Safety Data Sheet

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

SECTION 1. IDENTIFICATION:

Trade name: Erlotinib, Methanesulfonate Salt Product Number: <u>E-4667</u> 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

Harmful if swallowed

May be harmful if inhaled or through skin absorption

Ingestion may result in rash, dry skin, pruirits (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

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*-(3-Ethynylphenyl)-6,7-*bis*(2-methoxyethoxy)-4quinazolinamine Methanesulfonate Synonyms: CP-358774, NSC-718781, OSI-774, R1415, Tarceva Hazardous Ingredient: Erlotinib, Methanesulfonate Salt CAS Registry Number: 248594-19-6 Molecular Weight: 489.54 Molecular Formula: $C_{22}H_{23}N_3O_4 \bullet CH_4SO_3$

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 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

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.

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 liquidbinding 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 $^{\circ}C$

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

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

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

SECTION 11. TOXICOLOGICAL INFORMATION:

RTECS #: VA0971200 for HCl salt form

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 Primary irritant effect: none known

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

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

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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)

SECTION 13. DISPOSAL CONSIDERATIONS:

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

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

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

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