

# Safety Data Sheet

**Safety Data Sheet - LC Laboratories**  
**Revision Date: July 1, 2019**

## **SECTION 1. IDENTIFICATION:**

Trade name: Sunitinib, Free Base  
Product Number: [S-8877](#)  
Manufacturer/Supplier:  
LC Laboratories  
165 New Boston Street  
Woburn, MA 01801 USA  
1-781-937-0777 Fax: 1-781-938-5420

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## **SECTION 2. HAZARD(S) IDENTIFICATION:**

Hazard Description: Toxic  
Substance Class Identifier: Tumorigen; Drug; Human Data  
May be harmful if swallowed, inhaled, or absorbed through the skin  
Ingestion may result in fatigue, diarrhea, nausea, vomiting, dyspepsia (indigestion), dysgeusia (distortion of the sense of taste), anorexia (decreased appetite), headache, stomatitis (inflammation/ulceration of the mucous membranes lining of the mouth), xeroderma (dry skin), erythema (skin redness), rash, hair color changes, palmar-plantar erythrodysesthesia syndrome (also known as hand-foot syndrome manifested as redness, tenderness, peeling, blistering and ulceration of the palms and soles) and hypertension (elevated blood pressure), neutropenia/lymphopenia (reduction of different types of white blood cells), thrombocytopenia (low platelet count), anemia, hepatotoxicity (liver damage), renal impairment (kidney damage), and electrolyte disturbances  
May cause harm to the unborn child  
Very toxic to aquatic life  
Exposure may cause irritation of the respiratory tract, eye, and skin and allergic respiratory and skin reaction  
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



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## **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS:**

Chemical Name: *N*-[2-(Diethylamino)ethyl]-5-[(*Z*)-(5-fluoro-1,2-dihydro-2-oxo-3*H*-indol-3-ylidene)methyl]-2,4-dimethyl-1*H*-pyrrole-3-carboxamide

Synonyms: PHA-290940AD, PNU-290940AD, SU-11248, SU 011248, Sutent

Hazardous Ingredient: Sunitinib, Free Base

CAS Registry Number: 557795-19-4

Molecular Weight: 398.47

Molecular Formula: C<sub>22</sub>H<sub>27</sub>FN<sub>4</sub>O<sub>2</sub>

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#### **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

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#### **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.

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#### **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

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#### **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 °C

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#### **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

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## **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES:**

Form: crystalline solid; granular or powder

Color: bright yellow

Odor: none

Melting point/Melting range: 230-240/23 °C

Danger of explosion: none

Solubility in / Miscibility with water: very poorly soluble in water; maximum solubility in plain water is estimated to be about 10-20 µM; buffers, serum, or other additives may increase or decrease the aqueous solubility

Solvent content: none

Organic solvents: soluble in DMSO at 40 mg/mL; soluble in ethanol at 1.4 mg/mL with warming

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## **SECTION 10. STABILITY AND REACTIVITY:**

Stability: stable if stored as directed; avoid strong oxidizing agents

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, carbon dioxide, and nitrogen oxides

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## **SECTION 11. TOXICOLOGICAL INFORMATION:**

RTECS #: UX9355900

Acute toxicity: oral toxicity (TDLo): 40 mg/kg (mouse); *in vitro* toxicity (ICLo): 1-23 µmol/L

Primary irritant effect:

On the skin: may be an irritant; may be harmful if absorbed through the skin

On the eye: may be an irritant

Inhalation: may be harmful if inhaled; may be irritating to mucous membranes and upper respiratory tract

Ingestion: harmful if swallowed

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## **SECTION 12. ECOLOGICAL INFORMATION:**

General notes: Very toxic to aquatic life with long lasting effects

Releases to the environment should be avoided

Aquatic Toxicity: (Species, Method, End Point, Duration, Result) - toxicity data from the Pfizer MSDS dated March 27, 2014 for Sunitinib Malate Capsules

*Daphnia magna* (Water Flea) OECD EC50 48 Hours 3.1 mg/L

*Oncorhynchus mykiss* (Rainbow Trout) OECD LC50 96 Hours 7.8 mg/L

*Pseudokirchneriella subcapitata* (Green Alga) OECD EC50 72 Hours 0.32 mg/L

*Daphnia magna* (Water Flea) OECD NOEC 21 Days 0.053 mg/L  
*Ceriodaphnia dubia* (Daphnids) EPA NOEC 7 Days 0.32 mg/L  
*Pimephales promelas* (Fathead Minnow) OECD NOEC 32 Days 0.00027 mg/L  
Bacterial Inhibition: (Inoculum, Method, End Point, Result)  
Activated sludge OECD EC50 574 mg/L  
*Clostridium perfringens* FDA MIC 80 mg/L  
*Bacillus subtilis* (Bacterium) FDA MIC 80 mg/L  
*Nostoc sp.* (Freshwater Cyanobacteria) FDA MIC 5.0 mg/L  
Persistence and Degradability: No data available  
OECD Soil (various) Ready 8.8% After 28 Day(s)

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### **SECTION 13. DISPOSAL CONSIDERATIONS:**

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

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### **SECTION 14. TRANSPORT INFORMATION:**

UN number: 3077

DOT: Environmentally hazardous substance, solid, n.o.s. (Sunitinib), Class: 9,  
Packing group: III

IMDG: Environmentally hazardous substance, solid, n.o.s. (Sunitinib), Class: 9,  
Packing group: III

IATA: Environmentally hazardous substance, solid, n.o.s. (Sunitinib), Class: 9,  
Packing group: IIII

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### **SECTION 15. REGULATORY INFORMATION:**

Code letter and hazard designation of product:

T: Toxic; N: Dangerous to the environment

EU Risk And Safety phrases:

S22: Do not breathe dust

S36/37: Wear suitable protective clothing and gloves

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

R48/25: Toxic - danger of serious damage to health by prolonged exposure if  
swallowed

R50/53: Very toxic to aquatic organisms, may cause long-term adverse effects  
in the aquatic environment

R61: May cause harm to the unborn child

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### **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