



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

Revision date 05-Jul-2023

Revision Number 1

1. Identification

Product identifier

Product Name 9-Piperazino Levofloxacin Impurity

Other means of identification

Product Code(s) TRC-P480445-10MG

Synonyms None

Recommended use of the chemical and restrictions on use

Recommended use Laboratory use

Restrictions on use Not to be used for human or animal consumption

Details of the supplier of the safety data sheet

Supplier Address

VHG
LGC Standards
276 Abby Road
Manchester, NH 03103
UNITED STATES OF AMERICA

Tel : +1 (603) 622-7660
Fax : +1 (603) 622-5180
Email : lgcusa@lgcgroup.com

Web : lgcstandards.com

E-mail sds-request@lgcgroup.com

Emergency telephone number

Emergency Telephone

For Hazardous Materials or Dangerous Goods Incident
Spill, Leak, Fire Exposure, or Accident
Call CHEMTREC:
USA & Canada 1-800-424-9300
Rest of the world +1 703-741-5970

2. Hazard(s) identification



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

**TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity**

Revision date 05-Jul-2023

Classification

Classified according to OSHA.

Acute toxicity - Oral	Category 4
Serious eye damage/eye irritation	Category 2
Respiratory sensitization	Category 1
Skin sensitization	Category 1
Reproductive toxicity	Category 2
Specific target organ toxicity (single exposure)	Category 2

Hazards not otherwise classified (HNOC)

Not applicable

Label elements

Danger

Hazard statements

Classified according to OSHA.
Harmful if swallowed
Causes serious eye irritation
May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
Suspected of damaging fertility or the unborn child
May cause damage to organs



Precautionary Statements - Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product
In case of inadequate ventilation wear respiratory protection
Contaminated work clothing must not be allowed out of the workplace
Do not breathe dust/fume/gas/mist/vapors/spray



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

**TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity**

Revision date 05-Jul-2023

Precautionary Statements - Response

IF exposed or concerned: Get medical advice/attention

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

IF eye irritation persists: Get medical advice/attention

IF ON SKIN: Wash with plenty of water and soap

If skin irritation or rash occurs: Get medical advice/attention

Wash contaminated clothing before reuse

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing

If experiencing respiratory symptoms: Call a POISON CENTER or doctor

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

Rinse mouth

Precautionary Statements - Storage

Store locked up

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other information

No information available.

3. Composition/information on ingredients

Substance

Formula

$C_{18}H_{20}FN_3O_4$

Chemical name	CAS No	Weight-%	Trade secret
(3S)-10-Fluoro-3-methyl-9-(4-methylpiperazin-1-yl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic Acid	178912-62-4	100	*

4. First-aid measures

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. Get immediate medical advice/attention.

Eye contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. If symptoms persist, call a physician. Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

**TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity**

Revision date 05-Jul-2023

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 physician.

Ingestion

Do NOT induce vomiting. Rinse mouth. Never give anything by mouth to an unconscious person. May produce an allergic reaction. Get immediate medical advice/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.

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.

Indication of any immediate medical attention and special treatment needed

Note to physicians

May cause sensitization in susceptible persons. Treat symptomatically.

5. Fire-fighting measures

Suitable Extinguishing Media

Use extinguishing measures that are appropriate to local circumstances and the 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.

Specific hazards arising from the chemical

Product is or contains a sensitizer. May cause sensitization by inhalation and skin contact. May cause sensitization by skin contact.

Explosion data

Sensitivity to mechanical impact None.

Sensitivity to static discharge None.

Special protective equipment and precautions for fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

**TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity**

Revision date 05-Jul-2023

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.

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

Pick up and transfer to properly labeled containers.

7. Handling and storage

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. Provide extract ventilation to points where emissions occur. In case of insufficient ventilation, wear suitable respiratory equipment. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Take off contaminated clothing and wash before reuse.

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.

8. Exposure controls/personal protection

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.



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity

Revision date 05-Jul-2023

Appropriate engineering controls

Engineering controls Showers
Eyewash stations
Ventilation systems.

Individual protection measures, such as 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.

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.

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

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.

9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid
Appearance Solid
Color light yellow
Odor No information available
Odor threshold No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH	No data available	None known
Melting point / freezing point	No data available	None known
Initial boiling point and boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability	No data available	None known
Flammability Limit in Air		None known
Upper flammability or explosive limits	No data available	
Lower flammability or explosive limits	No data available	



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity

Revision date 05-Jul-2023

Vapor pressure	No data available	None known
Relative vapor density	No data available	None known
Relative density	No data available	None known
Water solubility	No data available	None known
Solubility(ies)	No data available	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature		None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known

Other information

Explosive properties	No information available
Oxidizing properties	No information available
Softening point	No information available
Molecular weight	361.37
VOC content	No information available
Liquid Density	No information available
Bulk density	No information available

10. Stability and reactivity

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	None known based on information supplied.
Hazardous decomposition products	None known based on information supplied.

11. Toxicological information

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available. May cause sensitization in susceptible persons. (based on components). May cause irritation of respiratory tract.
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.



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

**TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity**

Revision date 05-Jul-2023

Skin contact

Specific test data for the substance or mixture is not available. Repeated or prolonged skin contact may cause allergic reactions with susceptible persons. (based on components). May cause sensitization by skin contact. May cause irritation. Prolonged contact may cause redness and irritation.

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 diarrhea. 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.

Acute toxicity

Numerical measures of toxicity

No information available

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

Skin corrosion/irritation

May cause skin irritation.

Serious eye damage/eye irritation

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

Respiratory or skin sensitization

May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ cell mutagenicity

No information available.

Carcinogenicity

No information available.

Reproductive toxicity

Contains a known or suspected reproductive toxin. Classification based on data available for ingredients. Suspected of damaging fertility or the unborn child.



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

**TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity**

Revision date 05-Jul-2023

STOT - single exposure	Based on the classification criteria of the Globally Harmonized System as adopted in the country or region with which this safety data sheet complies, this product has been determined to cause systemic target organ toxicity from acute exposure. (STOT SE). May cause damage to organs if swallowed.
STOT - repeated exposure	No information available.
Aspiration hazard	No information available.
Other adverse effects	No information available.
Interactive effects	No information available.

12. Ecological information

Ecotoxicity	The environmental impact of this product has not been fully investigated.
Persistence and degradability	No information available.
Bioaccumulation	There is no data for this product.
Other adverse effects	No information available.

13. Disposal considerations

Disposal 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.

14. Transport information

<u>DOT</u>	Not regulated
-------------------	---------------



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

**TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity**

Revision date 05-Jul-2023

<u>TDG</u>	Not regulated
<u>MEX</u>	Not regulated
<u>IATA</u>	Not regulated
<u>IMDG</u>	Not regulated

15. Regulatory information

International Inventories

TSCA Complies under research and development exemption or is regulated by a different government agency.

Chemical name	CAS No	US TSCA Inventory listing	US TSCA inactive/active designation
(3S)-10-Fluoro-3-methyl-9-(4-methylpiperazin-1-yl)-7-oxo-2,3-dihydro-7H-pyrido[1,2,3-de][1,4]benzoxazine-6-carboxylic Acid	178912-62-4	-	Unknown *

*Contact supplier for details. One or more substances in this product are either not listed on the US TSCA inventory, listed on the confidential US TSCA inventory or are otherwise exempted from inventory listing requirements

DSL/NDSL	Contact supplier for inventory compliance status.
EINECS/ELINCS	Contact supplier for inventory compliance status.
ENCS	Contact supplier for inventory compliance status.
IECSC	Contact supplier for inventory compliance status.
KECL	Contact supplier for inventory compliance status.
PICCS	Contact supplier for inventory compliance status.
AIIC	Contact supplier for inventory compliance status.

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
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 and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances
AIIC - Australian Inventory of Chemical Substances



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity

Revision date 05-Jul-2023

US Federal Regulations

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Should this product meet EPCRA 311/312 Tier reporting criteria at 40 CFR 370, refer to Section 2 of this SDS for appropriate classifications.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. Other information

NFPA

Health hazards 2

Flammability 0

Instability 0

Special hazards -

HMIS

Health hazards 2 *

Flammability 0

Physical hazards 0

Personal protection X

Chronic Hazard Star Legend

* = Chronic Health Hazard

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

Legend Section 8: Exposure controls/personal protection



SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
OSHA HCS2012

**TRC-P480445-10MG - 9-Piperazino Levofloxacin
Impurity**

Revision date 05-Jul-2023

TWA
Ceiling

TWA (time-weighted average)
Maximum limit value

STEL
*

STEL (Short Term Exposure Limit)
Skin designation

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)
EPA (Environmental Protection Agency)
Acute Exposure Guideline Level(s) (AELG(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)
Japan GHS Classification
Australia 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)
National Toxicology Program (NTP)
New Zealand's Chemical Classification and Information Database (CCID)
Organization for Economic Co-operation and Development Environment, Health, and Safety Publications
Organization for Economic Co-operation and Development High Production Volume Chemicals Program
Organization for Economic Co-operation and Development Screening Information Data Set
World Health Organization

Revision date 05-Jul-2023

Revision Note No information available.

Disclaimer

The information in this Safety Data Sheet meets the requirements of the United States OCCUPATIONAL SAFETY AND HEALTH ACT and regulations promulgated thereunder (29 CFR 1910.1200 et. seq.) This document is intended only as a guide to the appropriate precautionary handling of the material by a person trained in, or supervised by a person trained in, chemical handling. The user is responsible for determining the application. Depending on usage, protective clothing including eye and face guards and respirators must be used to avoid contact with material or breathing chemical vapors/fumes. Exposure to this product may have serious adverse health effects. This chemical may interact with other substances. Since the potential uses are so varied, we cannot warn of all of the potential dangers of use or interaction with other chemicals or materials. We warrant that the chemical meets the specifications set forth on the label. We (LGC/VHG/ARMI) disclaim any other warranties, expressed or implied with regard to the product supplied hereunder, its merchantability or its fitness for a particular purpose. The user should recognize that this product can cause severe injury and even death, especially if improperly handled or the known dangers of use are not heeded. Read all precautionary information.

End of Safety Data Sheet