

# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision date 19-Feb-2025 Revision Number 2

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

1.1. Product identifier

Product Code(s) CAT 1287

Product Name levofloxacin hemihydrate

Form Not applicable

**REACH** registration number

NOTE [8] - No registration number is given for this substance because it is under the threshold in REACH Article 6(1) and not subject to the registration requirements according to REACH Title II

**EC No (EU Index No)** 604-067-2

**CAS No.** 138199-71-0

Pure substance/mixture Substance

Formula C36H42F2N6O9

Molecular weight 740.7

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

Recommended use Laboratory use

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

### **Supplier**

British Pharmacopoeia Commission MHRA 10 South Colonnade Canary Wharf London E14 4PU United Kingdom

Tel: +44 (0)20 3080 6561 eMail: bpcrs@mhra.gov.uk

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For further information, please contact

E-mail address bpcrs@mhra.gov.uk

### 1.4. Emergency telephone number

Emergency Telephone +44 (0)20 3080 6561 (Monday - Friday: 8am - 5pm)

Emergency Telephone - §45 - (EC)1272/2008				
Europe	112			
Austria	No information available			
Bulgaria				
Croatia				
Cyprus				
Czech Republic				
Denmark				
France				
Hungary				
Ireland				
Italy				
Lithuania				
Luxembourg				
Netherlands				
Norway				
Portugal				
Romania				
Slovakia				
Slovenia				
Spain				
Sweden				
Switzerland				

# **SECTION 2: Hazards identification**

# 2.1. Classification of the substance or mixture

Classification according to

Regulation (EC) No. 1272/2008 [CLP]

Acute toxicity - Oral	Category 4 - (H302)
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Eye irritation	Category 2 - (H319)
Respiratory sensitisation	Category 1 - (H334)
Skin sensitisation	Category 1 - (H317)
Reproductive toxicity	Category 2 - (H361)
Effects on or via lactation	Yes - (H362)
Specific target organ toxicity (single exposure)	Category 2 - (H371)

### 2.2. Label elements

Contains Levofloxacin Hemihydrate





Signal word Danger

#### **Hazard statements**

H302 - Harmful if swallowed.

H317 - May cause an allergic skin reaction.

H319 - Causes serious eye irritation.

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H361 - Suspected of damaging fertility or the unborn child.

H362 - May cause harm to breast-fed children.

H371 - May cause damage to organs.

### Precautionary Statements - EU (§28, 1272/2008)

P260 - Do not breathe dust, fume, gas, mist, vapors and spray

P263 - Avoid contact during pregnancy and while nursing

P264 - Wash face, hands and any exposed skin thoroughly after handling

P280 - Wear protective gloves, protective clothing, eye protection and face protection

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

#### 2.3. Other hazards

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No information available.

PBT & vPvB This substance does not meet the PBT/vPvB criteria of REACH, annex XIII.

**Endocrine Disruptor Information** This product does not contain any known or suspected endocrine disruptors.

	adet deed net eendam ding mienn en edepe	0.04 0.140010 4.0.4 0.0.0.
Chemical name	EU - REACH (1907/2006) - Article 59(1)	EU - REACH (1907/2006) - Endocrine
	- Candidate List of Substances of Very	Disruptor Assessment List of
	High Concern (SVHC) for Authorisation	Substances
Levofloxacin Hemihydrate	-	-

# **SECTION 3: Composition/information on ingredients**

### 3.1 Substances

Chemical name	Weight-%	REACH registration number	EC No (EU Index No)	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Specific concentration limit (SCL)	M-Factor	M-Factor (long-ter m)	Notes
Levofloxacin Hemihydrate 138199-71-0	100	-	604-067-2	Acute Tox. 4 (H302) Eye Irrit. 2 (H319) Resp. Sens. 1 (H334) Skin Sens. 1 (H317) Repr. 2 (H361) Lact. (H362) STOT SE 2 (H371)		-	-	-

#### Full text of H- and EUH-phrases: see section 16

Acute Toxicity Estimate
No information available

This product does not contain candidate substances of very high concern at a concentration >=0.1% (Regulation (EC) No. 1907/2006 (REACH), Article 59).

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### **SECTION 4: First aid measures**

#### 4.1. Description of first aid measures

**General advice** Show this safety data sheet to the doctor in attendance.

**Inhalation** May cause allergic respiratory reaction. If breathing has stopped, give artificial respiration.

Get medical attention immediately. Remove to fresh air. Avoid direct contact with skin. Use

barrier to give mouth-to-mouth resuscitation.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If

symptoms persist, call a doctor. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if

irritation develops and persists.

**Skin contact** Wash with soap and water. May cause an allergic skin reaction. Wash off immediately with

plenty of water for at least 15 minutes. If symptoms persist, call a doctor.

**Ingestion** Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious

person. May produce an allergic reaction. Get immediate medical attention.

Self-protection of the first aider Ensure that medical personnel are aware of the material(s) involved, take precautions to

protect themselves and prevent spread of contamination. Avoid contact with skin, eyes or clothing. Avoid direct contact with skin. Use barrier to give mouth-to-mouth resuscitation. Use personal protective equipment as required. See section 8 for more information.

4.2. Most important symptoms and effects, both acute and delayed

**Symptoms** May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing and/ or

wheezing. Itching. Rashes. Hives. May cause redness and tearing of the eyes. Burning

sensation.

Effects of Exposure May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility.

May cause damage to organs if swallowed. May cause damage to organs.

4.3. Indication of any immediate medical attention and special treatment needed

**Note to doctors**May cause sensitisation in susceptible persons. Treat symptomatically.

### SECTION 5: Firefighting measures

5.1. Extinguishing media

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surrounding environment.

Large Fire CAUTION: Use of water spray when fighting fire may be inefficient.

**Unsuitable extinguishing media** Do not scatter spilled material with high pressure water streams.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

Product is or contains a sensitiser. May cause sensitisation by inhalation. May cause

sensitisation by skin contact.

5.3. Advice for firefighters

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.

Use personal protection equipment.

### SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

**Personal precautions** Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal

protective equipment as required. Evacuate personnel to safe areas. Keep people away

from and upwind of spill/leak.

**Other information** Refer to protective measures listed in Sections 7 and 8.

6.2. Environmental precautions

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.

**Methods for cleaning up**Take up mechanically, placing in appropriate containers for disposal.

Prevention of secondary hazards Clean contaminated objects and areas thoroughly observing environmental regulations.

6.4. Reference to other sections

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**Reference to other sections** See section 8 for more information. See section 13 for more information.

### SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice. Avoid contact with

skin, eyes or clothing. Ensure adequate ventilation. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash it before reuse. Remove contaminated clothing and shoes.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this

product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before

re-use. Wash hands before breaks and immediately after handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Please refer to the manufacturer's certificate for specific storage and transport temperature

conditions. Store only in the original receptacle unless other advice is given on the CoA. Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach

of children. Store locked up.

Storage class (TRGS 510) LGK 11.

7.3. Specific end use(s)

Risk Management Methods (RMM) The information required is contained in this Safety Data Sheet.

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Biological occupational exposure

limits

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies.

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Derived No Effect Level (DNEL) - Workers No information available

Derived No Effect Level (DNEL) - General Public No information available.

Predicted No Effect Concentration (PNEC) No information available.

### 8.2. Exposure controls

Personal protective equipment

**Eye/face protection** Avoid contact with eyes. Wear safety glasses with side shields (or goggles).

Hand protection The protective gloves to be used must comply with the specifications of EC Directive

89/686/EEC and the related standard EN374. Wear suitable gloves.

Duration of contact

Glove thickness
0.11 mm

Glove thickness
0.11 mm

Glove thickness
0.11 mm

Glove thickness
0.11 mm

Glove thickness
480 minutes

Wear protective nitrile rubber gloves

Skin and body protection

Wear suitable protective clothing.

Respiratory protection

No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.

General hygiene considerations

Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Wash hands before breaks and after work. Wear suitable gloves and eye/face protection. Remove and wash contaminated clothing and gloves, including the inside, before

re-use. Wash hands before breaks and immediately after handling the product.

**Environmental exposure controls** Do not allow into any sewer, on the ground or into any body of water.

### SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

AppearanceSolidPhysical stateSolid

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Colour light yellow

Odour No information available
Odour threshold No information available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

Melting point / freezing point 213 - 218 °C None known Initial boiling point and boiling rangeNo data available None known Flammability No data available None known Flammability Limit in Air None known

Upper flammability or explosive No data available

limits

Lower flammability or explosive No data available

limits

Flash point No data available None known Autoignition temperature No data available None known Decomposition temperature SADT (°C) No data available None known None known

pH No data available None known
pH (as aqueous solution) No data available None known
Kinematic viscosity No data available None known
Dynamic viscosity No data available None known
Water solubility Soluble in water None known

Solubility(ies) DMSO Methanol slightly soluble

Partition coefficient
No data available
None known
Vapour pressure
No data available
None known
Relative density
No data available
None known

Bulk density
No data available
Liquid Density
Relative vapour density
No data available
No data available

Relative vapour density

No data available

None known

Particle characteristics

Particle Size No information available Particle Size Distribution No information available

9.2. Other information

Molecular formula C36H42F2N6O9

Molecular weight 740.7

#### 9.2.1. Information with regards to physical hazard classes

No information available

### 9.2.2. Other safety characteristics

No information available

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### SECTION 10: Stability and reactivity

10.1. Reactivity

**Reactivity** No information available.

10.2. Chemical stability

**Stability** Stable under normal conditions.

**Explosion data** 

Sensitivity to mechanical impact None. Sensitivity to static discharge None.

10.3. Possibility of hazardous reactions

Possibility of hazardous reactions 
None under normal processing.

10.4. Conditions to avoid

Conditions to avoid None known based on information supplied.

10.5. Incompatible materials

**Incompatible materials**None known based on information supplied.

10.6. Hazardous decomposition products

Hazardous decomposition products None known based on information supplied.

# SECTION 11: Toxicological information

# 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008 Information on likely routes of exposure

**Inhalation** Specific test data for the substance or mixture is not available. May cause sensitisation in

susceptible persons. (based on components).

Eye contact Specific test data for the substance or mixture is not available. Causes serious eye irritation.

(based on components). May cause redness, itching, and pain.

**Skin contact** Specific test data for the substance or mixture is not available. Repeated or prolonged skin

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contact may cause allergic reactions with susceptible persons. (based on components).

May cause sensitisation by skin contact.

**Ingestion** Specific test data for the substance or mixture is not available. May cause additional effects

as listed under "Inhalation". Ingestion may cause gastrointestinal irritation, nausea, vomiting

and diarrhoea. Harmful if swallowed. (based on components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms

Symptoms of allergic reaction may include rash, itching, swelling, trouble breathing, tingling of the hands and feet, dizziness, lightheadedness, chest pain, muscle pain, or flushing. Coughing and/ or wheezing. Itching. Rashes. Hives. May cause redness and tearing of the

eyes.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Acute toxicity Harmful if swallowed.

Numerical measures of toxicity No information available

**Skin corrosion/irritation**Based on available data, the classification criteria are not met.

Serious eye damage/eye irritation Classification based on data available for ingredients. Causes serious eye irritation.

Respiratory or skin sensitisation May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an

allergic skin reaction.

**Germ cell mutagenicity** Based on available data, the classification criteria are not met.

Carcinogenicity Based on available data, the classification criteria are not met.

Reproductive toxicity Contains a known or suspected reproductive toxin. Classification based on data available

for ingredients. May cause harm to breast-fed children. Suspected of damaging fertility or

the unborn child.

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**STOT - single exposure** May cause damage to organs if swallowed.

**STOT - repeated exposure**Based on available data, the classification criteria are not met.

**Aspiration hazard** Based on available data, the classification criteria are not met.

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

11.2.2. Other information

Other adverse effects No information available.

# **SECTION 12: Ecological information**

12.1. Toxicity

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

12.4. Mobility in soil

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

**PBT and vPvB assessment**Based on available data, the classification criteria are not met.

12.6. Endocrine disrupting properties

**Endocrine disrupting properties** Based on available data, the classification criteria are not met.

12.7. Other adverse effects

Other adverse effects No information available.

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**PMT or vPvM properties**Based on available data, the classification criteria are not met.

### SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Waste from residues/unused

products

Dispose of in accordance with local regulations. Dispose of waste in accordance with

environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

# **SECTION 14: Transport information**

### IATA

UN number or ID number	Not regulated
UN proper shipping name	Not regulated
Transport hazard class(es)	Not regulated
Packing group	Not regulated
Environmental hazards	Not applicable
	UN number or ID number UN proper shipping name Transport hazard class(es) Packing group Environmental hazards

14.6 Special precautions for user

Special Provisions None

#### **IMDG**

14.1	UN number or ID number	Not regulated
14.2	UN proper shipping name	Not regulated
14.3	Transport hazard class(es)	Not regulated
14.4	Packing group	Not regulated
14.5	<b>Environmental hazards</b>	Not applicable

14.6 Special precautions for user

Special Provisions None

**14.7 Maritime transport in bulk** No information available according to IMO instruments

**RID** 

14.1	UN number or ID number	Not regulated
14.2	UN proper shipping name	Not regulated
14.3	Transport hazard class(es)	Not regulated
14.4	Packing group	Not regulated
145	Environmental hazards	Not applicable

14.6 Special precautions for user

Special Provisions None

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ADR

14.1 UN number or ID number Not regulated 14.2 UN proper shipping name Not regulated 14.3 Transport hazard class(es) Not regulated 14.4 Packing group Not regulated 14.5 Environmental hazards Not applicable

14.6 Special precautions for user

**Special Provisions** None

ADN

14.1 UN number or ID number Not regulated 14.2 UN proper shipping name Not regulated 14.3 Transport hazard class(es) Not regulated 14.4 Packing group Not regulated 14.5 Environmental hazard Not applicable

14.6 Special precautions for user

**Special Provisions** None

### SECTION 15: Regulatory information

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

### National regulations

Germany

Water hazard class (WGK) slightly hazardous to water (WGK 1) **Chemical Prohibition Ordinance** Not applicable

(ChemVerbotsV)

**TRGS 905** Not applicable

Switzerland

Ordinance on the Incentive Tax on Volatile Organic Compounds (OVOC) SR 814.018 Not applicable SC 11/13 Storage of Hazardous Material WPO (GSchV) SR 814.201; WPA (GSchG) SR 814.20 Class B Major Accidents Ordinance SR 814.012 Not applicable

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#### **European Union**

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

#### Authorisations and/or restrictions on use:

This product does not contain substances subject to authorisation (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

### DIRECTIVE (EU) 2021/1187 on the marketing and use of explosives precursors

Not applicable

### **Persistent Organic Pollutants**

Not applicable

#### Ozone-depleting substances (ODS) regulation (EC) 2024/590

Not applicable

### International Inventories

TSCA LGC has not confirmed that the chemical substances in this product are on the TSCA

Inventory, and LGC is distributing this product solely for use either in applications statutorily exempt from TSCA and regulated under other laws (e.g., FFDCA, FIFRA) or in research and development activities in accordance with the TSCA Inventory R&D exemption provided

at 40 CFR 720.36. It is the end-user's responsibility to understand and follow the

requirements that apply to its use of this product.
Contact supplier for inventory compliance status

<u>Legend:</u>

DSL/NDSL

**ENCS** 

IECSC KECL

**PICCS** 

**AIIC** 

**EINECS/ELINCS** 

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory

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DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

**ENCS** - Japan Existing and New Chemical Substances

**IECSC** - China Inventory of Existing Chemical Substances

**KECL** - Korean Existing Chemicals Inventory

PICCS - Philippines Inventory of Chemicals and Chemical Substances

AICS - Australian Inventory of Chemical Substances

#### 15.2. Chemical safety assessment

**Chemical Safety Report** 

A Chemical Safety Assessment is not required for this substance

### **SECTION 16: Other information**

### Key or legend to abbreviations and acronyms used in the safety data sheet

### Full text of any hazard and/or precautionary statements referred to under Sections 2-15

H302 - Harmful if swallowed

H317 - May cause an allergic skin reaction

H319 - Causes serious eye irritation

H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

H361 - Suspected of damaging fertility or the unborn child

H362 - May cause harm to breast-fed children

H371 - May cause damage to organs

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

P330 - Rinse mouth

P501 - Dispose of contents and container in accordance with local, regional, national, and international regulations as applicable

P280 - Wear protective gloves, protective clothing, eye protection and face protection

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

P337 + P313 - If eye irritation persists: Get medical advice/attention

P261 - Avoid breathing dust, fume, gas, mist, vapors and spray

P284 - In case of inadequate ventilation wear respiratory protection

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor

P272 - Contaminated work clothing should not be allowed out of the workplace

P280 - Wear protective gloves

P302 + P352 - IF ON SKIN: Wash with plenty of water and soap

P321 - Specific treatment (see supplemental first aid instructions on this label)

P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention

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P362 + P364 - Take off contaminated clothing and wash it before reuse

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

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

P405 - Store locked up

P260 - Do not breathe dust, fume, gas, mist, vapors and spray

P263 - Avoid contact during pregnancy and while nursing

P308 + P311 - IF exposed or concerned: Call a POISON CENTER or doctor

Legend

Legenu	
ACGIH	American Conference of Governmental Industrial Hygienists
AIDII	Italian Association of Industrial Hygienists
ADN	Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
	(Europe)
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road (Europe)
AIIC	Australian Inventory of Industrial Chemicals
ATE	Acute Toxicity Estimate
ASTM	American Society for the Testing of Materials
bar	Biological Reference Values for Chemical Compounds in the Work Area
BAT	Biological tolerance values for occupational exposure
BEL	Biological exposure limits
bw	Body weight
Ceiling	Maximum limit value
CLP	Classification, Labelling and Packaging Regulation; Regulation (EC) No 1272/2008
CMR	Carcinogen, Mutagen or Reproductive Toxicant
DFG	German Research Foundation
DOT	Department of Transportation (United States)
DSL	Domestic Substances List (Canada)
ECHA	European Chemicals Agency
EC Number	European Community number
EmS	Emergency Schedule
ENCS	Existing and New Chemical Substances (Japan)
EPA	Environmental Protection Agency
EWC	European Waste Codes
GHS	Globally Harmonized System
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
ICAO	International Civil Aviation Organisation
IECSC	Inventory of Existing Chemical Substances in China
IMDG	International Maritime Dangerous Goods

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IMO	International Maritime Organization
ISO	International Organisation for Standardisation
KECI	Korean Existing Chemicals Inventory
LC50	Lethal Concentration to 50% of a test population
LD50	Lethal Dose to 50% of a test population (Median Lethal Dose)
MAL	Measuring Technical Hygienic Air Needs
MARPOL	International Convention for the Prevention of Pollution from Ships
MDLPS	Ministry of Labour and Social Policy
n.o.s.	Not Otherwise Specified
NOAEC	No Observed Adverse Effect Concentration
NOAEL	No Observed Adverse Effect Level
NOELR	No Observable Effect Loading Rate
NZIoC	New Zealand Inventory of Chemicals
OECD	Organization for Economic Cooperation and Development
OEL	Occupational exposure limits
PBT	Persistent, Bioaccumulative and Toxic substance
PICCS	Philippines Inventory of Chemicals and Chemical Substances
PMT	Persistent, Mobile and Toxic
PPE	Personal protective equipment
QSAR	Quantitative Structure Activity Relationship
REACH	Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH) Regulation (EC 1907/2006)
RID	Agreement concerning the International Carriage of Dangerous Goods by Rail (Europe)
SADT	Self-Accelerating Decomposition Temperature
SAR	Structure-activity relationship
SDS	Safety Data Sheet
SL	Surface Limit
STEL	Short Term Exposure Limit
STOT RE	Specific target organ toxicity - Repeated exposure
STOT SE	Specific target organ toxicity - Single exposure
SVHC	Substance of very high concern
TCSI	Taiwan Chemical Substance Inventory
TDG	Transport of Dangerous Goods (Canada)
TRGS	Technical Rule for Hazardous Substances
TSCA	Toxic Substances Control Act (United States)
TWA	Time-Weighted Average
UN	United Nations
VOC	Volatile organic compounds
vPvB	Very Persistent and Very Bioaccumulative
vPvM	Very Persistent and Very Mobile
Sen+	Sensitiser

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# SAFETY DATA SHEET

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### CAT 1287 - levofloxacin hemihydrate

Sk*	Skin designation
**	Hazard Designation

Classification procedure	
Classification according to Regulation (EC) No. 1272/2008 [CLP]	Method Used
Acute oral toxicity	Calculation method
Acute dermal toxicity	Calculation method
Acute inhalation toxicity - gas	Calculation method
Acute inhalation toxicity - vapour	Calculation method
Acute inhalation toxicity - dust/mist	Calculation method
Skin corrosion/irritation	Calculation method
Serious eye damage/eye irritation	Calculation method
Respiratory sensitisation	Calculation method
Skin sensitisation	Calculation method
Mutagenicity	Calculation method
Carcinogenicity	Calculation method
Reproductive toxicity	Calculation method
STOT - single exposure	Calculation method
STOT - repeated exposure	Calculation method
Chronic aquatic toxicity	Calculation method
Acute aquatic toxicity	Calculation method
Aspiration hazard	Calculation method
Ozone	Calculation method

#### Key literature references and sources for data used to compile the SDS

Agency for Toxic Substances and Disease Registry (ATSDR)

U.S. Environmental Protection Agency ChemView Database

European Food Safety Authority (EFSA)

European Chemicals Agency (ECHA) Committee for Risk Assessment (ECHA\_RAC)

European Chemicals Agency (ECHA) (ECHA\_API)

**Environmental Protection Agency** 

Acute Exposure Guideline Level(s) (AEGL(s))

U.S. Environmental Protection Agency Federal Insecticide, Fungicide, and Rodenticide Act

U.S. Environmental Protection Agency High Production Volume Chemicals

Food Research Journal

Hazardous Substance Database

International Uniform Chemical Information Database (IUCLID)

National Institute of Technology and Evaluation (NITE)

Australian National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NIOSH (National Institute for Occupational Safety and Health)

National Library of Medicine's ChemID Plus (NLM CIP)

National Library of Medicine's PubMed database (NLM PUBMED)

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#### CAT 1287 - levofloxacin hemihydrate

U.S. National Toxicology Program (NTP)

New Zealand's Chemical Classification and Information Database (CCID)

Organisation for Economic Co-operation and Development Environment, Health, and Safety Publications Organisation for Economic Co-operation and Development High Production Volume Chemicals Programme

Organisation for Economic Co-operation and Development Screening Information Data Set

World Health Organization

Revision date 19-Feb-2025

Reason for revision Classification Gloves Material

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

**Disclaimer** 

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**End of Safety Data Sheet** 

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