

# Safety Data Sheet

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

### SECTION 1. IDENTIFICATION:

Trade name: Erlotinib, Free Base  
Product Number: [E-4997](#)  
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: pharmaceutically active substance  
Substance Class Identifier: Tumorigen; Drug; Human Data  
Harmful if swallowed  
May be harmful if inhaled or through skin absorption  
Ingestion may result in rash, dry skin, pruritus (itch), diarrhea, nausea, vomiting, stomach pain, anorexia (decreased appetite), weight loss, fatigue, dyspnea (shortness of breath), stomatitis (inflammation/ulceration of the mucous membranes lining of the mouth), cough, liver failure, kidney failure, increased bleeding rates, gastrointestinal perforation, and corneal perforation or ulceration  
May be irritating to 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



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

Chemical Name: *N*-(3-Ethynylphenyl)-6,7-*bis*(2-methoxyethoxy)-4-quinazolinamine  
Synonyms: CP-358774, NSC-718781, OSI-774, R1415, Tarceva  
Hazardous Ingredient: Erlotinib, Free Base  
CAS Registry Number: 183321-74-6  
Molecular Weight: 393.44  
Molecular Formula: C<sub>22</sub>H<sub>23</sub>N<sub>3</sub>O<sub>4</sub>

#### **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 and 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: emits toxic fumes 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: white

Odor: none

Melting point/Melting range: 167-180 °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 5-20 µM; buffers, serum, or other additives may increase or decrease the aqueous solubility

Solvent content: none

Organic solvents: soluble in DMSO at 100 mg/mL; soluble in ethanol at 10 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 #: VA0971100

Acute toxicity: oral toxicity (LD50): 1000-2000 mg/kg (rat), >2000 mg/kg (mouse); dermal toxicity (LD50): >2000 mg/kg (rabbit) - toxicity data is from the Hoffman-La Roche MSDS dated January 11, 2011 for Tarceva

intraperitoneal toxicity (TDLo): 30-240 mg/kg (mouse); oral toxicity (TDLo): 525 mg/kg (mouse), 9.1-54.6 mg/kg (human)

Primary irritant effect: none known

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: may be harmful if swallowed

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

General notes: May cause long lasting harmful effects to aquatic life - following toxicity data is from the Hoffman-La Roche MSDS dated January 11, 2011 for Tarceva

Ready biodegradability - not readily biodegradable

0 %, 28 d

(MITI Test I, OECD No. 301 C)

Inherent biodegradability - not inherently biodegradable

0 %, 28 d

(Roche-internal respirometric inherent biodegradation test)

Ecotoxicity - barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (*Selenastrum capricornutum*)

EC50 (72 h) > 100 mg/l (nominal concentration)

NOEC (72 h) 1.39 mg/l (saturation concentration) (OECD No. 201)

Ecotoxicity - barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (*Daphnia magna*)

EC50 (48 h) > 100 mg/l (nominal concentration)

EC10 (48 h) 1.53 mg/l (saturation concentration)

NOEC (48 h) 0.70 mg/l (average measured concentration) (OECD No. 202)

Ecotoxicity - barely toxic for fish (nominal concentration = 100 mg/l), test performed with water accommodated fractions (zebrafish) LC50 (96 h) > 100 mg/l (nominal concentration)

LC0 (96 h) 1.80 mg/l (saturation concentration)

(OECD No. 203, semi-static)

Ecotoxicity - barely toxic for microorganisms (nominal concentration > 100 mg/l)

(activated sludge)

NOEC (3 h) 1000 mg/l (nominal concentration) (Activated Sludge Respir. Inhib. Test, OECD No. 209)

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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:**

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:

Xn: Harmful

EU Risk And Safety phrases:

S22: Do not breathe dust

S24/25: Avoid contact with skin and eyes

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

R53: May cause long-term adverse effects in the aquatic environment

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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