Levofloxacin Hemihydrate



Section 1 - CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME

Levofloxacin Hemihydrate

STATEMENT OF HAZARDOUS NATURE

CONSIDERED A HAZARDOUS SUBSTANCE ACCORDING TO OSHA 29 CFR 1910.1200.

NFPA



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SYNONYMS:

C18-H20-F-N3-O4.1/2H2O, "7H-pyrido[1, 2, 3-de]-1, 4-benzoxazine-6-carboxylic acid, ", "2, 3-dihydro-9-fluoro-3-methyl-10-(4-methyl-1-piperazinyl)-7-oxo-, ", "hemihydrate, (S)-", "levofloxacin hemihydrate [CAS RN: 138199-71-0]", DR3355, (-)-ofloxacin, (S)-ofloxacin, Levaquin, RWJ-25213,

"fluoroquinolone/ fluoroquinoline fluorinated quinolone/ quinoline", "antibiotic/ antibiotici"

Section 2 - HAZARDS IDENTIFICATION

HAZARD RATINGS



CANADIAN WHMIS SYMBOLS



EMERGENCY OVERVIEW RISK 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

! If applied to the eyes, this material causes severe eye damage.

! Phototoxic agents such as sulfonamides can cause inflammation of the conjunctiva and cornea, and clouding.

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 bloodstream, though, 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.

! 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.

INHALED

! The material is not thought to produce respiratory irritation (as classified using animal models).

Nevertheless, inhalation of dusts, or fume, especially for prolonged periods, may produce respiratory discomfort and occasionally, distress.

! Inhalation of dusts, generated by the material during the course of normal handling, may be damaging to the health of the individual. ! 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.

! Clinical signs of quinoline intoxication include lethargy, respiratory distress and prostration leading to coma.

CHRONIC HEALTH EFFECTS

! Limited evidence suggests that repeated or long-term occupational exposure may produce cumulative health effects involving organs or biochemical systems.

Prolonged or repeated use of antibiotics, at therapeutic doses, may produce bacterial resistance for some types of bacteria. Prolonged use may result in the overgrowth of non-susceptible organisms (i.e.

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.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS				
NAME	CAS R	N %		
levofloxacin	138199)-71-0 >98		

Section 4 - FIRST AID MEASURES

SWALLOWED

 \cdot If swallowed do NOT induce vomiting. \cdot 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 meets the eyes: \cdot Immediately hold eyelids apart and flush the eye continuously with running water. \cdot

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: \cdot Immediately remove all contaminated clothing, including footwear \cdot Flush skin and hair with running water (and soap if available).

INHALED

 \cdot If fumes or combustion products are inhaled remove from contaminated area. \cdot Lay patient down. Keep warm and rested.

NOTES TO PHYSICIAN

! Treat symptomatically.

Section 5 - FIRE FIGHTING MEASURES

Vapor Pressure (mmHG):	Negligible
Upper Explosive Limit (%):	Not available.
Specific Gravity (water=1):	Not available
Lower Explosive Limit (%): EXTINGUISHING M I	Not available EDIA

 \cdot Foam.

· Dry chemical powder.

FIRE FIGHTING

- \cdot Alert Emergency Responders and tell them location and nature of hazard.
- \cdot Wear breathing apparatus plus protective gloves.

GENERAL FIRE HAZARDS/HAZARDOUS COMBUSTIBLE PRODUCTS

 \cdot 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 (CO2), 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

- \cdot Clean up waste regularly and abnormal spills immediately.
- \cdot Avoid breathing dust and contact with skin and eyes.
- \cdot Wear protective clothing, gloves, safety glasses and dust respirator.
- \cdot Use dry clean up procedures and avoid generating dust.

 \cdot 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).

 \cdot Dampen with water to prevent dusting before sweeping.

• Place in suitable containers for disposal.

MAJOR SPILLS

! Moderate hazard.

· CAUTION: Advise personnel in area.

 \cdot 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.

 \cdot 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. \cdot Do NOT cut, drill, grind or weld such containers.

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

RECOMMENDED STORAGE METHODS

! Glass container.

· Polyethylene or polypropylene container.

 \cdot 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

• levofloxacin: CAS:100986-85-4 CAS:138199-71-0

PERSONAL PROTECTION



RESPIRATOR

• particulate.

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

 \cdot 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: \cdot 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.

 \cdot 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. \cdot 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 moisturizer is recommended.

 \cdot Rubber gloves (nitrile or low-protein, powder-free latex). Employees allergic to latex gloves should use nitrile gloves in preference.

 \cdot 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

 \cdot Polyvinyl

chloride

Gloves should be examined for wear and/ or degradation constantly.

OTHER

 \cdot For quantities up to 500 grams a laboratory coat may be suitable.

 \cdot 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.

 \cdot For quantities over 1 kilogram and manufacturing operations, wear disposable coverall of low permeability and disposable shoe covers.

 \cdot For manufacturing operations, air-supplied full body suits may be required for the provision of advanced respiratory protection. \cdot Eye wash unit.

 \cdot 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

Solid.

Does not mix with water.

State	Divided solid	Molecular Weight	370.38
Melting Range (°F)	Not available	Viscosity	Not Applicable
Boiling Range (°F)	Not available	Solubility in water (g/L)	Partly miscible
Flash Point (°F)	Not available	pH (1% solution)	Not applicable
Decomposition Temp (°F)	Not available.	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)	>1
Volatile Component (%vol)	Negligible	Evaporation Rate	Not applicable

APPEARANCE

Solid; does not mix well with water.

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

levofloxacin

TOXICITY AND IRRITATION

LEVOFLOXACIN:

! unless otherwise specified data extracted from RTECS - Register of Toxic Effects of Chemical Substances.

TOXICITY	IRRITATION
Intravenous (mouse) LD50: 1.65 mg/kg	Nil Reported
Respiratory depression and other respiratory changes record	led.

Section 12 - ECOLOGICAL INFORMATION

No data

Ecotoxicity

Ingredient	Persistence:	Persistence: Air	Bioaccumulation	Mobility
	Water/Soil			

Levofloxacin No Data Available No Data Available

Section 13 - DISPOSAL CONSIDERATIONS

Disposal Instructions

All waste must be handled in accordance with local, state and federal regulations. ! 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 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.

 \cdot 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 levofloxacin (CAS: , 100986-85-4, 138199-71-0)

Section 16 - OTHER INFORMATION

Ingredients with multiple CAS Nos

Ingredient Name CAS levofloxacin 100986-85-4, 138199-71-0

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