lemofloxacin

sc-279272

Material Safety Data Sheet

Hazard Alert Code Key:	EXTREME	HIGH	MODERATE	LOW

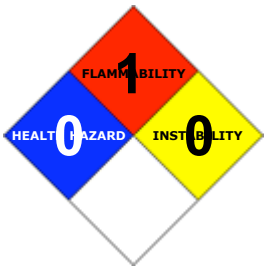
Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME
lemofloxacin

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



SUPPLIER
Santa Cruz Biotechnology, Inc.
2145 Delaware Avenue
Santa Cruz, California 95060
800.457.3801 or 831.457.3800

EMERGENCY
ChemWatch
Within the US & Canada: 877–715–9305
Outside the US & Canada: +800 2436 2255
(1–800-CHEMCALL) or call +613 9573 3112

SYNONYMS
C17H19F2N3O3, "1-ethyl-6, 8-difluoro-7-(3-methylpiperazin-1-yl)-4-oxo-quinoline-3-", "carboxylic acid hydrochloride", "3-quinolinecarboxylic acid, 1, 4-dihydro-6, 8-difluoro-1-ethyl-7-(3-", methyl)-1-piperazinyl-4-oxo-, "fluoroquinolone antibacterial", DM-10, NY-198, SC-47111, Bareon, Chimono, Lomebact, Maxaquin, Uniquin

Section 2 - HAZARDS IDENTIFICATION

CHEMWATCH HAZARD RATINGS

		Min	Max
Flammability:	1		
Toxicity:	2		
Body Contact:	2		
Reactivity:	1		
Chronic:	2		

Min/Nil=0
Low=1
Moderate=2
High=3
Extreme=4

CANADIAN WHMIS SYMBOLS

EMERGENCY OVERVIEW

RISK

Limited evidence of a carcinogenic effect.

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

■ Accidental ingestion of the material may be damaging to the health of the individual.
■ Fluoroquinolones have been associated with kidney damage, effects after exposure to UV light, seizures, changes in blood sugar levels (especially in diabetics), and crystal formation in the urine.
They can also cause disease in the joints.

EYE

■ Although the material is not thought to be an irritant, direct contact with the eye may cause transient discomfort characterized by tearing or conjunctival redness (as with windburn).
Slight abrasive damage may also result.

SKIN

■ Skin contact is not thought to have harmful health effects, however the material may still produce health damage following entry through wounds, lesions or abrasions.
■ There is some evidence to suggest that this material can cause inflammation of the skin on contact in some persons.
■ Open cuts, abraded or irritated skin should not be exposed to this material.
■ Entry into the blood-stream, through, for example, cuts, abrasions or lesions, may produce systemic injury with harmful effects.
Examine the skin prior to the use of the material and ensure that any external damage is suitably protected.

INHALED

■ The material is not thought to produce either adverse health effects or irritation of the respiratory tract following inhalation (as classified using animal models).
Nevertheless, adverse effects have been produced following exposure of animals by at least one other route and good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting.
■ Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

■ There has been concern that this material can cause cancer or mutations, but there is not enough data to make an assessment.
Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.
Long term exposure to high dust concentrations may cause changes in lung function i.e. pneumoconiosis; caused by particles less than 0.5 micron penetrating and remaining in the lung.
Exposure to small quantities may induce hypersensitivity reactions characterized by acute bronchospasm, hives (urticaria), deep dermal wheals (angioneurotic edema), running nose (rhinitis) and blurred vision . Anaphylactic shock and skin rash (non-thrombocytopenic purpura) may occur.
Exposure to this product can cause sensitization of skin under sunlight. The product can reach the skin via the bloodstream either if swallowed or ingested.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

NAME	CAS RN	%
lomefloxacin hydrochloride	98079-51-7	>98

Section 4 - FIRST AID MEASURES

SWALLOWED

· If swallowed do NOT induce vomiting. · If vomiting occurs, lean patient forward or place on left side (head-down position, if possible) to maintain open airway and prevent aspiration.

EYE

■ If this product comes in contact with the eyes: · Wash out immediately with fresh running water. · Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids.

SKIN

■ If skin contact occurs: · Immediately remove all contaminated clothing, including footwear · Flush skin and hair with running water (and soap if available).

INHALED

· If fumes or combustion products are inhaled remove from contaminated area. · Other measures are usually unnecessary.

NOTES TO PHYSICIAN

■ Treat symptomatically.

In the event of acute overdosage, the stomach should be emptied by inducing vomiting or by gastric lavage, and the patient should be carefully observed and given supportive treatment. Adequate hydration must be maintained. Hemodialysis or peritoneal dialysis is unlikely to aid in the removal of lomefloxacin as < 3% is removed by these modalities.

Clinical signs of acute toxicity in rodents progressed from salivation to tremors, decreased activity, dyspnea, and clonic convulsions prior to death. These signs were noted in rats and mice as lomefloxacin doses were increased.

Section 5 - FIRE FIGHTING MEASURES

Vapour Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not Available
Specific Gravity (water=1):	Not Available
Lower Explosive Limit (%):	Not Available

EXTINGUISHING MEDIA

· Foam.

· Dry chemical powder.

FIRE FIGHTING

· Alert Emergency Responders and tell them location and nature of hazard.

· Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

· Combustible solid which burns but propagates flame with difficulty.

· Avoid generating dust, particularly clouds of dust in a confined or unventilated space as dusts may form an explosive mixture with air, and any source of ignition, i.e. flame or spark, will cause fire or explosion. Dust clouds generated by the fine grinding of the solid are a particular hazard; accumulations of fine dust may burn rapidly and fiercely if ignited.

Combustion products include: carbon monoxide (CO), carbon dioxide (CO_2), hydrogen chloride, phosgene, hydrogen fluoride, nitrogen oxides (NOx), other pyrolysis products typical of burning organic material.

May emit poisonous fumes.

May emit corrosive fumes.

FIRE INCOMPATIBILITY

■ Avoid contamination with oxidizing agents i.e. nitrates, oxidizing acids,chlorine bleaches, pool chlorine etc. as ignition may result.

PERSONAL PROTECTION

Glasses:

Chemical goggles.

Gloves:

Respirator:

Particulate

Section 6 - ACCIDENTAL RELEASE MEASURES

MINOR SPILLS

· Clean up waste regularly and abnormal spills immediately.

· Avoid breathing dust and contact with skin and eyes.

· Wear protective clothing, gloves, safety glasses and dust respirator.

· Use dry clean up procedures and avoid generating dust.

· Vacuum up or sweep up. NOTE: Vacuum cleaner must be fitted with an exhaust micro filter (HEPA type) (consider explosion-proof machines designed to be grounded during storage and use).

· Dampen with water to prevent dusting before sweeping.

· Place in suitable containers for disposal.

MAJOR SPILLS

■ Moderate hazard.

· CAUTION: Advise personnel in area.

· Alert Emergency Responders and tell them location and nature of hazard.

Section 7 - HANDLING AND STORAGE

PROCEDURE FOR HANDLING

· Avoid all personal contact, including inhalation.

· Wear protective clothing when risk of exposure occurs.

Empty containers may contain residual dust which has the potential to accumulate following settling. Such dusts may explode in the presence of an appropriate ignition source.

· Do NOT cut, drill, grind or weld such containers.

· In addition ensure such activity is not performed near full, partially empty or empty containers without appropriate workplace safety authorisation or permit.

RECOMMENDED STORAGE METHODS

■ Glass container.

· Polyethylene or polypropylene container.
· Check all containers are clearly labelled and free from leaks.

STORAGE REQUIREMENTS

· Store in original containers.
· Keep containers securely sealed.

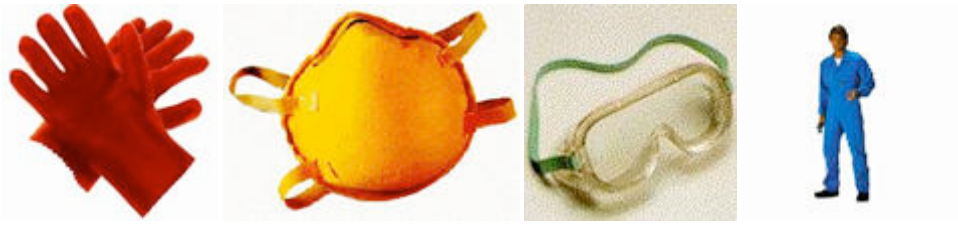
Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

EXPOSURE CONTROLS

The following materials had no OELs on our records

• lomefloxacin hydrochloride: CAS:98079-51-7

PERSONAL PROTECTION



RESPIRATOR

Particulate
Consult your EHS staff for recommendations

EYE

■ When handling very small quantities of the material eye protection may not be required.
For laboratory, larger scale or bulk handling or where regular exposure in an occupational setting occurs:
· Chemical goggles
· Face shield. Full face shield may be required for supplementary but never for primary protection of eyes
· Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lens or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59].

HANDS/FEET

■ Suitability and durability of glove type is dependent on usage. Important factors in the selection of gloves include: such as:
· frequency and duration of contact,
· chemical resistance of glove material,
· glove thickness and
· dexterity
Select gloves tested to a relevant standard (e.g. Europe EN 374, US F739).
· When prolonged or frequently repeated contact may occur, a glove with a protection class of 5 or higher (breakthrough time greater than 240 minutes according to EN 374) is recommended.
· When only brief contact is expected, a glove with a protection class of 3 or higher (breakthrough time greater than 60 minutes according to EN 374) is recommended.
· Contaminated gloves should be replaced.
Gloves must only be worn on clean hands. After using gloves, hands should be washed and dried thoroughly. Application of a non-perfumed moisturiser is recommended.
· Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.
· Double gloving should be considered.
· PVC gloves.
· Protective shoe covers.
· Head covering.
Experience indicates that the following polymers are suitable as glove materials for protection against undissolved, dry solids, where abrasive particles are not present.
· polychloroprene
· nitrile rubber
· butyl rubber
· fluorocaoutchouc
· polyvinyl chloride
Gloves should be examined for wear and/ or degradation constantly.

OTHER

· For quantities up to 500 grams a laboratory coat may be suitable.
· For quantities up to 1 kilogram a disposable laboratory coat or coverall of low permeability is recommended. Coveralls should be buttoned at collar and cuffs.
· For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.
· For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection.
· Eye wash unit.
· Ensure there is ready access to an emergency shower.

· For Emergencies: Vinyl suit.

ENGINEERING CONTROLS

■ Enclosed local exhaust ventilation is required at points of dust, fume or vapor generation.
HEPA terminated local exhaust ventilation should be considered at point of generation of dust, fumes or vapors.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL PROPERTIES

State	Divided Solid	Molecular Weight	351.351
Melting Range (°F)	554- 572 (decomp)	Viscosity	Not Applicable
Boiling Range (°F)	Not Applicable	Solubility in water (g/L)	Partly Miscible
Flash Point (°F)	Not Available	pH (1% solution)	Not Available
Decomposition Temp (°F)	554	pH (as supplied)	Not Applicable
Autoignition Temp (°F)	Not Available	Vapour Pressure (mmHG)	Negligible
Upper Explosive Limit (%)	Not Available	Specific Gravity (water=1)	Not Available
Lower Explosive Limit (%)	Not Available	Relative Vapor Density (air=1)	Not Applicable
Volatile Component (%vol)	Negligible	Evaporation Rate	Not Applicable

APPEARANCE

White to pale yellow crystalline solid; does not mix well with water. Lomefloxacin HCl is stable to heat and moisture but is sensitive to light in dilute aqueous solution

Section 10 - CHEMICAL STABILITY

CONDITIONS CONTRIBUTING TO INSTABILITY

· Presence of incompatible materials.
· Product is considered stable.

STORAGE INCOMPATIBILITY

■ Avoid reaction with oxidizing agents.

For incompatible materials - refer to Section 7 - Handling and Storage.

Section 11 - TOXICOLOGICAL INFORMATION

lomefloxacin hydrochloride

TOXICITY AND IRRITATION

LOMEFLOXACIN HYDROCHLORIDE:
■ unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Oral (Rat) LD50: 3800 mg/kg	Eye (rabbit): 100 mg - Mild
Oral (Mouse) LD50: >4000 mg/kg	
Intraperitoneal (Mouse) LD50: 698 mg/kg	
Intravenous (Mouse) LD50: 246 mg/kg	

The events with the highest incidence (~1%) in patients, regardless of relationship to drug, were headache (3.6%), nausea (3.5%), photosensitivity (2.3%), dizziness (2.1%), diarrhea
(1.4%), and abdominal pain (1.2%).. Convulsions have been reported in patients receiving lomefloxacin. Whether the convulsions were directly related to lomefloxacin administration has not yet been established. However, convulsions, increased intracranial pressure, and toxic psychoses have been reported in patients receiving other quinolones. Nevertheless, lomefloxacin has been associated with a possible increased risk of seizures compared to other quinolones. Some of these may occur with a relative absence of predisposing factors. Quinolones may also cause central nervous system (CNS) stimulation, which may lead to tremors, restlessness, lightheadedness, confusion, and hallucinations. If any of these reactions occurs in patients receiving lomefloxacin, the drug should be discontinued and appropriate measures instituted.
Psychiatric disturbances, agitation, anxiety, and sleep disorders may be more common with lomefloxacin than other products in the quinolone class.
Serious and occasionally fatal hypersensitivity (anaphylactoid or anaphylactic) reactions, some following the first dose, have been reported in patients receiving quinolone therapy. Some reactions were accompanied by cardiovascular collapse, loss of consciousness, tingling, pharyngeal or facial edema, dyspnea, urticaria, or itching. Only a few of these patients had a history of previous hypersensitivity reactions. Serious hypersensitivity reactions have also been reported following treatment with lomefloxacin
Moderate to severe phototoxic reactions have occurred in patients exposed to direct or indirect sunligfht or to artificial ultraviolet light during or following treatment with lomefloxacin.
These phototoxic reactions have occurred with and without the use of sunscreens or sunblocks. Single doses of lomefloxacin have been associated with these types of reactions. In a few cases, recovery was prolonged for several weeks. As with some other types of

phototoxicity, there is the potential for exacerbation of the reaction on re-exposure to sunlight or artificial ultraviolet light prior to complete recovery from the reaction. In rare cases, reactions have recurred up to several weeks after stopping lomefloxacin therapy.
The oral administration of multiple doses of lomefloxacin to juvenile dogs at 0.3 times and to rats at 5.4 times the recommended adult human dose based on mg/m2 (0.6 and 34 times the recommended adult human dose based on mg/kg, respectively) caused arthropathy and lameness. Histopathologic examination of the weight-bearing joints of these animals revealed permanent lesions of the cartilage. Other quinolones also produce erosions of cartilage of weight-bearing joints and other signs of arthropathy in juvenile animals of various species.

Carcinogenesis, mutagenesis, impairment of fertility:

Carcinogenesis: Hairless (Skh-1) mice were exposed to UVA light for 3.5 hours five times every two weeks for up to 52 weeks while concurrently being administered lomefloxacin. The lomefloxacin doses used in this study caused a phototoxic response. In mice treated with both UVA and lomefloxacin concomitantly, the time to development of skin tumors was 16 weeks. In mice treated concomitantly in this model with both UVA and other quinolones, the times to development of skin tumors ranged from 28 to 52 weeks.
Ninety-two percent (92%) of the mice treated concomitantly with both UVA and lomefloxacin developed well-differentiated squamous cell carcinomas of the skin. These squamous cell carcinomas were nonmetastatic and were endophytic in character. Two-thirds of these squamous cell carcinomas contained large central keratinous inclusion masses and were thought to arise from the vestigial hair follicles in these hairless animals.
In this model, mice treated with lomefloxacin alone did not develop skin or systemic tumors.
The clinical significance of these findings to humans is unknown.
Mutagenesis: One in vitro mutagenicity test (CHO/HGPRT assay) was weakly positive at lomefloxacin concentrations 226 ug/mL and negative at concentrations < 226 ug/mL. Two other in vitro mutagenicity tests (chromosomal aberrations in Chinese hamster ovary cells, chromosomal aberrations in human lymphocytes) and two in vivo mouse micronucleus mutagenicity tests were all negative.
Impairment of fertility: Lomefloxacin did not affect the fertility of male and female rats at oral doses up to 8 times the recommended human dose based on mg/m2 (34 times the recommended human dose based on mg/kg).
Teratogenic effects: Reproductive function studies have been performed in rats at doses up to 8 times the recommended human dose based on mg/m2 (34 times the recommended human dose based on mg/kg), and no impaired fertility or harm to the foetus was reported due to lomefloxacin. Increased incidence of foetal loss in monkeys has been observed at approximately 3 to 6 times the recommended human dose based on mg/m2 (6 to 12 times the recommended human dose based on mg/kg). No teratogenicity has been observed in rats and monkeys at up to 16 times the recommended human dose exposure. In the rabbit, maternal toxicity and associated foetotoxicity, decreased placental weight, and variations of the coccygeal vertebrae occurred at doses 2 times the recommended human exposure based on mg/m2. There are, however, no adequate and well-controlled studies in pregnant women.

Section 12 - ECOLOGICAL INFORMATION

No data

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations.
¦ Puncture containers to prevent re-use and bury at an authorized landfill.
Legislation addressing waste disposal requirements may differ by country, state and/ or territory. Each user must refer to laws operating in their area. In some areas, certain wastes must be tracked.
A Hierarchy of Controls seems to be common - the user should investigate:
· Reduction
· Reuse
· Recycling
· Disposal (if all else fails)
This material may be recycled if unused, or if it has not been contaminated so as to make it unsuitable for its intended use. Shelf life considerations should also be applied in making decisions of this type. Note that properties of a material may change in use, and recycling or reuse may not always be appropriate.
DO NOT allow wash water from cleaning equipment to enter drains. Collect all wash water for treatment before disposal.
· Recycle wherever possible.
· Consult manufacturer for recycling options or consult Waste Management Authority for disposal if no suitable treatment or disposal facility can be identified.

Section 14 - TRANSPORTATION INFORMATION

NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS: DOT, IATA, IMDG

Section 15 - REGULATORY INFORMATION

No data for lomefloxacin hydrochloride (CAS: , 98079-51-7)

Section 16 - OTHER INFORMATION

Reasonable care has been taken in the preparation of this information, but the author makes no warranty of merchantability or any other warranty, expressed or implied, with respect to this information. The author makes no

representations and assumes no liability for any direct, incidental or consequential damages resulting from its use. For additional technical information please call our toxicology department on +800 CHEMCALL.

■ Classification of the preparation and its individual components has drawn on official and authoritative sources as well as independent review by the Chemwatch Classification committee using available literature references.
A list of reference resources used to assist the committee may be found at:
www.chemwatch.net/references.

■ The (M)SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

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