



Safety Data Sheet (SDS) According to the OSHA Hazard Communication Standard 29 CFR 1910.1200

Issuing Date: 2015-03-26

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Version: 4

SECTION 1. Identification

Product identifier

Product No 4765
Product name Gefitinib
UN number UN3077

Recommended use of the chemical and restrictions on use

Identified uses For Research Use Only. Not for Use in Diagnostic Procedures.

Manufacturer, importer, supplier

Manufacturer address Cell Signaling Technology, Inc.
3 Trask Lane
Danvers, MA 01923
United States
TEL: +1 978 867 2300
FAX: +1 978 867 2400
Website www.cellsignal.com
Email address support@cellsignal.com
Emergency telephone number In case of emergency call CHEMTREC 1-800-424-9300

SECTION 2. Hazard(s) identification

Classification

This substance/mixture is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute oral toxicity	Category 4
Skin corrosion/irritation	Category 2
Serious eye damage/eye irritation	Category 1
Carcinogenicity	Category 2
Reproductive toxicity	Category 2
Specific target organ toxicity - repeated exposure (STOT RE)	Category 2
Chronic aquatic toxicity	Category 2

GHS Label elements, including precautionary statements

**Signal Word**

Danger

Hazard statement(s)

Harmful if swallowed.
 Causes skin irritation.
 Causes serious eye damage.
 Suspected of causing cancer.
 Suspected of damaging fertility or the unborn child.
 May cause damage to organs through prolonged or repeated exposure.
 Toxic to aquatic life with long lasting effects.

Precautionary Statement(s)

Obtain special instructions before use.
 Do not handle until all safety precautions have been read and understood.
 Do not breathe dust/fume/gas/mist/vapors/spray.
 Wash face, hands and any exposed skin thoroughly after handling.
 Do not eat, drink or smoke when using this product.
 Wear protective gloves/protective clothing/eye protection/face protection.
 Avoid release to the environment.
 IF exposed or concerned: Get medical advice/attention
 IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell
 Rinse mouth
 IF ON SKIN: Wash with plenty of soap and water
 If skin irritation occurs: Get medical advice/attention
 Take off contaminated clothing and wash before reuse
 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 Immediately call a POISON CENTER or doctor/physician.
 Store locked up.
 Collect spillage.
 Dispose of contents/container to an approved waste disposal plant.

Supplementary Hazard Information**Hazards not otherwise classified (HNOC)**

Avoid contact during pregnancy and while nursing.

SECTION 3. Composition/information on ingredients

Formula $C_{22}H_{24}ClFN_4O_3$
Molecular Weight 446.90 g/mol

Synonyms Iressa

Chemical name	CAS No	Weight-%
N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine	184475-35-2	100

SECTION 4. First-aid measures

Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. Call a physician immediately.
Skin contact	Wash skin with soap and water. Remove and wash contaminated clothing before re-use.
Inhalation	Move to fresh air.
Ingestion	Clean mouth with water and afterwards drink plenty of water. Consult a physician.

Most important symptoms and effects, both acute and delayed

Nausea. Diarrhea. Skin irritation. Dry skin. Rashes.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Advice for emergency responders

General advice	For further assistance, contact your local Poison Control Center.
Protection of first-aiders	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves

SECTION 5. Fire-fighting measures**Extinguishing media**

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment
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Specific hazards arising from the chemical

No information available.

Explosion Data

Sensitivity to Mechanical Impact	None
Sensitivity to Static Discharge	None

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel	Ensure adequate ventilation.
Other information	No information available.

Environmental precautions

Do not flush into surface water or sanitary sewer system.

Methods and material for containment and cleaning up

Methods for containment	Prevent further leakage or spillage if safe to do so.
Methods for cleaning up	Use personal protective equipment. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for

disposal. Avoid dust formation. Clean contaminated surface thoroughly.

SECTION 7. Handling and storage

Precautions for safe handling

Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Remove and wash contaminated clothing before re-use. Avoid dust formation. Wash thoroughly after handling. Do not eat, drink or smoke when using this product. Avoid contact during pregnancy/while nursing.

Conditions for safe storage, including any incompatibilities

Technical measures/Storage conditions	Keep containers tightly closed in a dry, cool and well-ventilated place.
Packaging material	No information available
Incompatible products	None known based on information supplied

SECTION 8. Exposure controls/personal protection

Control parameters

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Appropriate engineering controls

Showers, eyewash stations, and ventilation systems.

Individual protection measures, such as personal protective equipment

Personal protective equipment (PPE) needs to be selected depending on the implemented engineering controls, frequency/duration of work activities and the concentrations of the hazardous substance.

Eye/face protection	Safety glasses with side-shields
Skin and body protection	Wear protective gloves/clothing.
Respiratory protection	In case of inadequate ventilation wear respiratory protection.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practice.

SECTION 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid
Appearance	Powder
Color	White to off-white
Odor	No information available
Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	No information available		
Melting point/freezing point	180-203.5 °C		
Boiling point or initial boiling point and boiling range	No information available		
Flash point	No information available		
Evaporation rate	No information available		
Flammability	No information available		

Lower explosion limit	No information available
Upper explosion limit	No information available
Vapor pressure	No information available
Relative vapor density	No information available
Density and/or relative density	No information available
Solubility	Practically insoluble
Solubility in other solvents	No information available.
Partition coefficient: n-octanol/water	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Viscosity	No information available
Viscosity, dynamic	No information available

Other information

Softening point	No information available
Molecular Weight	446.90
VOC content	No information available
Liquid Density	No information available
Bulk density	No information available

SECTION 10. Stability and reactivity

Reactivity

No information available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

Hazardous reactions	None under normal processing.
Hazardous polymerization	None under normal processing.

Conditions to Avoid

No information available

Incompatible Materials

None known based on information supplied

Hazardous Decomposition Products

None known based on information supplied

SECTION 11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause irritation of respiratory tract.
Eye contact	Causes serious eye damage.
Skin contact	Irritating to skin.
Ingestion	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea.

Information on toxicological effects

This material should only be handled by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals. It should be borne in mind that the toxicological and physiological properties of this compound is not well defined.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Symptoms	Nausea. Diarrhea. Skin irritation. Dry skin. Rashes.
Skin corrosion/irritation	Irritating to skin.
Serious eye damage/eye irritation	Risk of serious damage to eyes.
Sensitization	No information available.
Mutagenic effects	No information available.
Carcinogenicity	No component of this product present at levels greater than or equal to 0.1% is identifiable as probable, possible or confirmed carcinogen by IARC, ACGIH, NTP, or OSHA.
Reproductive toxicity	May damage fertility or the unborn child. Experiments have shown reproductive toxicity effects on laboratory animals.
STOT - single exposure	No information available.
STOT - repeated exposure	Liver.
Neurological effects	No information available.
Aspiration Hazard	No information available.

SECTION 12. Ecological information

Ecotoxicity

Toxic to aquatic life with long lasting effects

Chemical name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine	EbC50 1.02 mg/L (Green algae) 72H ErC50 >2.2 mg/L (Green algae) 72H	-	EC50 3.1 mg/L (Daphnia magna) 48H

Persistence and degradability	Not readily biodegradable. <5% 28 day period.
Mobility	Mobility in soil: Low.
Bioaccumulation	Not likely to bioaccumulate.

Chemical name	Octanol-Water Partition Coefficient
N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine	3.2

Other adverse effects

No information available.

SECTION 13. Disposal considerations

Waste Disposal Methods

Should not be released into the environment. Dispose of in accordance with all applicable national environmental laws and regulations.

Disposal considerations

Do not empty into drains; dispose of this material and its container in a safe way. Dispose of wastes in an approved waste disposal facility.

SECTION 14. Transport information

DOT

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Gefitinib)
Transport hazard class(es)	9
Packing group	III

IATA

UN number	UN3077
UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Gefitinib)
Transport hazard class(es)	9
Packing group	III

SECTION 15. Regulatory information

North American Inventory Listing

All components of this product are NOT included on the Toxic Substance Control Act (TSCA) Inventory, DSL, or NDSL. All components of this product are NOT included on DSL or NDSL.

Canadian Workplace Hazardous Materials Information System (WHMIS) Classification

This product does not meet the criteria for classification under the Hazardous Products Act.

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

SARA 311/312 Hazard Categories

Acute Health Hazard	Yes
Chronic Health Hazard	Yes
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

Clean Water Act

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level.

pertaining to releases of this material.

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

This product does not contain any substances regulated under applicable state right-to-know regulations

U.S. FIFRA Label Information

This product does not contain any substances regulated as pesticides.

US Commerce Department - Export Administration Regulations Information

This product does not contain any substances regulated under the Chemical Weapons Convention (CWC).

U.S. Drug Enforcement Administration Information

This product does not contain any substances regulated under the DEA.

SECTION 16. Other information

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Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet