



**Safety Data Sheet (SDS)** According to the OSHA Hazard Communication Standard 29 CFR 1910.1200  
**Issuing Date:** 2015-03-26 **Revision Date:** 2015-03-26

**Version:** 2

**SECTION 1. Identification**

**Product identifier**

**Product number** 4765  
**Product name** Gefitinib  
**UN number** UN3077  
**Other means of identification** 4765S

**Recommended use of the chemical and restrictions on use**

**Identified uses** This product is intended for research purposes only.  
**Uses advised against** This product is not intended for use in diagnostic procedures or therapeutics.  
 This product is not intended for use in humans or animals.

**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  
**Company phone number** 978-867-2300  
**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)

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

**Precautionary Statement(s)**

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wash face, hands and any exposed skin thoroughly after handling. Do not eat, drink or smoke when using this product. Do not breathe dust/fume/gas/mist/vapors/spray.

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.

Dispose of contents/container to an approved waste disposal plant.

**Supplementary Hazard Information**

No information available.

**Hazards not otherwise classified (HNOC)** Toxic to aquatic life with long lasting effects.

**SECTION 3. Composition/information on ingredients**

<b>Formula</b>	C <sub>22</sub> H <sub>24</sub> ClFN <sub>4</sub> O <sub>3</sub>
<b>Molecular Weight</b>	446.90 g/mol
<b>Chemical nature</b>	Monoconstituent substance
<b>Synonyms</b>	Gefitinib; IRESSA®; ZD-1839; 4-Quinazolinamine, N-(3-chloro-4-fluorophenyl)-7-methoxy-6-[3-(4-morpholin) propoxy]

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**

<b>Eye contact</b>	Immediate medical attention is required.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Inhalation</b>	Move to fresh air.
<b>Ingestion</b>	Clean mouth with water and afterwards drink plenty of water.

**Most important symptoms and effects, both acute and delayed**

Diarrhea, rash, acne, dry skin, nausea, vomiting, pruritus, anorexia, asthenia, peripheral edema, amblyopia, dyspnea, conjunctivitis and vesiculobullous rash.

**Indication of any immediate medical attention and special treatment needed**

Treat symptomatically.

**Advice for emergency responders**

<b>General advice</b>	For further assistance, contact your local Poison Control Center.
<b>Protection of first-aiders</b>	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.

**Unsuitable Extinguishing Media** CAUTION: Use of water spray when fighting fire may be inefficient.

### 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 and collect in suitable container for disposal. Avoid dust formation. Clean contaminated surface thoroughly.

## SECTION 7. Handling and storage

### Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

### 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.

<b>Eye/face protection</b>	Safety glasses with side-shields.
<b>Skin and body protection</b>	Wear protective gloves/clothing.
<b>Respiratory protection</b>	If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.
<b>Hygiene measures</b>	Handle in accordance with good industrial hygiene and safety practice.

## SECTION 9. Physical and chemical properties

**Information on basic physical and chemical properties**

<b>Physical state</b>	Solid
<b>Appearance</b>	Powder
<b>Color</b>	White to off-white
<b>Odor</b>	No information available
<b>Odor Threshold</b>	No information available
<b>pH</b>	No information available
<b>Melting point/freezing point</b>	180-203.5 °C
<b>Initial boiling point and boiling range</b>	No information available
<b>Flash point</b>	No information available.
<b>Evaporation rate</b>	No information available
<b>Flammability (solid, gas)</b>	No information available
<b>Upper flammability limit</b>	No information available.
<b>Lower flammability limit</b>	No information available.
<b>Vapor pressure</b>	No information available
<b>Vapor density</b>	No information available
<b>Relative density</b>	No information available
<b>Solubility</b>	Practically insoluble
<b>Solubility in other solvents</b>	No information available
<b>Partition coefficient: n-octanol/water</b>	No information available
<b>Autoignition temperature</b>	No information available
<b>Decomposition temperature</b>	No information available.
<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available
<b>Molecular Weight</b>	446.90 g/mol
<b>VOC content</b>	No information available
<b>Viscosity</b>	No information available.
<b>Density</b>	No information available.
<b>Solubility in other solvents</b>	Soluble in dimethyl sulfoxide (DMSO) @ 100 mg/mL

## SECTION 10. Stability and reactivity

**Reactivity**

No information available.

**Chemical stability**

Stable under recommended storage conditions.

**Possibility of hazardous reactions**

<b>Hazardous reactions</b>	None under normal processing.
<b>Hazardous polymerization</b>	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**

<b>Inhalation</b>	Inhalation of particulates may cause mechanical irritation to upper respiratory tract. May cause additional effects as listed under "Ingestion".
<b>Eye contact</b>	Corrosive to the eyes and may cause severe damage including blindness.
<b>Skin contact</b>	Irritating to skin.
<b>Ingestion</b>	May be harmful if swallowed. Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Reproductive Toxicity.

**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**

<b>Symptoms</b>	Diarrhea, rash, acne, dry skin, nausea, vomiting, pruritus, anorexia, asthenia, peripheral edema, amblyopia, dyspnea, conjunctivitis and vesiculobullous rash.
<b>Skin corrosion/irritation</b>	Irritating to skin.
<b>Serious eye damage/eye irritation</b>	Risk of serious damage to eyes.
<b>Sensitization</b>	No information available.
<b>Mutagenic effects</b>	The weight of evidence demonstrates that this material is not genotoxic.
<b>Carcinogenicity</b>	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. Laboratory experiments on animals have reported the development of tumors
<b>Reproductive toxicity</b>	This material is classified as a Pregnancy Category D: Positive evidence of risk. When pregnant rats were treated with 5 mg/kg from the beginning of organogenesis to the end of weaning gave birth, there was a reduction in the number of offspring born alive. This effect was more severe at 20 mg/kg and was accompanied by high neonatal mortality soon after parturition. In this study a dose of 1 mg/kg caused no adverse effects.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	Liver. Eyes. Reproductive system. Respiratory system. Skin.
<b>Neurological effects</b>	No information available.
<b>Aspiration Hazard</b>	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** <5% 28 day period: OECD 301F.  
**Bioaccumulation** Not likely to bioaccumulate.  
**Mobility** Is not likely mobile in the environment due its low water solubility

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

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.

### 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  
**Special provisions** 146, 335, A112, B54, B120, IB8, IP3, N20, T1, TP33  
**Emergency response guide number** 171

#### IATA

**UN number** UN3077  
**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Gefitinib)  
**Transport hazard class(es)** 9  
**Packing group** III  
**Special provisions** A158, A179, A97

### SECTION 15. Regulatory information

#### North American Inventory Listing

Chemical Name	TSCA 8(b)	TSCA 12(b)	DSL	NDSL

N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine	Not Listed	Not Listed	Not Listed	Not Listed
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**Canadian Workplace Hazardous Materials Information System (WHMIS) Classification**

	Class D2A - Very Toxic Material at $\geq 0.1\%$ Class D2B - Toxic Material at $\geq 1\%$
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**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**

<b>Acute Health Hazard</b>	Yes
<b>Chronic Health Hazard</b>	Yes
<b>Fire Hazard</b>	No
<b>Sudden Release of Pressure Hazard</b>	No
<b>Reactive Hazard</b>	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**

**Issuing Date:** 2015-03-26

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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