

Neratinib, Free Base

Catalog Number: orb61185

Material Safety Data Sheet

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

Product identifier

Product name: Neratinib, Free Base
Catalog No.: orb61185

Details of the supplier of the safety data sheet

Company: Biorbyt Ltd.
Tel: +44 (0)1223 859 353
Fax: +44 (0)1223 280 240

SECTION 2. HAZARD(S) IDENTIFICATION:

Hazard Description: pharmaceutically active ingredient

May be harmful if swallowed, inhaled, or absorbed through the skin

Ingestion may cause diarrhea, nausea, vomiting, anorexia (decreased appetite), dehydration, hypokalemia (reduced serum potassium level), fatigue, increased serum creatinine, epistaxis (nose bleed), gastritis, pyelonephritis (urinary tract infection extending into the kidneys), thrombocytopenia (reduced blood platelets), anemia, and mild skin rash

May adversely affect fetal development

Exposure may cause irritation of the skin, eyes, mucous membranes, and upper respiratory tract

Signal Word: Warning

H303 - May be harmful if swallowed

H313 - May be harmful in contact with skin

H333 - May be harmful if inhaled

H335 - May cause respiratory irritation

H361 - Suspected of damaging fertility or the unborn child

GHS Precautionary Statements:

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

P264 - Wash skin thoroughly after handling

P280 - Wear protective gloves/eye protection/face protection

P308 + P311 - IF exposed or concerned: Call a POISON CENTER or doctor/physician

P314 - Get medical advice/attention if you feel unwell

P501 - Dispose of contents/container in accordance with local/regional/national/international regulations



SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS:

Chemical Name: (2E)-N-[4-[[3-Chloro-4-(2-pyridinylmethoxy)phenyl]amino]-3-cyano-7-ethoxy-6-quinolinyl]-4-(dimethylamino)-2-butenamide

Synonyms: HKI-272

Hazardous Ingredient: Neratinib, Free Base

CAS Registry Number: 698387-09-6

Molecular Weight: 557.04

Molecular Formula: C₃₀H₂₉ClN₆O₃

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 °C

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION:

Personal protective equipment as follows:

Breathing equipment: NIOSH/MSHA-approved respirator

Protection of hands: chemical-resistant rubber gloves

Eye protection: chemical safety goggles

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES:

Form: crystalline solid; granular or powder

Color: off-white to pale yellow

Odor: none

Melting point/Melting range: 139-158 °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:

Organic solvents: soluble in DMSO at 2 mg/mL with warming; very poorly soluble in ethanol

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

SECTION 11. TOXICOLOGICAL INFORMATION:

RTECS #: not available

Acute toxicity:

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:

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

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:

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

R63: Possible risk of harm to unborn child