

SAFETY DATA SHEET

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



Orbifloxacin Liquid Formulation

Version	Revision Date:	SDS Number:	Date of last issue: 28.09.2024
3.5	14.04.2025	9372691-00009	Date of first issue: 27.08.2021

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

1.1 Product identifier

Trade name : Orbifloxacin Liquid Formulation

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-stance/Mixture : Veterinary product

Recommended restrictions on use : Not applicable

1.3 Details of the supplier of the safety data sheet

Company : MSD
Walton Manor, Walton
MK7 7AJ Milton Keynes - United Kingdom

Telephone : +1-908-740-4000

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

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Reproductive toxicity, Category 2 H361d: Suspected of damaging the unborn child.

Specific target organ toxicity - repeated exposure, Category 2, Eye H373: May cause damage to organs through prolonged or repeated exposure if swallowed.

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)

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Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H361d Suspected of damaging the unborn child. H373 May cause damage to organs (Eye) through pro- longed or repeated exposure if swallowed.
Precautionary statements	:	Prevention: P201 Obtain special instructions before use. P280 Wear protective gloves/ protective clothing/ eye protection/ face protection. Response: P308 + P313 IF exposed or concerned: Get medical advice/ attention. Storage: P405 Store locked up.

Hazardous components which must be listed on the label:
Orbifloxacin

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)
Orbifloxacin	113617-63-3	Repr. 2; H361d	$\geq 3 - < 10$
Lactic acid	50-21-5 200-018-0	Skin Corr. 1C; H314 Eye Dam. 1; H318	$\geq 1 - < 3$
Sodium hydroxide	1310-73-2 215-185-5 011-002-00-6	Met. Corr. 1; H290 Skin Corr. 1A; H314 Eye Dam. 1; H318 specific concentra-	$\geq 1 - < 2$

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		tion limit Skin Corr. 1A; H314 ≥ 5 % Skin Corr. 1B; H314 2 - < 5 % Skin Irrit. 2; H315 0.5 - < 2 % Eye Irrit. 2; H319 0.5 - < 2 % EUH071 ≥ 2 %	
Substances with a workplace exposure limit :			
Propylene glycol	57-55-6 200-338-0		≥ 10 - < 20
Silicon dioxide	7631-86-9 231-545-4		≥ 1 - < 10

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 | : 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. |

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4.2 Most important symptoms and effects, both acute and delayed

Risks : Suspected of damaging the unborn child.
May cause damage to organs through prolonged or repeated exposure if swallowed.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water spray
Alcohol-resistant foam
Carbon dioxide (CO₂)
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
Metal 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.

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Prevent spreading over a wide area (e.g. by containment or oil barriers).
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 : Soak up with inert absorbent material.
For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent.
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 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 assessment
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.

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Advice on common storage : Do not store with the following product types:
Strong oxidizing agents
Gases

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propylene glycol	57-55-6	TWA (Total vapour and particles)	150 ppm 474 mg/m ³	GB EH40
		TWA (particles)	10 mg/m ³	GB EH40
Orbifloxacin	113617-63-3	TWA	0.2 mg/m ³ (OEB 2)	Internal
Silicon dioxide	7631-86-9	TWA (inhalable dust)	6 mg/m ³ (Silica)	GB EH40
		TWA (Respirable dust)	2.4 mg/m ³ (Silica)	GB EH40
Sodium hydroxide	1310-73-2	STEL	2 mg/m ³	GB EH40

Derived No Effect Level (DNEL)

Substance name	End Use	Exposure routes	Potential health effects	Value
Propylene glycol	Workers	Inhalation	Long-term local effects	10 mg/m ³
	Workers	Inhalation	Long-term systemic effects	168 mg/m ³
	Consumers	Inhalation	Long-term local effects	10 mg/m ³
	Consumers	Inhalation	Long-term systemic effects	50 mg/m ³
Silicon dioxide	Workers	Inhalation	Long-term systemic effects	4 mg/m ³
Sodium hydroxide	Consumers	Inhalation	Long-term local effects	1 mg/m ³
	Workers	Inhalation	Long-term local effects	1 mg/m ³

Predicted No Effect Concentration (PNEC)

Substance name	Environmental Compartment	Value
Propylene glycol	Fresh water	260 mg/l
	Freshwater - intermittent	183 mg/l

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	Marine water	26 mg/l
	Sewage treatment plant	20000 mg/l
	Fresh water sediment	572 mg/kg dry weight (d.w.)
	Marine sediment	57.2 mg/kg dry weight (d.w.)
	Soil	50 mg/kg dry weight (d.w.)

8.2 Exposure controls

Engineering measures

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections).

All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

Laboratory operations do not require special containment.

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. Filter should conform to BS EN 14387
Filter type	:	Combined particulates and organic vapour type (A-P)

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	:	suspension
Colour	:	light brown
Odour	:	odourless
Odour Threshold	:	No data available
pH	:	No data available
Melting point/freezing point	:	No data available
Initial boiling point and boiling range	:	No data available
Flash point	:	No data available
Evaporation rate	:	No data available

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Flammability (solid, gas)	:	Not applicable
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	:	No data available
Particle size	:	No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

Not classified as a reactivity hazard.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions	:	Can react with strong oxidizing agents.
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10.4 Conditions to avoid

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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.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Components:

Orbifloxacin:

Acute oral toxicity : LD50 (Rat): > 3,000 mg/kg
Remarks: No mortality observed at this dose.

LD50 (Mouse): > 2,000 mg/kg
Remarks: No mortality observed at this dose.

LD50 (Dog): > 600 mg/kg
Symptoms: Vomiting
Remarks: No mortality observed at this dose.

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

Acute toxicity (other routes of administration) : LD50 (Rat): > 200 mg/kg
Application Route: Intramuscular

LD50 (Mouse): 500 mg/kg
Application Route: Intramuscular

LD50 (Rat): 233 mg/kg
Application Route: Intravenous

LD50 (Mouse): 250 mg/kg
Application Route: Intravenous

Lactic acid:

Acute oral toxicity : LD50 (Rat): > 2,000 mg/kg
Remarks: Based on data from similar materials

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Acute inhalation toxicity : LC50 (Rat): > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.
Remarks: Based on data from similar materials

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity
Remarks: Based on data from similar materials

Sodium hydroxide:

Acute inhalation toxicity : Assessment: Corrosive to the respiratory tract.

Propylene glycol:

Acute oral toxicity : LD50 (Rat): 22,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 44.9 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg
Assessment: The substance or mixture has no acute dermal toxicity

Silicon dioxide:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg
Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): > 2.08 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity

Acute dermal toxicity : LD50 (Rabbit): > 5,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Species : Rabbit
Result : No skin irritation

Components:

Orbifloxacin:

Species : Rabbit

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Method : Draize Test
Result : No skin irritation

Lactic acid:

Species : Rabbit
Method : OECD Test Guideline 404
Result : Corrosive after 1 to 4 hours of exposure
Remarks : Based on data from similar materials

Sodium hydroxide:

Result : Corrosive after 3 minutes or less of exposure

Propylene glycol:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Silicon dioxide:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Product:

Species : Rabbit
Result : Mild eye irritation

Components:

Orbifloxacin:

Species : Rabbit
Method : Draize Test
Result : Mild eye irritation

Lactic acid:

Species : Chicken eye
Remarks : Based on data from similar materials

Result : Irreversible effects on the eye

Sodium hydroxide:

Result : Irreversible effects on the eye
Remarks : Based on skin corrosivity.

Propylene glycol:

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Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	No eye irritation

Silicon dioxide:

Species	:	Rabbit
Method	:	OECD Test Guideline 405
Result	:	No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

Not classified based on available information.

Respiratory sensitisation

Not classified based on available information.

Product:

Test Type	:	Magnusson-Kligman-Test
Exposure routes	:	Dermal
Species	:	Guinea pig
Result	:	Not a skin sensitizer.

Components:

Orbifloxacin:

Test Type	:	Maximisation Test
Exposure routes	:	Dermal
Species	:	Guinea pig
Result	:	Not a skin sensitizer.

Lactic acid:

Test Type	:	Buehler Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative
Remarks	:	Based on data from similar materials

Sodium hydroxide:

Test Type	:	Human repeat insult patch test (HRIPT)
Exposure routes	:	Skin contact
Result	:	negative

Propylene glycol:

Test Type	:	Maximisation Test
Exposure routes	:	Skin contact
Species	:	Guinea pig
Result	:	negative

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Germ cell mutagenicity

Not classified based on available information.

Components:

Orbifloxacin:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: equivocal Test Type: Mouse Lymphoma Result: positive Test Type: Chromosomal aberration Test system: Human lymphocytes Result: positive
Genotoxicity in vivo	:	Test Type: Micronucleus test Species: Mouse Cell type: Bone marrow Application Route: Intraperitoneal injection Result: negative Test Type: unscheduled DNA synthesis assay Species: Rat Cell type: Liver cells Application Route: Oral Result: negative
Germ cell mutagenicity- Assessment	:	Weight of evidence does not support classification as a germ cell mutagen.

Lactic acid:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Method: OECD Test Guideline 471 Result: negative Remarks: Based on data from similar materials 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
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Propylene glycol:

Genotoxicity in vitro	:	Test Type: Bacterial reverse mutation assay (AMES) Result: negative Test Type: Chromosome aberration test in vitro
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Method: OECD Test Guideline 473
Result: negative

Genotoxicity in vivo : Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative

Silicon dioxide:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)
Method: OECD Test Guideline 471
Result: negative

Genotoxicity in vivo : Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)
Species: Rat
Application Route: Ingestion
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

Orbifloxacin:

Species : Rat
Application Route : Oral
Exposure time : 2 Years
NOAEL : 200 mg/kg body weight
Result : negative

Species : Mouse
Application Route : Oral
Exposure time : 2 Years
NOAEL : 200 mg/kg body weight
Result : negative

Lactic acid:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative
Remarks : Based on data from similar materials

Propylene glycol:

Species : Rat
Application Route : Ingestion
Exposure time : 2 Years
Result : negative

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Silicon dioxide:

Species	:	Rat
Application Route	:	Ingestion
Exposure time	:	103 weeks
Result	:	negative

Reproductive toxicity

Suspected of damaging the unborn child.

Components:

Orbifloxacin:

Effects on fertility	:	Test Type: Two-generation reproduction toxicity study Species: Rat Application Route: Oral General Toxicity - Parent: NOAEL: 50 mg/kg body weight Early Embryonic Development: NOAEL: 50 mg/kg body weight Result: No adverse effects
Effects on foetal development	:	Test Type: Embryo-foetal development Species: Rat Application Route: Oral Embryo-foetal toxicity: LOAEL: 333 mg/kg body weight Result: No teratogenic effects, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses Test Type: Embryo-foetal development Species: Rabbit Application Route: Oral General Toxicity Maternal: NOAEL: 20 mg/kg body weight Embryo-foetal toxicity: NOAEL: 60 mg/kg body weight Result: No effects on early embryonic development, Embryotoxic effects and adverse effects on the offspring were detected only at high maternally toxic doses, Reduced maternal body weight gain Test Type: Development Species: Dog Application Route: Oral Developmental Toxicity: LOAEL: 2.5 mg/kg body weight Result: Effects on postnatal development, Skeletal malformations
Reproductive toxicity - Assessment	:	Some evidence of adverse effects on development, based on animal experiments.

Lactic acid:

Effects on foetal development	:	Test Type: Embryo-foetal development
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Species: Mouse
Application Route: Ingestion
Result: negative

Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal development : Test Type: Embryo-foetal development
Species: Mouse
Application Route: Ingestion
Result: negative

Silicon dioxide:

Effects on foetal development : Test Type: Embryo-foetal 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 (Eye) through prolonged or repeated exposure if swallowed.

Product:

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

Repeated dose toxicity

Product:

Species : Dog
NOAEL : 22.5 mg/kg
LOAEL : 37.5 mg/kg
Application Route : Oral
Exposure time : 30 Days
Symptoms : Gastrointestinal disturbance

Species : Dog
LOAEL : 75 mg/kg
Application Route : Oral
Exposure time : 10 Days
Symptoms : Salivation, Gastrointestinal disturbance, Vomiting

Species : Cat
LOAEL : 45 mg/kg
Application Route : Oral

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Exposure time : 30 Days
Target Organs : Eye
Symptoms : Salivation, Lachrymation, Gastrointestinal disturbance, Liver disorders

Components:

Orbifloxacin:

Species : Rat
NOAEL : 20 mg/kg
LOAEL : 80 mg/kg
Application Route : Oral
Exposure time : 3 Months
Target Organs : Testis, Liver, Kidney, spleen

Species : Mouse
NOAEL : 80 mg/kg
LOAEL : 250 mg/kg
Application Route : Oral
Exposure time : 3 Months

Species : Juvenile dog
NOAEL : 50 mg/kg
LOAEL : 250 mg/kg
Application Route : Oral
Exposure time : 14 Days
Target Organs : Heart, Bone
Symptoms : Gastrointestinal disturbance
Remarks : mortality observed

Species : Juvenile dog
NOAEL : 2 mg/kg
LOAEL : 3 mg/kg
Application Route : Oral
Exposure time : 90 Days
Target Organs : Bone
Remarks : No significant adverse effects were reported

Species : Dog
NOAEL : 37.5 mg/kg
Application Route : Oral
Exposure time : 30 Days

Species : Cat
NOAEL : 7.5 mg/kg
LOAEL : 22.5 mg/kg
Application Route : Oral
Exposure time : 1 Months
Symptoms : Gastrointestinal disturbance

Lactic acid:

Species : Rat

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NOAEL : > 100 mg/kg
Application Route : Ingestion
Exposure time : 13 Weeks
Remarks : Based on data from similar materials

Species : Rat
LOAEL : 886 mg/kg
Application Route : Skin contact
Exposure time : 13 Weeks

Propylene glycol:

Species : Rat, male
NOAEL : $\geq 1,700$ mg/kg
Application Route : Ingestion
Exposure time : 2 yr

Silicon dioxide:

Species : Rat
NOAEL : 1.3 mg/m³
Application Route : inhalation (dust/mist/fume)
Exposure time : 13 Weeks

Aspiration toxicity

Not classified based on available information.

Experience with human exposure

Components:

Orbifloxacin:

Ingestion : Symptoms: central nervous system effects, Gastrointestinal disturbance, liver function change, anaphylaxis, Rash
Remarks: May cause photosensitisation.

SECTION 12: Ecological information

12.1 Toxicity

Components:

Lactic acid:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): > 100 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203
Remarks: Based on data from similar materials

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 202
Remarks: Based on data from similar materials

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Toxicity to algae/aquatic plants : ErC50 (*Pseudokirchneriella subcapitata* (green algae)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

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 : EC50 : > 10 - 100 mg/l
Exposure time: 3 h
Method: OECD Test Guideline 209
Remarks: Based on data from similar materials

Propylene glycol:

Toxicity to fish : LC50 (*Oncorhynchus mykiss* (rainbow trout)): 40,613 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Ceriodaphnia dubia* (water flea)): 18,340 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants : ErC50 (*Skeletonema costatum* (marine diatom)): 19,300 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : NOEC (*Pseudomonas putida*): > 20,000 mg/l
Exposure time: 18 h

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 13,020 mg/l
Exposure time: 7 d
Species: *Ceriodaphnia dubia* (water flea)

Silicon dioxide:

Toxicity to fish : LC50 (*Danio rerio* (zebra fish)): > 10,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (*Daphnia magna* (Water flea)): > 1,000 mg/l
Exposure time: 24 h
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : EC50 (*Desmodesmus subspicatus* (green algae)): > 10,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

NOEC (*Desmodesmus subspicatus* (green algae)): 10,000 mg/l

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Exposure time: 72 h
Method: OECD Test Guideline 201
Remarks: Based on data from similar materials

12.2 Persistence and degradability

Components:

Lactic acid:

Biodegradability : Result: Not readily biodegradable.
Remarks: Based on data from similar materials

Propylene glycol:

Biodegradability : Result: Readily biodegradable.
Biodegradation: 98.3 %
Exposure time: 28 d
Method: OECD Test Guideline 301F

12.3 Bioaccumulative potential

Components:

Lactic acid:

Partition coefficient: n-octanol/water : log Pow: -0.62

Propylene glycol:

Partition coefficient: n-octanol/water : log Pow: -1.07
Method: Regulation (EC) No. 440/2008, Annex, A.8

12.4 Mobility in soil

No data available

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.

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
IATA	: Not regulated as a dangerous good

14.3 Transport hazard class(es)

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

14.4 Packing group

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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IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : 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.

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) : Conditions of restriction for the following entries should be considered:
Number on list 3

Substance(s) or mixture(s) are listed here according to their appearance in the regulation, irrespective of their use/purpose or the conditions of the restriction. Please refer to the conditions in corresponding Regulation to determine whether an entry is applicable to the placing on the market or not.

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 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

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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.

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

H290 : May be corrosive to metals.
H314 : Causes severe skin burns and eye damage.
H318 : Causes serious eye damage.
H361d : Suspected of damaging the unborn child.

Full text of other abbreviations

Eye Dam. : Serious eye damage
Met. Corr. : Corrosive to metals
Repr. : Reproductive toxicity
Skin Corr. : Skin corrosion
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; AIIIC - 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 - 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) Ef-

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fect 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:

Repr. 2	H361d
STOT RE 2	H373

Classification procedure:

Calculation method
Based on product data or assessment

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.

GB / EN