Safety Data Sheet

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

SECTION 1. IDENTIFICATION:

Trade name: Gefitinib Product Number: <u>G-4408</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; Human Data Harmful if swallowed May be harmful if inhaled or absorbed through the skin Irritating to the skin and eyes Ingestion may result in diarrhea, nausea, vomiting, anorexia (reduced appetite), weight loss, rash, dry skin, pruritus (itching), acne, and asthenia (weakness) Very toxic to aquatic organisms Possible risk of impaired fertility 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-(3-Chloro-4-fluorophenyl)-7-methoxy-6-[3-(4-morpholinyl)propoxy]-4-quinazolinamine Synonyms: Gefonib, Iressa, ZD-1839 Hazardous Ingredient: Gefitinib CAS Registry Number: 184475-35-2 Molecular Weight: 446.90 Molecular Formula: $C_{22}H_{24}CIFN_4O_3$

SECTION 4. FIRST-AID MEASURES:

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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 °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 Color: white to off-white Odor: none Melting point/Melting range: 180-203.5 °C Danger of explosion: none Solubility in / Miscibility with water: very poorly soluble in water Solvent content: none Organic solvents: soluble in DMSO, up to about 100 mg/ml; very poorly soluble in ethanol

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 #: VA0952000

Acute toxicity: oral toxicity (TDLo): 3.6 mg/kg (human), 100 mg/kg (mouse) 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: may be harmful if swallowed

SECTION 12. ECOLOGICAL INFORMATION:

Very toxic to aquatic life with long lasting effects - following toxicity data is from the AstraZeneca MSDS dated March 19, 2013 for Iressa Ecotoxicity EbC50 green algae 72 H 1.02 mg/l ErC50 green algae 72 H > 2.2 mg/l NOEC green algae 72 H 0.23 mg/l EC50 Daphnia magna 48 H 3.1 mg/l NOEC Daphnia magna 21 d 0.52 mg/l NOEC Freshwater midge, Chironomus riparius 28 d 13 mg/l NOEC Pimephales promelas (fathead minnow) 32 d 0.032 mg/l

SECTION 13. DISPOSAL CONSIDERATIONS:

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

SECTION 14. TRANSPORT INFORMATION:

UN number: 3077 DOT: Environmentally hazardous substance, solid, n.o.s. (Gefitinib), Class: 9, Packing group: III

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

SECTION 15. REGULATORY INFORMATION:

Code letter and hazard designation of product: Hazard-determining components of labeling: EU Risk And Safety phrases: S36/37: Wear suitable protective clothing and gloves R22: Harmful if swallowed R36/38: Irritating to eyes and skin

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