

Safety Data Sheet

SAFETY DATA SHEET - LC LABORATORIES REVISION DATE: JULY 1, 2019

SECTION 1. IDENTIFICATION:

Trade name: Gemcitabine, Hydrochloride Salt

Product Number: [G-4177](#)

Manufacturer/Supplier:

LC Laboratories

165 New Boston Street

Woburn, MA 01801 USA

1-781-937-0777 Fax: 1-781-938-5420

SECTION 2. HAZARD(S) IDENTIFICATION:

Hazard Description: pharmaceutically active substance

Substance Class Identifier: Tumorigen; Drug; Human Data; Reproductive Effector

May be harmful if inhaled, swallowed, or absorbed through the skin

Irritating to eyes and skin

Exposure may cause heritable genetic damage

Exposure may result in possible risk of impaired fertility and possible risk of harm to the unborn child

Ingestion may result in nausea, vomiting, edema, rash, elevated liver enzymes, and flu-like syndrome and may have adverse blood effects including decreased red blood cell counts, decreased white blood cell counts, and decreased platelet counts

Signal Word: Danger


GHS Hazard Statements:

H302+312+332 - Harmful if swallowed, in contact with skin or if inhaled

GHS Precautionary Statements:

P2562 - Do not get in eyes, on skin or on clothing

WARNING: For Laboratory Research Use Only



SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS:

Chemical Name: 4-Amino-1-[3,3-difluoro-4-hydroxy-5-(hydroxymethyl)oxolan-2-yl]pyrimidin-2-one Hydrochloride

Synonyms: 2'-Deoxy-2',2'-difluorocytidine Hydrochloride, dFdC, Gemcitabine, Gemcitera, Gemsar, Gemzar, LY-188011

Hazardous Ingredient: Gemcitabine, Hydrochloride Salt

CAS Registry Number: 122111-03-9

Molecular Weight: 299.66

Molecular Formula: $C_9H_{11}F_2N_3O_4 \cdot HCl$

SECTION 4. FIRST-AID MEASURES:

After Inhalation: If inhaled, remove to fresh air; if breathing is difficult, give oxygen; if breathing stops, give artificial respiration

After skin contact: flush with copious amounts of water; remove contaminated clothing and shoes; call a physician

After eye contact: check for and remove contact lenses; flush with copious amounts of water; assure adequate flushing by separating the eyelids with fingers; call a physician

After swallowing: if swallowed, wash out mouth with copious amounts of water; call a physician

SECTION 5. FIRE-FIGHTING MEASURES:

Suitable extinguishing agents: water spray, carbon dioxide, dry chemical powder or foam

Protective equipment: wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes

Unusual fire hazard: may emit toxic fumes under fire conditions such as carbon monoxide, etc.

SECTION 6. ACCIDENTAL RELEASE MEASURES:

Person-related safety precautions: cordon off area of spill; wear self-contained breathing apparatus, protective clothing and heavy rubber gloves

Measures for cleaning/collecting: absorb solutions with finely- powdered liquid-binding material (diatomite, universal binders); decontaminate surfaces and equipment by scrubbing with alcohol; dispose of contaminated material according to Section 13

SECTION 7. HANDLING AND STORAGE:

Information for safe handling: avoid contact with skin, eyes and clothing; material may be an irritant

Storage: store solid and solutions at $-20\text{ }^{\circ}\text{C}$

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION:

Personal protective equipment as follows:

Breathing equipment: NIOSH/MSHA-approved respirator

Protection of hands: handle with Nitrile rubber gloves with minimum thickness of 0.11 mm (4.3 mil). This recommendation should not be interpreted as offering an approval for any specific use conditions. Please review this recommendation with a safety officer to evaluate if it is appropriate for the anticipated use.

Eye protection: chemical safety goggles

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES:

Form: crystalline solid; granular or powder

Color: white

Odor: none

Melting point/Melting range: not determined

Danger of explosion: none

Solubility in / Miscibility with water: soluble in water at 25 mg/mL with slight warming; buffers, serum, or other additives may increase or decrease the aqueous solubility

Solvent content:

Organic solvents: soluble in DMSO at 12.5 mg/mL with slight warming; very poorly soluble in ethanol

SECTION 10. STABILITY AND REACTIVITY:

Stability: avoid acids and bases

Thermal decomposition / conditions to be avoided: protect from light and heat

Dangerous products of decomposition: thermal decomposition may produce toxic gases such as carbon monoxide and carbon dioxide, and nitrogen oxides

SECTION 11. TOXICOLOGICAL INFORMATION:

RTECS #: HA3840000

Acute toxicity: intravenous toxicity (LD50): 500 mg/kg (mouse), 236 mg/kg (rats)

Primary irritant effect:

On the skin: causes irritation; may be harmful if absorbed through the skin

On the eye: causes irritation

Inhalation: may be harmful if inhaled

Ingestion: harmful if swallowed

SECTION 12. ECOLOGICAL INFORMATION:

General notes: Releases to the environment should be avoided

Aquatic Toxicity: (Species, Method, End Point, Duration, Result) - toxicity data from the Pfizer MSDS dated June 20, 2011 for Gemcitabine Hydrochloride

Oncorhynchus mykiss (Rainbow Trout) LC50 96 Hours > 1043 mg/L

Pimephales promelas (Fathead Minnow) LC50 96 Hours > 1014 mg/L

Daphnia Magna (Water Flea) EC50 48 Hours > 999 mg/L

Selenastrum capricornutum (Green Alga) EC50 5.4 mg/L

Bacterial Inhibition: (Inoculum, Method, End Point, Result)

Nostoc sp. (Freshwater Cyanobacteria) MIC 800 mg/L

Aspergillus niger (Fungus) MIC

SECTION 13. DISPOSAL CONSIDERATIONS:

Dispose of in accordance with prevailing country, federal, state and local regulations

SECTION 14. TRANSPORT INFORMATION:

UN number: 2811

DOT: Toxic solid, organic, n.o.s. (Gemcitabine Hydrochloride), 6.1, III

IATA: Toxic solid, organic, n.o.s. (Gemcitabine Hydrochloride), 6.1, III

IMO: Toxic solid, organic, n.o.s. (Gemcitabine Hydrochloride), 6.1, III

SECTION 15. REGULATORY INFORMATION:

Code letter and hazard designation of product:

Xn: Harmful

Xi: Irritant

EU Risk And Safety phrases:

S24/25: Avoid contact with skin and eyes

S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice

S36/37/39: Wear suitable protective clothing, gloves and eye/face protection

S45: In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)

S53: Avoid exposure - obtain special instructions before use

R36/38: Irritating to eyes and skin

R46: May cause heritable genetic damage

R62: Possible risk of impaired fertility

R63: Possible risk of harm to the unborn child

SECTION 16. OTHER INFORMATION:

The above information is believed to be correct based on our present knowledge but does not purport to be complete. For research use only by trained personnel. The burden of safe use of this material rests entirely with the user. LC Laboratories disclaims all liability

Reviewed: July 1, 2019