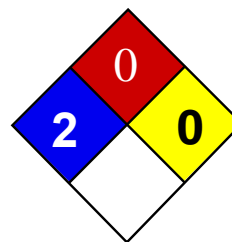


MATERIAL SAFETY DATA SHEET

Gefitinib



Health	2
Fire	0
Reactivity	0
Personal Protection	E

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Gefitinib

PRODUCT CODES: Orb61034

MANUFACTURER: Biorbyt Ltd.

ADDRESS: 5 Orwell Furlong, Cowley Road, Cambridge, Cambridgeshire, CB4 0WY, UK

INTERNATIONAL PHONE: +44 (0)1223 859 353

FAX PHONE: +44(0)1223 280 240

WEBSITE: biorbyt.com

SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

Component	Description	Volume	Safety Information
Gefitinib	Solid	1589-25: 25 mg 1589-5: 5 mg	See below

SECTION 3: HAZARDS IDENTIFICATION

Product Name/Chemical Name	CAS Number	EC-No.	MW	Chemical Formula
Gefitinib	184475-35-2	--	446.9	C ₂₂ H ₂₄ ClFN ₄ O ₃

Gefitinib:

Emergency Overview

OSHA Hazards: Harmful by ingestion, Irritant

GHS Classification: Acute toxicity, Oral (Category 3)

Acute aquatic toxicity (Category 1)

GHS Label elements, including pictograms and hazard statements

Pictogram:



Signal word: Danger

Hazard statement(s):

H302 Harmful if swallowed.
H400 Very toxic to aquatic life.

Precautionary statement(s):

P273 Avoid release to the environment.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician

HMIS Classification

Health hazard: 2

Flammability: 0

Physical hazards: 0

NFPA Rating

Health Hazard: 2

Fire: 0

Reactivity Hazard: 0

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: May be harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Ingestion: Harmful if swallowed.

SECTION 4: FIRST AID MEASURES

General advice: Consult a physician. Show this safety data sheet to the doctor in attendance. Move out of dangerous area.

If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact: Wash off with soap and plenty of water. Consult a physician.

In case of eye contact: Flush eyes with water as a precaution.

If swallowed: Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

5: FIRE-FIGHTING MEASURES

Condition of flammability: Not flammable or combustible.

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

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Special protective equipment for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.

Hazardous combustion products: Hazardous decomposition products formed under fire conditions— carbon oxides, nitrogen oxides, hydrogen chloride, hydrogen fluoride.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions: Wear respiratory protection. Avoid dust formation. Avoid breathing vapors, mist, gas, or dust. Ensure adequate ventilation. Evacuate personnel to safe areas.

Environmental precautions: Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided.

Methods for cleaning up: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed. Normal measures for preventive fire protection.

Conditions for safe storage

Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: -20 °C

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Contains no substances with occupational exposure limit values.

Personal protective equipment

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face particle respirator type N100 (US) or type P3 (EN 143) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Hand protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Eye protection

Face shield and safety glasses. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin and body protection

Complete suit protecting against chemicals. The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Hygiene measures

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of the workday.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Property	Gefitinib
Appearance:	White to off-white solid
pH:	No data available
Water Solubility:	Slightly soluble
Specific Gravity (g/ml):	No data available
Boiling Point (°C):	No data available
Melting Point (°C):	374-377.6 °C (705.2-711.68 °F)
Flash Point (°C):	No data available
Ignition Temperature (°C):	No data available
Density	No data available

SECTION 10: STABILITY AND REACTIVITY

Property	Gefitinib
Chemical stability	Stable under recommended storage conditions
Conditions to avoid:	No data available
Materials to avoid:	Strong oxidizing agents
Hazardous decomposition products:	Carbon oxides, nitrogen oxides, hydrogen chloride, hydrogen fluoride

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SECTION 11: TOXICOLOGICAL INFORMATION

Gefitinib:

Acute toxicity: LD50 Oral – rat – 2000 mg/kg

Skin corrosion/irritation: no data available

Serious eye damage/eye irritation: no data available

Respiratory or skin sensitization: no data available

Germ cell mutagenicity: no data available

Carcinogenicity:

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.

NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity: no data available

Teratogenicity: no data available

Specific target organ toxicity – single exposure (GHS): no data available

Specific target organ toxicity – repeated exposure (GHS): no data available

Aspiration hazard: no data available

Potential Health Effects

Inhalation: May be harmful if inhaled. May cause respiratory tract irritation.

Skin: May be harmful if absorbed through skin. May cause skin irritation.

Eyes: May cause eye irritation.

Ingestion: Harmful if swallowed.

Signs and Symptoms of Exposure: To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

Synergistic effects: no data available

Additional information: RTECS: not available

SECTION 12: ECOLOGICAL INFORMATION

Gefitinib:

Persistence and degradability: no data available

Toxicity: Toxicity to daphnia and other aquatic invertebrates: EC50 – Daphnia magna (water flea) – 0.52mg/l – 21 d

Bioaccumulative potential: no data available

Mobility in soil: no data available

PBT and vPvB assessment: no data available

Other adverse effects: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal. Very toxic to aquatic life.

SECTION 13: DISPOSAL CONSIDERATIONS

Product: Offer surplus and non-recyclable solutions to a licensed disposal company. Contact licensed professional waste disposal service to dispose of this material. Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber.

Contaminated packaging: Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

Gefitinib:

DOT (US): UN-number: 3077, Class: 9, Packing group: III; Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Gefitinib); Marine pollutant: Yes; Poison inhalation hazard: No

IMDG: UN-number: 3077, Class: 9, Packing group: III; EMS-No: F-A, S-F; Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Gefitinib); Marine pollutant: Yes

IATA: UN-number: 3077, Class: 9, Packing group: III; Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Gefitinib)

SECTION 15: REGULATORY INFORMATION

Gefitinib:

OSHA Hazards: Harmful by ingestion, Irritant

SARA 302 Components: SARA 302: No chemical in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components: SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title II, Section 313.

SARA 311/312 Hazards: Acute Health Hazard

Massachusetts Right To Know Components: No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components: Gefitinib, CAS-No. 184475-35-2

New Jersey Right To Know Components: Gefitinib, CAS-No. 184475-35-2

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California Prop. 65 Components: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

EU regulations

Component	Risk Phrases	Safety Phrases
Gefitinib	R22, R38, R41, R48/22, R51/53	S22, S24/25, S36/37/39

SECTION 16: OTHER INFORMATION

OTHER INFORMATION:

PREPARATION INFORMATION:

DISCLAIMER:

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Biobyt Ltd., shall not be held liable for any damage resulting from handling or from contact with the above product. See reverse side of invoice or packing slip for additional terms and conditions of sale.