



# SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 14-Nov-2022

Revision Number 3

**73162 - Gefitinib**

## Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1. Product identifier

Document Number DX21185

Product Name Gefitinib

Synonyms Gefonib; ZD1839;

Pure substance/mixture Substance

Contains N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine

Molecular weight 446.9

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

Recommended Use Laboratory chemicals

Uses advised against No information available

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

#### **Manufacturer**

STEMCELL Technologies SARL  
40 Rue des Berges, Miniparc Polytec, Bâtiment Sirocco, 38000 Grenoble, France  
+33 (0) 4 76 04 75 30

STEMCELL Technologies Germany GmbH  
Stolberger Str. 200, 50933, Köln, Germany  
+33 (0) 4 76 04 75 30

STEMCELL Technologies UK Ltd.  
Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL  
+33 (0) 4 76 04 75 30

For further information, please contact

### 1.4. Emergency telephone number

Emergency Telephone No information available

Emergency Telephone - \$45 - (EC)1272/2008

Europe 112

## Section 2: HAZARDS IDENTIFICATION

### 2.1. Classification of the substance or mixture



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Regulation (EC) No 1272/2008

Acute toxicity - Oral	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)	Category 2 - (H373)
Acute aquatic toxicity	Category 1 - (H400)
Chronic aquatic toxicity	Category 2 - (H411)

### 2.2. Label elements

Contains N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine



### Signal word

Danger

### Hazard statements

#### Hazard statements

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  
H400 - Very toxic to aquatic life  
H411 - Toxic to aquatic life with long lasting effects  
H303 - May be harmful if swallowed

### Precautionary Statements - EU (§28, 1272/2008)

P280 - Wear eye protection/ face protection  
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing  
P310 - Immediately call a POISON CENTER or doctor  
P280 - Wear protective gloves/protective clothing/eye protection/face protection  
P201 - Obtain special instructions before use  
P202 - Do not handle until all safety precautions have been read and understood  
P308 + P313 - IF exposed or concerned: Get medical advice/attention  
P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
P314 - Get medical advice/attention if you feel unwell  
P501 - Dispose of contents/container to industrial incineration plant

### Additional information



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This product requires tactile warnings if supplied to the general public

### 2.3. Other hazards

No information available

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Chemical name	EC No.	CAS No.	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine	-	184475-35-2	100	Carc. 2 (H351) Repr. 2 (H361) STOT RE 2 (H373) Eye Dam. 1 (H318) Aquatic Acute 1 (H400) Aquatic Chronic 2 (H411) Acute Tox. 4 (H302) Skin Irrit. 2 (H315)	No data available

Full text of H- and EUH-phrases: see section 16

## Section 4: FIRST AID MEASURES

### 4.1. Description of first aid measures

<b>General advice</b>	Immediate medical attention is required. IF exposed or concerned: Get medical advice/attention. Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air. Get medical attention immediately if symptoms occur.
<b>Eye contact</b>	Get immediate medical advice/attention. Do not rub affected area. Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while rinsing. Remove contact lenses, if present and easy to do. Continue rinsing.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Do NOT induce vomiting. Call a physician.
<b>Self-protection of the first aider</b>	Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).



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

**Symptoms** Burning sensation.

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

**Note to physicians** Treat symptomatically.

## Section 5: FIRE-FIGHTING 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

**Specific hazards arising from the chemical** No information available.

### 5.3. Advice for firefighters

**Special protective equipment for fire-fighters** Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.

## Section 6: ACCIDENTAL RELEASE MEASURES

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

**Personal precautions** Evacuate personnel to safe areas. Avoid contact with skin, eyes or clothing. Ensure adequate ventilation. Use personal protective equipment as required.

**Other Information** Refer to protective measures listed in Sections 7 and 8.

**For emergency responders** Use personal protection recommended in Section 8.

### 6.2. Environmental precautions

**Environmental precautions** Prevent further leakage or spillage if safe to do so.

### 6.3. Methods and material for containment and cleaning up

**Methods for containment** Prevent further leakage or spillage if safe to do so.



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**Methods for cleaning up** Take up mechanically, placing in appropriate containers for disposal.

**Prevention of secondary hazards** Clean contaminated objects and areas thoroughly observing environmental regulations.

#### 6.4. Reference to other sections

**Reference to other sections** See section 8 for more information. See section 13 for more information.

### Section 7: HANDLING AND STORAGE

#### 7.1. Precautions for safe handling

**Advice on safe handling** Remove contaminated clothing and shoes. Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated clothing and wash before reuse.

**General hygiene considerations** Avoid contact with skin, eyes or clothing. Wash hands before breaks and immediately after handling the product. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.

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

**Storage Conditions** Keep out of the reach of children. Store locked up. Store in accordance with information listed on the Product Information Sheet (PIS).

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

##### Identified Uses

**Risk Management Methods (RMM)** The information required is contained in this Material Safety Data Sheet.

### Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

#### 8.1. Control parameters

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

**Derived No Effect Level (DNEL)** No information available.

**Predicted No Effect Concentration** No information available.



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(PNEC)

### 8.2. Exposure controls

#### Personal protective equipment

Eye/face protection	Tight sealing safety goggles.
Hand protection	Wear suitable gloves. Impervious gloves.
Skin and body protection	Wear suitable protective clothing. Long sleeved clothing.
Respiratory protection	No protective equipment is needed under normal use conditions. If exposure limits are exceeded or irritation is experienced, ventilation and evacuation may be required.
General hygiene considerations	Avoid contact with skin, eyes or clothing. Wash hands before breaks and immediately after handling the product. Wear suitable gloves and eye/face protection. Do not eat, drink or smoke when using this product.
Environmental exposure controls	No information available.

## Section 9: PHYSICAL AND CHEMICAL PROPERTIES

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

Physical state	Solid
Appearance	Crystalline
Color	No information available
Odor	No data available.
Odor threshold	No data available

Property	Values	Remarks • Method
pH	No data available	None known
Melting point / freezing point	No data available	None known
Boiling point / boiling range	No data available	None known
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	Product is not flammable.	
Flammability Limit in Air		None known
Upper flammability limit:	No data available	
Lower flammability limit:	No data available	
Vapor pressure	No data available	None known
Vapor density	No data available	None known
Relative density	No data available	None known



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Water solubility	No data available	None known
Solubility(ies)	DMF: 20 mg/mL; DMSO: 20 mg/mL; DMF:PBS(pH 7.2)(1:1): 0.5 mg/mL; Ethanol: 0.3 mg/mL;	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known
Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available	
Oxidizing properties	No information available	

### 9.2. Other information

Softening point	No information available
Molecular weight	446.9
Molecular formula	C <sub>22</sub> H <sub>24</sub> ClFN <sub>4</sub> O <sub>3</sub>
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

## Section 10: STABILITY AND REACTIVITY

### 10.1. Reactivity

Reactivity	No information available.
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### 10.2. Chemical stability

Stability	Stable under recommended transport or storage conditions.
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### Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None.

### 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	None under normal processing.
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Hazardous polymerization	Hazardous polymerization does not occur.
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### 10.4. Conditions to avoid

Conditions to avoid	None known based on information supplied.
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### 10.5. Incompatible materials



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**Incompatible materials** Strong oxidizing agents.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products** Carbon monoxide. Carbon dioxide (CO<sub>2</sub>). Hydrogen chloride gas. Hydrogen fluoride. Nitrogen oxides (NO<sub>x</sub>).

## Section 11: TOXICOLOGICAL INFORMATION

### 11.1. Information on toxicological effects

#### Information on likely routes of exposure

#### **Product Information**

<b>Inhalation</b>	Specific test data for the substance or mixture is not available. May cause irritation of respiratory tract.
<b>Eye contact</b>	Severely irritating to eyes. Causes serious eye damage. May cause burns. May cause irreversible damage to eyes. Specific test data for the substance or mixture is not available. (based on components).
<b>Skin contact</b>	Specific test data for the substance or mixture is not available. Causes skin irritation. (based on components).
<b>Ingestion</b>	Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Specific test data for the substance or mixture is not available. Harmful if swallowed. (based on components).

### Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** Burning. May cause blindness. Redness. May cause redness and tearing of the eyes.

### Numerical measures of toxicity

#### **Acute toxicity**

**The following values are calculated based on chapter 3.1 of the GHS document**

**ATEmix (oral)** 500.00 mg/kg

**Unknown acute toxicity** 100 % of the mixture consists of ingredient(s) of unknown toxicity.

0 % of the mixture consists of ingredient(s) of unknown acute oral toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute dermal toxicity.

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (gas).

100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (vapor).



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100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist).

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

**Skin corrosion/irritation** Classification based on data available for ingredients. Irritating to skin.

#### Product Information

**Serious eye damage/eye irritation** Classification based on data available for ingredients. Causes burns. Risk of serious damage to eyes.

#### Product Information

**Respiratory or skin sensitization** No information available.

#### Product Information

**Germ cell mutagenicity** No information available.

#### Product Information

**Carcinogenicity** Classification based on data available for ingredients.

#### Product Information

**Reproductive toxicity** Classification based on data available for ingredients.

#### Product Information

**STOT - single exposure** No information available.

#### Product Information

**STOT - repeated exposure** May cause damage to organs.

#### Product Information

**Aspiration hazard** No information available.

## Section 12: ECOLOGICAL INFORMATION

### 12.1. Toxicity

**Ecotoxicity** Very toxic to aquatic life. Toxic to aquatic life with long lasting effects.

**Unknown aquatic toxicity** Contains 0 % of components with unknown hazards to the aquatic environment.

#### Product Information

### 12.2. Persistence and degradability



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**Persistence and degradability** No information available.

#### 12.3. Bioaccumulative potential

**Bioaccumulation** No information available.

#### 12.4. Mobility in soil

**Mobility in soil** No information available.

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

**PBT and vPvB assessment** No information available.

#### 12.6. Other adverse effects

**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. Dispose of waste in accordance with environmental legislation.

**Contaminated packaging** Do not reuse empty containers.

### Section 14: TRANSPORT INFORMATION

**Note:** Transport in accordance with local, state, and federal regulations. When sold in quantities of less than or equal to 1 mL, or 1 g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.

#### IMDG

<b>14.1 UN Number</b>	UN3077
<b>14.2 UN proper shipping name</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Gefitinib)
<b>14.3 Transport hazard class(es)</b>	9 Miscellaneous dangerous substances and articles
<b>14.4 Packing Group</b>	III
<b>14.5 Marine pollutant</b>	Not applicable
<b>14.6 Special Provisions</b>	None



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**14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code** No information available

#### RID

14.1 UN Number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

#### ADR

14.1 UN Number	Not regulated
14.2 UN proper shipping name	Not regulated
14.3 Transport hazard class(es)	Not regulated
14.4 Packing Group	Not regulated
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	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 Miscellaneous dangerous substances and articles
14.4 Packing Group	III
14.5 Environmental hazard	Not applicable
14.6 Special Provisions	None

## Section 15: REGULATORY INFORMATION

### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

#### European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

#### Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

#### Persistent Organic Pollutants

Not applicable



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### **Dangerous substance category per Seveso Directive (2012/18/EU)**

E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

E2 - Hazardous to the Aquatic Environment in Category Chronic 2

**Ozone-depleting substances (ODS) regulation (EC) 1005/2009** Not applicable

### **International Inventories**

<b>TSCA</b>	Does not comply
<b>DSL/NDL</b>	Does not comply
<b>EINECS/ELINCS</b>	Does not comply
<b>ENCS</b>	Does not comply
<b>IECSC</b>	Does not comply
<b>KECL</b>	Does not comply
<b>PICCS</b>	Does not comply
<b>AICS</b>	Does not comply

### **Legend:**

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDL** - Canadian Domestic Substances List/Non-Domestic Substances List

**EINECS/ELINCS** - European Inventory of Existing Chemical Substances/European 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**

**Chemical Safety Report** No information available

## Section 16: OTHER INFORMATION

### **Key or legend to abbreviations and acronyms used in the safety data sheet**

#### **Full text of H-Statements referred to under section 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

H400 - Very toxic to aquatic life

H411 - Toxic to aquatic life with long lasting effects

### **Legend**



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SVHC: Substances of Very High Concern for Authorization:

**Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

TWA	TWA (time-weighted average)	STEL	STEL (Short Term Exposure Limit)
Ceiling	Maximum limit value	*	Skin designation

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This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

**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. STEMCELL Technologies Inc. shall not be held liable for any damage resulting from handling or from contact with the product.