

# **Orbifloxacin Liquid Formulation**

Revision Date: SDS Number: Date of last issue: 2024/04/06 Version 785433-00020 10.0 2024/09/28 Date of first issue: 2016/06/28

#### 1. PRODUCT AND COMPANY IDENTIFICATION

Chemical product name Orbifloxacin Liquid Formulation

Supplier's company name, address and phone number

Company name of supplier 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 Veterinary product Restrictions on use Not applicable

#### 2. HAZARDS IDENTIFICATION

GHS classification of chemical product

Reproductive toxicity Category 2

Specific target organ toxicity - :

repeated exposure (Oral)

Category 2 (Eye)

**GHS** label elements

Hazard pictograms

Signal word

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 Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read

and understood.

P260 Do not breathe mist or vapours.

P280 Wear protective gloves/ protective clothing/ eye protec-



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tion/ face protection.

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.

#### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

#### Components

Chemical name	CAS-No.	Concentration (% w/w)	ENCS No.
Propylene glycol	57-55-6	>= 10 - < 20	2-234
Orbifloxacin	113617-63-3	>= 3 - < 10	-
Lactic acid	50-21-5	>= 1 - < 10	2-1369
Sodium hydroxide	1310-73-2	>= 1 - < 10	1-410

#### 4. FIRST AID MEASURES

In case of eye contact

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. 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 : Suspected of damaging the unborn child.



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and effects, both acute and

delayed

Protection of first-aiders

May cause damage to organs through prolonged or repeated

exposure if swallowed.

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).

Treat symptomatically and supportively.

5. FIREFIGHTING MEASURES

Notes to physician

Suitable extinguishing media Water spray

> Alcohol-resistant foam Carbon dioxide (CO2)

Dry chemical

Unsuitable extinguishing

media

None known.

Specific hazards during fire-

fighting

Exposure to combustion products may be a hazard to health.

Hazardous combustion prod: :

ucts

Carbon oxides Metal oxides

Specific extinguishing meth-

ods

Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Use water spray to cool unopened containers.

Remove undamaged containers from fire area if it is safe to do

Evacuate area.

Special protective equipment :

for firefighters

In the event of fire, wear self-contained breathing apparatus.

Use personal protective equipment.

**6. ACCIDENTAL RELEASE MEASURES** 

Personal precautions, protec- :

tive equipment and emer-

gency procedures

Use personal protective equipment.

Follow safe handling advice (see section 7) and personal pro-

tective equipment recommendations (see section 8).

Avoid release to the environment. **Environmental precautions** 

Prevent further leakage or spillage if safe to do so.

Prevent spreading over a wide area (e.g. by containment or oil

barriers).

Retain and dispose of contaminated wash water.

Local authorities should be advised if significant spillages

cannot be contained.

Methods and materials for containment and 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.



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Clean up remaining materials from spill with suitable absor-

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 deter-

mine which regulations are applicable.

Sections 13 and 15 of this SDS provide information regarding

certain local or national requirements.

#### 7. HANDLING AND STORAGE

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 as-

sessment

Take care to prevent spills, waste and minimize release to the

environment.

Avoidance of contact

Hygiene measures

Oxidizing agents

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.

Storage

Conditions for safe storage : Keep in properly labelled containers.

Store locked up.

Store in accordance with the particular national regulations.

Materials to avoid : Do not store with the following product types:

Strong oxidizing agents

Packaging material : Unsuitable material: None known.

#### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Threshold limit value and permissible exposure limits for each component in the work environment

Components CAS	S-No. Value type	Control parame-	Basis
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		(Form of exposure)	ters / Concentra- tion standard / Permissible con- centration	
Orbifloxacin	113617-63-3	TWA	0.2 mg/m3 (OEB 2)	Internal
Sodium hydroxide	1310-73-2	OEL-C	2 mg/m3	JP OEL JSOH
		С	2 mg/m3	ACGIH

**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

Respiratory protection If adequate local exhaust ventilation is not available or expo-

sure assessment demonstrates exposures outside the rec-

ommended guidelines, use respiratory protection. Combined particulates and organic vapour type

Filter type Hand protection

> Material Chemical-resistant gloves

Remarks Impermeable protective gloves

Eye protection Wear safety glasses with side shields or goggles.

If the work environment or activity involves dusty conditions,

mists or aerosols, wear the appropriate goggles.

Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or

aerosols.

Skin and body protection Work uniform or laboratory coat.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state suspension

Colour light brown

Odour odourless

Odour Threshold No data available

Melting point/freezing point No data available

Boiling point, initial boiling

point and boiling range

No data available

Flammability (solid, gas) Not applicable



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Flammability (liquids) : No data available

Lower explosion limit and upper explosion limit / flammability limit

Upper explosion limit / Up- :

per flammability limit

No data available

Lower explosion limit /

Lower flammability limit

No data available

Flash point : No data available

Decomposition temperature : No data available

pH : No data available

Evaporation rate : No data available

Auto-ignition temperature : No data available

Viscosity

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Density and / or relative density

Relative density : No data available

Density : No data available

Relative vapour density : No data available

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Molecular weight : No data available

Particle characteristics

Particle size : No data available

#### 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.



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Chemical stability : Stable under normal conditions. Possibility of hazardous reac- : Can react with strong oxidizing agents.

tions

Conditions to avoid : None known. Incompatible materials Oxidizing agents

Hazardous decomposition No hazardous decomposition products are known.

products

# 11. TOXICOLOGICAL INFORMATION

Inhalation Information on likely routes of:

exposure Skin contact

Ingestion Eye contact

### **Acute toxicity**

Not classified based on available information.

## Components:

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

LD50 (Rabbit): > 2,000 mg/kg Acute dermal toxicity

Assessment: The substance or mixture has no acute dermal

toxicity

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

Remarks: No data available Acute dermal toxicity

Acute toxicity (other routes of:

administration)

LD50 (Rat): > 200 mg/kg

Application Route: Intramuscular

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



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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

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.

Skin corrosion/irritation

Not classified based on available information.

**Product:** 

Species : Rabbit

Result : No skin irritation

**Components:** 

Propylene glycol:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Orbifloxacin:

Species : Rabbit
Method : Draize Test
Result : No skin irritation

Lactic acid:

Species : Rabbit

Method : OECD Test Guideline 404



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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

## Serious eye damage/eye irritation

Not classified based on available information.

**Product:** 

Species : Rabbit

Result : Mild eye irritation

**Components:** 

Propylene glycol:

Species : Rabbit

Result : No eye irritation

Method : OECD Test Guideline 405

Orbifloxacin:

Species : Rabbit

Result : Mild eye irritation
Method : Draize Test

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.

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.



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### **Components:**

Propylene glycol:

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

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

Germ cell mutagenicity

Not classified based on available information.

Components:

Propylene glycol:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)

Result: negative

Test Type: Chromosome aberration test in vitro

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

Orbifloxacin:

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)



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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

### Carcinogenicity

Not classified based on available information.

### Components:

## Propylene glycol:

Species: RatApplication Route: IngestionExposure time: 2 YearsResult: negative



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#### 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

## Reproductive toxicity

Suspected of damaging the unborn child.

## **Components:**

# Propylene glycol:

Effects on fertility : Test Type: Two-generation reproduction toxicity study

Species: Mouse

**Application Route: Ingestion** 

Result: negative

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

Application Route: Ingestion

Result: negative

## 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 develop-

ment

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 ad-



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verse effects on the offspring were detected only at high ma-

ternally 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 malfor-

mations

Reproductive toxicity - As-

sessment

Some evidence of adverse effects on development, based on

animal experiments.

#### Lactic acid:

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Mouse

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



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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
Exposure time : 30 Days
Target Organs : Eye

Symptoms : Salivation, Lachrymation, Gastrointestinal disturbance, Liver

disorders

#### **Components:**

# Propylene glycol:

Species : Rat, male

NOAEL : >= 1,700 mg/kg

Application Route : Ingestion

Exposure time : 2 yr

#### Orbifloxacin:

Species: RatNOAEL: 20 mg/kgLOAEL: 80 mg/kgApplication Route: OralExposure time: 3 Months

Target Organs : Testis, Liver, Kidney, spleen

Species: MouseNOAEL: 80 mg/kgLOAEL: 250 mg/kgApplication Route: OralExposure 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



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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

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

**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.

12. ECOLOGICAL INFORMATION

**Ecotoxicity** 

**Components:** 

Propylene glycol:

Toxicity to fish LC50 (Oncorhynchus mykiss (rainbow trout)): 40,613 mg/l

Exposure time: 96 h

aquatic invertebrates

Toxicity to daphnia and other : EC50 (Ceriodaphnia dubia (water flea)): 18,340 mg/l

Exposure time: 48 h



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Toxicity to algae/aquatic : ErC50 (Skeletonema costatum (marine diatom)): 19,300 mg/l

plants Exposure time: 72 h

Method: OECD Test Guideline 201

Toxicity to daphnia and other:

ic toxicity)

aquatic invertebrates (Chron-Exposure time: 7 d

Toxicity to microorganisms : NOEC (Pseudomonas putida): > 20,000 mg/l

Exposure time: 18 h

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

NOEC (Ceriodaphnia dubia (water flea)): 13,020 mg/l

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

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

EC50: > 10 - 100 mg/lToxicity to microorganisms

Exposure time: 3 h

Method: OECD Test Guideline 209

Remarks: Based on data from similar materials

Persistence and degradability

**Components:** 

Propylene glycol:

Biodegradability Result: Readily biodegradable.

> Biodegradation: 98.3 % Exposure time: 28 d

Method: OECD Test Guideline 301F

Lactic acid:

Biodegradability Result: Not readily biodegradable.

Remarks: Based on data from similar materials



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П

**Bioaccumulative potential** 

**Components:** 

Propylene glycol:

Partition coefficient: n-

octanol/water

log Pow: -1.07

Method: Regulation (EC) No. 440/2008, Annex, A.8

Lactic acid:

Partition coefficient: n-

octanol/water

log Pow: -0.62

Mobility in soil

No data available

Hazardous to the ozone layer

Not applicable

Other adverse effects

No data available

13. DISPOSAL CONSIDERATIONS

**Disposal methods** 

Waste from residues : Dispose of in accordance with local regulations.

Do not dispose of waste into sewer.

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.

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
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo : Not applicable



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aircraft)

Packing instruction (passen: Not applicable

ger aircraft)

**IMDG-Code** 

UN number Not applicable Proper shipping name Not applicable Not applicable Class Not applicable Subsidiary risk Not applicable Packing group Not applicable Labels **EmS Code** Not applicable Marine pollutant Not applicable

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

Not applicable for product as supplied.

#### **National Regulations**

Refer to section 15 for specific national regulation.

#### 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**

**Priority Assessment Chemical Substance** 

Therity Accessificat Chemical Casciance	
Chemical name	Number
Propane-1,2-diol	106

#### 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

Not applicable



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# **Substances Subject to be Notified Names**

Article 57-2 (Enforcement Order Table 9)

Chemical name	Concentration (%)	Remarks
Propylene glycol	>=10 - <20	From April 1st, 2025
Lactic acid	>=1 - <10	From April 1st, 2025
Sodium hydroxide	>=1 - <10	-

# **Substances Subject to be Indicated Names**

Article 57 (Enforcement Order Article 18)

Chemical name	Remarks
Propylene glycol	From April 1st, 2025
Lactic acid	From April 1st, 2025
Sodium hydroxide	-

## Skin and Eye Damage Substances for PPE Requirements (ISHL MO Art. 594-2)

Chemical name	
Lactic acid (DL-, L-, D-)	
Sodium hydroxide	

# 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

#### Ordinance on Prevention of Tetraalkyl Lead Poisoning

Not applicable

#### **Ordinance on Prevention of Organic Solvent Poisoning**

Not applicable

# Enforcement Order of the Industrial Safety and Health Law - Attached table 1 (Dangerous Substances)

Not applicable

#### **Poisonous and Deleterious Substances Control Law**

Not applicable

# Act on Confirmation, etc. of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof

Not applicable

#### **High Pressure Gas Safety Act**

Not applicable

## **Explosive Control Law**

Not applicable

# **Vessel Safety Law**

Not regulated as a dangerous good



# **Orbifloxacin Liquid Formulation**

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#### **Aviation Law**

Not regulated as a dangerous good

#### Marine Pollution and Sea Disaster Prevention etc Law

Bulk transportation : Noxious liquid substance(Category Z) Pack transportation Not classified as marine pollutant

#### **Narcotics and Psychotropics Control Act**

Narcotic or Psychotropic Raw Material (Export / Import Permission)

Not applicable

Specific Narcotic or Psychotropic Raw Material (Export / Import permission)

Not applicable

#### Waste Disposal and Public Cleansing Law

Industrial waste

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

**AICS** not determined

DSL not determined

**IECSC** not determined

#### 16. OTHER INFORMATION

In this SDS, if the concentration of substances subject to notification under the Industrial Safety and Health Law is indicated as a range, it includes cases where it is a trade secret.

#### **Further information**

Sheet

Sources of key data used to : Internal technical data, data from raw material SDSs, OECD compile the Safety Data

eChem Portal search results and European Chemicals Agen-

cy, http://echa.europa.eu/

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

Date format : yyyy/mm/dd

Full text of other abbreviations

**ACGIH** USA. ACGIH Threshold Limit Values (TLV)

JP OEL JSOH Japan. The Japan Society for Occupational Health. Recom-

mendation of Occupational Exposure Limits

ACGIH / C Ceiling limit

JP OEL JSOH / OEL-C Occupational Exposure Limit-Ceiling

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;



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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 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.

JP / EN