Safety Data Sheet

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

SECTION 1. IDENTIFICATION:

Trade name: Regorafenib, Free Base
Product Number: R-8024
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: Harmful; pharmaceutically active substance
Harmful if swallowed
May be harmful if inhaled or absorbed through the skin
Ingestion may result in elevated liver enzymes (ALT/AST)/hepatotoxicity, hyperbilirubinemia (increased levels of bilirubin in the blood), palmar-plantar erythrodysesthesia syndrome (also known as hand-foot syndrome manifested as redness, tenderness, peeling, blistering, and ulceration of the palms and soles), rash, alopecia (hair loss), asthenia (lack of muscle strength), fatigue, anorexia (decreased appetite), weight loss, diarrhea, mucositis (inflammation and ulceration of the mucous membranes lining the digestive tract), infection, hypertension (elevated blood pressure), dysphonia (impairment of theability to produce voice sounds using the vocal organs), anemia, lymphopenia/neutropenia (reduced levels of different types of white blood cells), thrombocytopenia (reduced blood platelets), increased INR (slower coagulation), hemorrhage, elevated levels of serum lipase/amylase, hypothyroidism, dysgeusia (distortion of the sense of taste), xerostomia (dry mouth), gastroesophageal reflux, gastrointestinal perforation, hypocalcemia (low serum calcium levels), hypophosphatemia (reduced serum phosphate level), hyponatremia (reduced serum sodium level), hypokalemia (reduced serum potassium level), musculoskeletal stiffness, pain, headache, tremor, proteinuria (excess serum proteins in the urine)
Exposure may cause irritation of the skin, eyes, mucous membranes, and upper respiratory tract
Signal Word: Warning

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-[4-[[[[4-Chloro-3-(trifluoromethyl)phenyl]amino]carbonyl]amino]-3-fluorophenoxy]-*N*-methyl-2-pyridinecarboxamide
Synonyms: BAY 73-4506, Fluoro-Sorafenib, Stivarga
Hazardous Ingredient: Regorafenib, Free Base
CAS Registry Number: 755037-03-7
Molecular Weight: 482.82
Molecular Formula: $C_{21}H_{15}ClF_4N_4O_3$

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 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:
Odor:
Melting point/Melting range: not tested
Danger of explosion: none
Solubility in / Miscibility with water: not determined
Solvent content:
Organic solvents: soluble in DMSO

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

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SECTION 11. TOXICOLOGICAL INFORMATION:
RTECS #: not available
Acute toxicity: not known
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 cause respiratory tract irritation; may be harmful if inhaled
Ingestion: harmful if swallowed

SECTION 12. ECOLOGICAL INFORMATION:
General notes: no data available
Treat as potentially toxic if released into the environment

SECTION 13. DISPOSAL CONSIDERATIONS:
Dispose of in accordance with prevailing country, federal, state and local regulations

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SECTION 14. TRANSPORT INFORMATION:
DOT:
Proper shipping name: none
Non-Hazardous for transport: this substance is considered to be non-hazardous for transport
IATA class:
Proper shipping name: none
Non-Hazardous for transport: this substance is considered to be non-hazardous for transport

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SECTION 15. REGULATORY INFORMATION:
Code letter and hazard designation of product:
Hazard-determining components of labeling:
EU Risk And Safety phrases:
S22: Do not breathe dust
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
S28: After contact with skin, wash immediately with plenty of water
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)
R22: Harmful if swallowed

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 for any damage resulting from use of this material.
Reviewed: July 1, 2019