic	:	No data available	9
Ex	plosive properties	:	Not explosive	
Ox	idizing properties	:	The substance o	r mixture is not classified as oxidizing.
Мс	lecular weight	:	No data available	9
	rticle characteristics rticle size	:	No data available	9

#### SECTION 10. STABILITY AND REACTIVITY

Reactivity Chemical stability Possibility of hazardous reac- tions	:	Not classified as a reactivity hazard. Stable under normal conditions. Can react with strong oxidizing agents.
Conditions to avoid Incompatible materials Hazardous decomposition products	:	Oxidizing agents

#### SECTION 11. TOXICOLOGICAL INFORMATION

Exposure routes

: Inhalation Skin contact Ingestion Eye contact





ersion 5	Revision Date: 06.04.2024		0S Number: 5421-00018	Date of last issue: 30.09.2023 Date of first issue: 28.06.2016
Not c	<b>e toxicity</b> lassified based on availa <b>conents:</b>	ble	information.	
	ylene glycol:			
Acute	oral toxicity	:	LD50 (Rat): 22,00	00 mg/kg
Acute	inhalation toxicity	:	LC50 (Rat): > 44. Exposure time: 4 Test atmosphere:	h
Acute	e dermal toxicity	:	LD50 (Rabbit): > Assessment: The toxicity	2,000 mg/kg substance or mixture has no acute derma
Orbif	loxacin:			
Acute	e oral toxicity	:	LD50 (Rat): > 3,0 Remarks: No mor	00 mg/kg tality observed at this dose.
			LD50 (Mouse): > Remarks: No mor	2,000 mg/kg tality observed at this dose.
			LD50 (Dog): > 60 Symptoms: Vomit Remarks: No mor	
Acute	inhalation toxicity	:	Remarks: No data	a available
Acute	e dermal toxicity	:	Remarks: No data	a available
	e toxicity (other routes of histration)	:	LD50 (Rat): > 200 Application Route	
			LD50 (Mouse): 50 Application Route	
			LD50 (Rat): 233 r Application Route	
			LD50 (Mouse): 25 Application Route	
Silico	on dioxide:			
	oral toxicity	:	LD50 (Rat): > 5,0 Method: OECD T	
Acute	inhalation toxicity	:	LC50 (Rat): > 2.0 Exposure time: 4 Test atmosphere: Assessment: The	h



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			tion toxicity	
Acute de	ermal toxicity	:	LD50 (Rabbit)	: > 5,000 mg/kg
Lactic a	acid:			
Acute or	ral toxicity	:	LD50 (Rat): > Remarks: Bas	2,000 mg/kg ed on data from similar materials
Acute in	halation toxicity	:	Assessment:	e: 4 h
Acute de	ermal toxicity	:	Assessment: toxicity	: > 2,000 mg/kg The substance or mixture has no acute derr sed on data from similar materials
Sodium	hydroxide:			
Acute in	halation toxicity	:	Assessment:	Corrosive to the respiratory tract.
Skin co	rrosion/irritation			
	sified based on ava	ailable	information.	
Product			5.1.1.1	
Species Result		:	Rabbit No skin irritati	on
Result		•		
<u>Compo</u>	<u>nents:</u>			
	ene glycol:			
Species Method		:	Rabbit OECD Test G	uideline 404
Result		:	No skin irritati	
Orbiflox	kacin:			
Species		:	Rabbit	
Method		:	Draize Test	
Result		:	No skin irritati	on
Silicon	dioxide:			
Species		:	Rabbit	
		:		
		:	Rabbit OECD Test G No skin irritati	





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Speci		:	Rabbit	
Metho Resul		:	OECD Test Gu	
Rema		:		1 to 4 hours of exposure from similar materials
Sodiu	ım hydroxide:			
Resul	t	:	Corrosive after	3 minutes or less of exposure
	us eye damage/eye			
	assified based on ava	ailable	information.	
Produ		_	Dabbit	
Specie Resul		:	Rabbit Mild eye irritatio	an
Resul	L	•	wind eye irritatio	
<u>Comp</u>	oonents:			
	lene glycol:			
Specie		:	Rabbit	
Resul <sup>®</sup> Metho		÷	No eye irritatior OECD Test Gu	
Metho		•	OLOD Test Gu	
Orbifl	oxacin:			
Speci		:	Rabbit	
Resul		:	Mild eye irritatio Draize Test	on
Metho	DO	•	Draize Test	
Silico	n dioxide:			
Speci		:	Rabbit	
Resul <sup>®</sup> Metho		:	No eye irritatior OECD Test Gu	
Metho		•	OECD Test Gu	
	c acid:			
Specie		:	Chicken eye	
Rema	rks	:	Based on data	from similar materials
Resul	t	:	Irreversible effe	ects on the eye
Sodiu	ım hydroxide:			
Resul		:	Irreversible effe	
Rema	rks	:	Based on skin o	corrosivity.

# Skin sensitisation

Not classified based on available information.



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Been	instant consideration			
-	<b>iratory sensitisation</b> lassified based on ava		information.	
Prod	uct:			
Test		:	Magnusson-Kl	igman-Test
	sure routes	:	Dermal	
Speci Resu		:	Guinea pig Not a skin sen	sitizer.
		-		
<u>Com</u>	ponents:			
	ylene glycol:			
Test		:	Maximisation	Test
Expo: Speci	sure routes ies	:	Skin contact Guinea pig	
Resu		:	negative	
Orbif	loxacin:			
Test		:	Maximisation 7	Fest
Expo	sure routes	:	Dermal	
Speci Resu		:	Guinea pig Not a skin sen	oitizor
Resu	п	•	NOT a SKIN SEN	Silizer.
Lacti	c acid:			
Test		:	Buehler Test	
Expo: Speci	sure routes	:	Skin contact Guinea pig	
Resu		:	negative	
Rema	arks	:		from similar materials
Sodiu	um hydroxide:			
Test <sup>-</sup>	Туре	:		insult patch test (HRIPT)
•	sure routes	:	Skin contact	
Resu	π	:	negative	
Chro	nic toxicity			
	n cell mutagenicity			
Not c	lassified based on ava	ailable	information.	
<u>Com</u>	ponents:			
	ylene glycol:			
Geno	otoxicity in vitro	:	Test Type: Bad Result: negativ	cterial reverse mutation assay (AMES ve
				romosome aberration test in vitro D Test Guideline 473 /e



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Gend	otoxicity in vivo	cytogenetic Species: Mo	use Route: Intraperitoneal injection
Orbi	floxacin:		
	otoxicity in vitro	: Test Type: E Result: equiv	Bacterial reverse mutation assay (AMES) vocal
		Test Type: N Result: posit	louse Lymphoma ive
			Chromosomal aberration : Human lymphocytes ive
Geno	otoxicity in vivo	Species: Mo Cell type: Bo	one marrow Route: Intraperitoneal injection
		Test Type: u Species: Ra Cell type: Liv Application F Result: nega	/er cells Route: Oral
	n cell mutagenicity - ssment	: Weight of ev cell mutager	idence does not support classification as a germ
Silic	on dioxide:		
Geno	otoxicity in vitro		Bacterial reverse mutation assay (AMES) CD Test Guideline 471 Itive
Geno	otoxicity in vivo	cytogenetic Species: Ra	Route: Ingestion
	i <b>c acid:</b> otoxicity in vitro	Method: OE Result: nega	Bacterial reverse mutation assay (AMES) CD Test Guideline 471 Itive ased on data from similar materials





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Test Type: In vitro mammalian cell gene mutation test Method: OECD Test Guideline 476 **Result:** negative Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro Method: OECD Test Guideline 473 Result: negative Remarks: Based on data from similar materials

#### Carcinogenicity

Not classified based on available information.

Components:	
<b>Propylene glycol:</b> Species Application Route Exposure time Result	: Rat Ingestion : 2 Years : negative
Orbifloxacin:	
Species Application Route Exposure time NOAEL Result	: Rat : Oral : 2 Years : 200 mg/kg body weight : negative
Species Application Route Exposure time NOAEL Result	<ul> <li>Mouse</li> <li>Oral</li> <li>2 Years</li> <li>200 mg/kg body weight</li> <li>negative</li> </ul>
Silicon dioxide:	
Species Application Route Exposure time Result	: Rat Ingestion : 103 weeks : negative
Lactic acid:	
Species Application Route Exposure time Result Remarks	<ul> <li>Rat</li> <li>Ingestion</li> <li>2 Years</li> <li>negative</li> <li>Based on data from similar materials</li> </ul>

#### **Reproductive toxicity**

Suspected of damaging the unborn child.



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Prop	ponents: ylene glycol: ts on fertility	Species: Mou	
Effec ment	ts on foetal develop-	Result: negat : Test Type: Er Species: Mou	nbryo-foetal development ise oute: Ingestion
	iloxacin: ts on fertility	Species: Rat Application R General Toxi	city - Parent: NOAEL: 50 mg/kg body weight nic Development: NOAEL: 50 mg/kg body
Effec ment	ts on foetal develop-	Species: Rat Application R Embryo-foeta Result: No te	I toxicity: LOAEL: 333 mg/kg body weight ratogenic effects, Embryotoxic effects and ad- on the offspring were detected only at high ma-
		Species: Rab Application R General Toxic Embryo-foeta Result: No ef toxic effects a	oute: Oral city Maternal: NOAEL: 20 mg/kg body weight Il toxicity: NOAEL: 60 mg/kg body weight fects on early embryonic development, Embryo- and adverse effects on the offspring were detect- h maternally toxic doses, Reduced maternal
Repression session	oductive toxicity - As- nent	: Some eviden animal experi	ce of adverse effects on development, based on ments.

### Silicon dioxide:



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Effect	s on foetal develop-	:		ryo-foetal development
ment			Species: Rat Application Rou Result: negative	
Lactio	c acid:			
Effect ment	s on foetal develop-	:	Species: Mouse	
			Application Rou Result: negative	
STOT	- single exposure			
Not cl	assified based on avai	ilable	information.	
STOT	- repeated exposure	•		
May c	ause damage to organ	ns (Ey	ve) through prolo	nged or repeated exposure if swallowed.
Produ	<u>uct:</u>			
	t Organs	:	Eye	
Asses	ssment	:	May cause darr exposure.	age to organs through prolonged or repeate
Repe	ated dose toxicity			
<u>Produ</u>	uct:			
			Dog	
Speci		•		
NOAE	EL	:	22.5 mg/kg	
NOAE	EL EL	:	22.5 mg/kg 37.5 mg/kg	
NOAE LOAE Applic	EL EL cation Route	:	22.5 mg/kg 37.5 mg/kg Oral	
NOAE LOAE Applic	EL EL cation Route sure time		22.5 mg/kg 37.5 mg/kg	disturbance
NOAE LOAE Applic Expos Symp Speci	EL EL cation Route sure time toms es		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog	disturbance
NOAE LOAE Applic Expos Symp Speci LOAE	EL EL cation Route sure time toms es EL		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog 75 mg/kg	disturbance
NOAE LOAE Applic Expos Symp Speci LOAE Applic	EL EL cation Route sure time toms es EL cation Route		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog 75 mg/kg Oral	disturbance
NOAE LOAE Applic Expos Symp Speci LOAE Applic	EL EL cation Route sure time toms es EL cation Route sure time		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog 75 mg/kg Oral 10 Days	disturbance rrointestinal disturbance, Vomiting
NOAE LOAE Applic Expos Symp Speci LOAE Applic Expos Symp Speci	EL EL cation Route sure time toms es EL cation Route sure time toms es		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog 75 mg/kg Oral 10 Days Salivation, Gast Cat	
NOAE LOAE Applic Expos Symp Speci LOAE Applic Expos Symp Speci LOAE	EL EL cation Route sure time toms es EL cation Route sure time toms es		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog 75 mg/kg Oral 10 Days Salivation, Gast Cat 45 mg/kg	
NOAE LOAE Applic Expos Symp Speci LOAE Applic Expos Symp Speci LOAE Applic	EL EL cation Route sure time toms es EL cation Route sure time toms es EL cation Route		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog 75 mg/kg Oral 10 Days Salivation, Gast Cat 45 mg/kg Oral	
NOAE LOAE Applic Expos Symp Speci LOAE Applic Expos Symp Speci LOAE Applic Expos	EL EL cation Route sure time toms es EL cation Route sure time toms es		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog 75 mg/kg Oral 10 Days Salivation, Gast Cat 45 mg/kg	
NOAE LOAE Applic Expos Symp Speci LOAE Applic Expos Symp Speci LOAE Applic Expos	EL EL Sure time toms es EL cation Route sure time toms es EL cation Route sure time sure time tors		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog 75 mg/kg Oral 10 Days Salivation, Gast Cat 45 mg/kg Oral 30 Days Eye	rointestinal disturbance, Vomiting
NOAE LOAE Applic Expos Symp Speci LOAE Applic Expos Symp Speci LOAE Applic Expos Targe Symp	EL EL Sure time toms es EL cation Route sure time toms es EL cation Route sure time sure time tors		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog 75 mg/kg Oral 10 Days Salivation, Gast Cat 45 mg/kg Oral 30 Days Eye Salivation, Lach	rointestinal disturbance, Vomiting
NOAE LOAE Applic Expos Symp Speci LOAE Applic Expos Symp Speci LOAE Applic Expos Targe Symp	EL EL sation Route sure time toms es EL sation Route sure time toms es EL sation Route sure time to Organs toms		22.5 mg/kg 37.5 mg/kg Oral 30 Days Gastrointestinal Dog 75 mg/kg Oral 10 Days Salivation, Gast Cat 45 mg/kg Oral 30 Days Eye Salivation, Lach	



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	EL cation Route sure time	: >= 1,700 mg/k : Ingestion : 2 yr	g	
Spec NOA LOAE Appli Expo	EL	: Rat : 20 mg/kg : 80 mg/kg : Oral : 3 Months : Testis, Liver, k	(idney, spleen	
	EL	: Mouse : 80 mg/kg : 250 mg/kg : Oral : 3 Months		
Expo Targe	EL EL cation Route sure time et Organs otoms	: Juvenile dog : 50 mg/kg : 250 mg/kg : Oral : 14 Days : Heart, Bone : Gastrointestina : mortality obset		
Expo	EL EL cation Route sure time et Organs	: Juvenile dog : 2 mg/kg : 3 mg/kg : Oral : 90 Days : Bone : No significant :	adverse effects were reported	
		: Dog : 37.5 mg/kg : Oral : 30 Days		
Expo	EL	: Cat : 7.5 mg/kg : 22.5 mg/kg : Oral : 1 Months : Gastrointestina	al disturbance	
Spec NOA		: Rat : 1.3 mg/m3 : inhalation (dus	st/mist/fume)	

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Expos	sure time	:	13 Weeks	
Lactio	c acid:			
Speci		:	Rat	
NOAE		÷	> 100 mg/kg	
	ation Route	:	Ingestion	
Expos Rema	sure time Irks	:	13 Weeks Based on data fr	om similar materials
Speci	es	:	Rat	
LÒAE	L	:	886 mg/kg	
	cation Route sure time	:	Skin contact 13 Weeks	
Acnir	ation toxicity			
•	assified based on availa	ble	information.	
Expe	rience with human exp	osı	ıre	
Comp	oonents:			
Orbif	oxacin:			
	l'an		Symptoms: contr	
Ingest	lion	•	disturbance, liver	al nervous system effects, Gastrointestinal function change, anaphylaxis, Rash ause photosensitisation.
	12. ECOLOGICAL INFO		disturbance, liver Remarks: May ca	function change, anaphylaxis, Rash
CTION	12. ECOLOGICAL INFO	DRI	disturbance, liver Remarks: May ca	function change, anaphylaxis, Rash
CTION	12. ECOLOGICAL INFO	DRI	disturbance, liver Remarks: May ca	function change, anaphylaxis, Rash
CTION Ecoto <u>Comr</u>	12. ECOLOGICAL INFO	DRI	disturbance, liver Remarks: May ca	function change, anaphylaxis, Rash
CTION Ecoto <u>Comp</u> Propy	12. ECOLOGICAL INFO	DRI	disturbance, liver Remarks: May ca	function change, anaphylaxis, Rash ause photosensitisation. chus mykiss (rainbow trout)): 40,613 mg/l
CTION Ecoto Comp Propy Toxici Toxici	12. ECOLOGICAL INFO exicity <u>conents:</u> /lene glycol:	:	disturbance, liver Remarks: May ca MATION LC50 (Oncorhyn Exposure time: 9	r function change, anaphylaxis, Rash ause photosensitisation. chus mykiss (rainbow trout)): 40,613 mg/l 6 h nnia dubia (water flea)): 18,340 mg/l
CTION Ecoto Comp Propy Toxici Toxici aquat	12. ECOLOGICAL INFO pxicity ponents: ylene glycol: ty to fish ty to daphnia and other ic invertebrates ty to algae/aquatic	:	disturbance, liver Remarks: May ca MATION LC50 (Oncorhyn Exposure time: 9 EC50 (Ceriodaph Exposure time: 4 ErC50 (Skeleton Exposure time: 7	function change, anaphylaxis, Rash ause photosensitisation. chus mykiss (rainbow trout)): 40,613 mg/l 6 h nnia dubia (water flea)): 18,340 mg/l 8 h ema costatum (marine diatom)): 19,300 mg
CTION Ecoto Comp Propy Toxici aquat Toxici plants Toxici aquat	12. ECOLOGICAL INFO pxicity ponents: /lene glycol: ty to fish ty to daphnia and other ic invertebrates ty to algae/aquatic ty to daphnia and other ic invertebrates (Chron-	:	disturbance, liver Remarks: May ca MATION LC50 (Oncorhyn Exposure time: 9 EC50 (Ceriodaph Exposure time: 4 ErC50 (Skeleton Exposure time: 7 Method: OECD 1	r function change, anaphylaxis, Rash ause photosensitisation. chus mykiss (rainbow trout)): 40,613 mg/l 6 h nnia dubia (water flea)): 18,340 mg/l 8 h ema costatum (marine diatom)): 19,300 mg 2 h Fest Guideline 201 whnia dubia (water flea)): 13,020 mg/l
CTION Ecoto Comp Propy Toxici aquat Toxici plants Toxici aquat ic toxi	12. ECOLOGICAL INFO pxicity ponents: /lene glycol: ty to fish ty to daphnia and other ic invertebrates ty to algae/aquatic ty to daphnia and other ic invertebrates (Chron-	:	disturbance, liver Remarks: May ca MATION LC50 (Oncorhyn Exposure time: 9 EC50 (Ceriodaph Exposure time: 4 ErC50 (Skeleton Exposure time: 7 Method: OECD 1 NOEC (Ceriodaph Exposure time: 7	function change, anaphylaxis, Rash ause photosensitisation. chus mykiss (rainbow trout)): 40,613 mg/l 6 h nnia dubia (water flea)): 18,340 mg/l 8 h ema costatum (marine diatom)): 19,300 mg 2 h Fest Guideline 201 ohnia dubia (water flea)): 13,020 mg/l d nonas putida): > 20,000 mg/l
CTION Ecoto Comp Propy Toxici aquat Toxici aquat ic toxi Toxici	12. ECOLOGICAL INFO points: ylene glycol: ty to fish ty to daphnia and other ic invertebrates ty to algae/aquatic ty to daphnia and other ic invertebrates (Chron- city)	:	disturbance, liver Remarks: May ca MATION LC50 (Oncorhyn Exposure time: 9 EC50 (Ceriodaph Exposure time: 4 ErC50 (Skeleton Exposure time: 7 Method: OECD T NOEC (Ceriodaph Exposure time: 7 NOEC (Pseudon	function change, anaphylaxis, Rash ause photosensitisation. chus mykiss (rainbow trout)): 40,613 mg/l 6 h nnia dubia (water flea)): 18,340 mg/l 8 h ema costatum (marine diatom)): 19,300 mg 2 h Fest Guideline 201 ohnia dubia (water flea)): 13,020 mg/l d nonas putida): > 20,000 mg/l



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	Exposure time: 96 h Method: OECD Test Guideline 203
Toxicity to daphnia and other aquatic invertebrates	<ul> <li>EC50 (Daphnia magna (Water flea)): &gt; 1,000 mg/l</li> <li>Exposure time: 24 h</li> <li>Method: OECD Test Guideline 202</li> </ul>
Toxicity to algae/aquatic plants	<ul> <li>EC50 (Desmodesmus subspicatus (green algae)): &gt; 10,000 mg/l</li> <li>Exposure time: 72 h</li> <li>Method: OECD Test Guideline 201</li> <li>Remarks: Based on data from similar materials</li> </ul>
	NOEC (Desmodesmus subspicatus (green algae)): 10,000 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Lactic acid:	
Toxicity to fish	<ul> <li>LC50 (Danio rerio (zebra fish)): &gt; 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 Remarks: Based on data from similar materials</li> </ul>
Toxicity to daphnia and other aquatic invertebrates	<ul> <li>EC50 (Daphnia magna (Water flea)): &gt; 100 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 Remarks: Based on data from similar materials</li> </ul>
Toxicity to algae/aquatic plants	<ul> <li>ErC50 (Pseudokirchneriella subcapitata (green algae)): &gt; 100 mg/l</li> <li>Exposure time: 72 h</li> <li>Method: OECD Test Guideline 201</li> <li>Remarks: Based on data from similar materials</li> </ul>
	NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l Exposure time: 72 h Method: OECD Test Guideline 201 Remarks: Based on data from similar materials
Toxicity to microorganisms	<ul> <li>EC50: &gt; 10 - 100 mg/l</li> <li>Exposure time: 3 h</li> <li>Method: OECD Test Guideline 209</li> <li>Remarks: Based on data from similar materials</li> </ul>
Persistence and degradabi	lity
<u>Components:</u>	
Propylene glycol:	

### SAFETY DATA SHEET



### Orbifloxacin Liquid Formulation

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Biodegradability		Bi Ex	Result: Readily biodegradable. Biodegradation: 98.3 % Exposure time: 28 d Method: OECD Test Guideline 301F		
Lacti	c acid:				
Biode	Biodegradability		Result: Not readily biodegradable. Remarks: Based on data from similar materials		
Bioad	ccumulative potentia	I			
Com	ponents:				
Prop	ylene glycol:				
Partition coefficient: n- octanol/water			log Pow: -1.07 Method: Regulation (EC) No. 440/2008, Annex, A.8		
Lacti	c acid:				
Partition coefficient: n- octanol/water		: loę	log Pow: -0.62		
Mobi	lity in soil				
No da	ata available				
Othe	r adverse effects				
No da	ata available				

#### SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods		
Waste from residues	:	Do not dispose of waste into sewer.
		Dispose of in accordance with local regulations.
Contaminated packaging	:	Empty containers should be taken to an approved waste han- dling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

### SECTION 14. TRANSPORT INFORMATION

#### International Regulations

UNRTDG		
UN number	:	Not applicable
Proper shipping name	:	Not applicable
Class	:	Not applicable
Subsidiary risk	:	Not applicable
Packing group	:	Not applicable
Labels	:	Not applicable
Environmentally hazardous	:	no
IATA-DGR		
UN/ID No.	:	Not applicable

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Revision Date:

SDS Number:

ersion 5	Revision Date: 06.04.2024	SDS Number: 785421-00018	Date of first issue: 30.09.2023 Date of first issue: 28.06.2016
Prop	er shipping name	: Not applicable	
Class		: Not applicable	
	idiary risk	: Not applicable	
	ing group	: Not applicable	
Labe		: Not applicable	
aircra	ing instruction (cargo aft) ing instruction (passen-	: Not applicable : Not applicable	
	ircraft)	. Not applicable	
	G-Code		
	umber	: Not applicable	
	er shipping name	: Not applicable	
Class		: Not applicable	
	idiary risk	: Not applicable : Not applicable	
Labe	ing group	: Not applicable	
	Code	: Not applicable	
	ne pollutant	: Not applicable	
Tran	sport in bulk according	g to Annex II of MAR	POL 73/78 and the IBC Code
Not a	pplicable for product as	supplied.	
Natio	onal Regulations		
ADO	3		
UN ı	number	: Not applicable	
	per shipping name	: Not applicable	
Clas		: Not applicable	
	sidiary risk	: Not applicable	
	king group	: Not applicable	
Labe		: Not applicable	
Haz	chem Code	: Not applicable	
•	ial precautions for use	er	
Not a	pplicable		
ECTION	15. REGULATORY INF	ORMATION	
Safet	ty. health and environr	nental regulations/le	gislation specific for the substance or r
ture	,	<b>.</b>	
	apeutic Goods (Poisons dard) Instrument		ase use the original publication to check for ecific conditions or threshold limits that mi emical)
Prohi	ibition/Licensing Require	ments	: There is no applicable prohibitior
Prohi	ibition/Licensing Require	ements	authorisation and restricted use requirements, including for carcir
Prohi	ibition/Licensing Require	ements	: There is no applicable prohibition authorisation and restricted use requirements, including for carcir gens referred to in Schedule 10 of the model WHS Act and Regula- tions.
			authorisation and restricted use requirements, including for carcir gens referred to in Schedule 10 of the model WHS Act and Regula-



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DSI		: not determined			
-					
IEC	50	: not determined			
SECTION 16: ANY OTHER RELEVANT INFORMATION					
Fur	ther information				
Sou	rision Date Irces of key data used to apile the Safety Data set		al data, data from raw material SDSs, OECD search results and European Chemicals Agen- europa.eu/		
Date	e format	: dd.mm.yyyy			
Full text of other abbreviations					
AC0 AU	GIH OEL		hreshold Limit Values (TLV) place Exposure Standards for Airborne Con-		
AU	GIH / C OEL / TWA OEL / Peak limit	: Ceiling limit : Exposure stand : Exposure stand	lard - time weighted average lard - peak		

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 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 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.

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