

Safety Data Sheet (SDS) According to the REACH Regulation (EC) No. 1907/2006

Issuing Date: 2015-03-26

Revision Date: 2024-12-20

Version: 4

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

Product No 4765  
Product name Gefitinib

### Contains

Chemical name N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-yl)propox Not Listed  
yquinazolin-4-amine (90 - 100%)

Index No.

CAS No

184475-35-2

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

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

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

### 1.3. Details of the supplier of the safety data sheet

Importer	Manufacturer
Cell Signaling Technology Europe B.V. Dellaertweg 9b 2316 WZ Leiden The Netherlands TEL: +31 (0)71 7200 200 FAX: +31 (0)71 891 0019	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](http://www.cellsignal.com)  
E-mail Address [info@cellsignal.eu](mailto:info@cellsignal.eu)

### 1.4. Emergency telephone number

**CHEMTREC** 24 hours a day, 7 days a week, 365 days a year  
+1 703 527 3887 (INTERNATIONAL) +1 800 424 9300 (NORTH AMERICA)

Europe 112

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Acute oral toxicity	Category 4 - (H302)
Skin corrosion/irritation	Category 2 - (H315)

Serious eye damage/eye irritation	Category 1 - (H318)
Carcinogenicity	Category 2 - (H351)
Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity - repeated exposure (STOT RE)	Category 2 - (H373)
Chronic aquatic toxicity	Category 2 - (H411)

## 2.2. Label elements



### Signal word

Danger

### Hazard statement(s)

H302 - Harmful if swallowed.

H315 - Causes skin irritation.

H318 - Causes serious eye damage.

H351 - Suspected of causing cancer.

H361 - Suspected of damaging fertility or the unborn child.

H373 - May cause damage to organs through prolonged or repeated exposure.

H411 - Toxic to aquatic life with long lasting effects.

### Precautionary statement(s)

P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

P264 - Wash face, hands and any exposed skin thoroughly after handling.

P270 - Do not eat, drink or smoke when using this product.

P273 - Avoid release to the environment.

P280 - Wear protective gloves/protective clothing/eye protection/face protection.

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

P302 + P352 - IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313 - IF exposed or concerned: Get medical advice/attention.

P310 - Immediately call a POISON CENTER or doctor/physician.

P314 - Get medical advice/attention if you feel unwell.

P330 - Rinse mouth.

P332 + P313 - If skin irritation occurs: Get medical advice/attention.

P362 + P364 - Take off contaminated clothing and wash it before reuse.

P391 - Collect spillage.

P405 - Store locked up.

P501 - Dispose of contents/container to an approved waste disposal plant.

## 2.3. Other hazards

Avoid contact during pregnancy/while nursing.

For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16

## SECTION 3: Composition/information on ingredients

**3.1 Substances**

**Synonyms** Iressa  
**Formula** C<sub>22</sub>H<sub>24</sub>ClFN<sub>4</sub>O<sub>3</sub>

Chemical name	CAS No	Weight-%	EC No	Classification (1272/2008)	REACH Registration Number
N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine	184475-35-2	100	-	Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Carc. 2 (H351) Repr. 2 (H361) STOT RE 2 (H373) Aquatic Chronic 2 (H411)	no data available

For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16

## SECTION 4: First aid measures

**4.1. Description of first aid measures**

**General advice** Use first aid treatment according to the nature of the injury. When symptoms persist or in all cases of doubt seek medical advice.

**Inhalation** Move to fresh air.

**Skin contact** Wash skin with soap and water. Remove and wash contaminated clothing before re-use.

**Eye contact** Rinse thoroughly with plenty of water, also under the eyelids. Call a physician immediately.

**Ingestion** Clean mouth with water and afterwards drink plenty of water. Consult a physician.

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

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

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

**Notes to physician** Treat symptomatically.

## SECTION 5: Firefighting measures

**5.1. Extinguishing media**

**Suitable Extinguishing Media** Use extinguishing measures that are appropriate to local circumstances and the surrounding environment

**Unsuitable Extinguishing Media** No information available

**5.2. Special hazards arising from the substance or mixture**

Thermal decomposition can lead to release of irritating gases and vapors.

**5.3. Advice for firefighters**

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment.

## SECTION 6: Accidental release measures

**6.1. Personal precautions, protective equipment and emergency procedures**

**For non-emergency personnel** Evacuate personnel to safe areas. Ensure adequate ventilation.  
**For emergency responders** Use personal protection recommended in Section 8.

**6.2. Environmental precautions**

Do not flush into surface water or sanitary sewer system.

**6.3. 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.

**6.4. Reference to other sections**

See Sections 8 & 13 for additional information.

**SECTION 7: Handling and storage**

**7.1. 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.

**7.2. Conditions for safe storage, including any incompatibilities**

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

**7.3. Specific end use(s)**

Use as a laboratory reagent.

**SECTION 8: Exposure controls/personal protection**

**8.1. Control parameters**

Contains no substances with occupational exposure limit values.

**8.2. Exposure controls**

**Appropriate engineering controls**  
Showers, eyewash stations, and ventilation systems

**Individual protection measures, such as personal protective equipment**  
**Eye/face protection** Safety glasses with side-shields.  
**Skin protection** Wear protective gloves and protective clothing.  
**Hand protection** Impervious gloves.  
**Other** Wear suitable protective clothing.  
**Respiratory protection** In case of inadequate ventilation wear respiratory protection.

**Environmental Exposure Controls**  
No information available

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## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

<b>Physical state</b>	Solid - Powder
<b>Color</b>	White to off-white
<b>Odor</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>	No information available	No information available
<b>Melting point/freezing point</b>	180-203.5 °C	
<b>Boiling point or initial boiling point and boiling range</b>	No information available	No information available
<b>Flash point</b>	No information available	No information available.
<b>Evaporation rate</b>	No information available	No information available
<b>Flammability</b>	No information available	No information available
<b>Upper/lower flammability or explosive limits</b>		No information available
<b>Vapor pressure</b>	No information available	No information available
<b>Relative vapor density</b>	No information available	No information available
<b>Density and/or relative density</b>	No information available	No information available
<b>Solubility</b>	Practically insoluble	
<b>Partition coefficient: n-octanol/water</b>	No information available	No information available
<b>Autoignition temperature</b>	No information available	No information available
<b>Decomposition temperature</b>	No information available	No information available.
<b>Viscosity</b>	No information available	No information available
<b>Explosive properties</b>	No information available	No information available
<b>Oxidizing properties</b>	No information available	No information available

### 9.2. Other information

<b>Softening point</b>	No information available
<b>Molecular Weight</b>	446.90 g/mol
<b>Solubility in other solvents</b>	Soluble in dimethyl sulfoxide (DMSO) @ 100 mg/mL
<b>VOC content</b>	No information available
<b>Liquid Density</b>	No information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

No information available.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

<b>Hazardous polymerization</b>	Hazardous polymerization does not occur.
<b>Hazardous reactions</b>	None under normal processing

### 10.4. Conditions to avoid

None known based on information supplied.

### 10.5. Incompatible materials

No information available.

#### 10.6. Hazardous decomposition products

None under normal use conditions

### SECTION 11: Toxicological information

#### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

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.

#### Information on likely routes of exposure

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

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

<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>	No information available.
<b>Carcinogenicity</b>	No information available.
<b>Reproductive toxicity</b>	May damage fertility or the unborn child. Experiments have shown reproductive toxicity effects on laboratory animals.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	Liver.
<b>Aspiration Hazard</b>	No information available.

#### 11.2. Information on other hazards

No information available.

### SECTION 12: Ecological information

#### 12.1. Toxicity

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

#### 12.2. Persistence and degradability

Not readily biodegradable <5% 28 day period

**12.3. Bioaccumulative potential**

**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

**Bioconcentration factor (BCF)** No information available.

**12.4. Mobility in soil**

Mobility in soil: Low.

**12.5. Results of PBT and vPvB assessment**

No information available.

**12.6. Endocrine disrupting properties**

This product does not contain any known or suspected endocrine disruptors

**12.7. Other adverse effects**

No information available

## SECTION 13: Disposal considerations

**13.1. Waste treatment methods**

**Waste from residues / unused products** Dispose of in accordance with local regulations.

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal.

**Other information** Waste codes should be assigned by the user based on the application for which the product was used.

## SECTION 14: Transport information

**IMDG/IMO**

**14.1 UN number** UN3077

**14.2 UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Gefitinib)

**14.3 Transport hazard class(es)** 9

**14.4 Packing group** III

**14.5 Environmental hazards** Yes

**14.6 Special precautions for user** None

**14.7 Maritime transport in bulk according to IMO instruments** Not regulated

**ADR/RID**

**14.1 UN number** UN3077

**14.2 UN proper shipping name** Environmentally hazardous substance, solid, n.o.s. (Gefitinib)

**14.3 Transport hazard class(es)** 9

**14.4 Packing group** III

**14.5 Environmental hazards** Yes

**14.6 Special precautions for user** None

**IATA**

14.1 UN number	UN3077
14.2 UN proper shipping name	Environmentally hazardous substance, solid, n.o.s. (Gefitinib)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
14.5 Environmental hazards	Yes
14.6 Special precautions for user	None

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Registration, Evaluation, Authorization and Restriction of Chemicals (REACH)**

This product does not contain Substances of Very High Concern (SVHC).

**SEVESO Directive Information**

E2 - Hazardous to the Aquatic Environment in Category Chronic 2

**International inventories**

TSCA 8(b)	-
DSL/NDSL	-
EINECS/ELINCS	-
ENCS	-
IECSC	-
KECL	-
PICCS	-
AICS	-

**International inventories legend**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory  
**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List  
**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances  
**ENCS** - Japan Existing and New Chemical Substances  
**IECSC** - China Inventory of Existing Chemical Substances  
**KECL** - Korean Existing and Evaluated Chemical Substances  
**PICCS** - Philippines Inventory of Chemicals and Chemical Substances  
**AICS** - Australian Inventory of Chemical Substances

**15.2. Chemical safety assessment**

For this substance a chemical safety assessment has not been carried out

**SECTION 16: Other information****Full text of H-Statements referred to under Sections 2 and 3**

H302 - Harmful if swallowed  
H315 - Causes skin irritation  
H318 - Causes serious eye damage  
H351 - Suspected of causing cancer  
H361 - Suspected of damaging fertility or the unborn child  
H373 - May cause damage to organs through prolonged or repeated exposure  
H401 - Toxic to aquatic life  
H411 - Toxic to aquatic life with long lasting effects



**Classification procedure:** Expert judgment and weight of evidence determination.

**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.