Safety Data Sheet

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

SECTION 1. IDENTIFICATION:

Trade name: Sunitinib, Malate Salt
Product Number: S-8803
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: Toxic
Substance Class Identifier: Drug; Human Data; Reproductive Effector
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

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 (2*S*)-2-hydroxy-butanedioic acid
Synonyms: PHA-290940AD, PNU-290940AD, SU-11248, SU 011248, Sutent
Hazardous Ingredient: Sunitinib, Malate Salt
CAS Registry Number: 341031-54-7
Molecular Weight: 532.56
Molecular Formula: $C_{22}H_{27}FN_4O_2 \bullet C_4H_6O_5$

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.

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 ºC

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: yellow-orange
Odor: none
Melting point/Melting range: 192-202 ºC
Danger of explosion: none
Solubility in / Miscibility with water: very poorly soluble in water; maximum solubility in plain water is estimated to be about 10-50 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; very poorly soluble in ethanol

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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 and carbon dioxide, and nitrogen oxides

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SECTION 11. TOXICOLOGICAL INFORMATION:
RTECS #: UX9356900
Acute toxicity: oral toxicity (TDLo): 140 - 5000 mg/kg (Mouse), 19.9-179 mg/kg (human)
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

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 perfingens 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)

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

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

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