

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

**Issuing Date:** 2015-03-27

**Revision Date:** 2018-03-13

**Version:** 3

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

### 1.1. Product identifier

**Product No** 5083  
**Product name** Erlotinib  
**Reach registration number** This substance/mixture contains only ingredients which have been registered, or are exempt from registration, according to Regulation (EC) No. 1907/2006.

### Contains

Chemical Name	Index No.	CAS No
N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)qui nazolin-4-amine (90 - 100%)	Not Listed	183321-74-6

<b>Formula</b>	C <sub>22</sub> H <sub>23</sub> N <sub>3</sub> O <sub>4</sub>
<b>Molecular Weight</b>	393.44 g/mol

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

**Identified uses** For research use only

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

Importer (Applicable in EU only)	Manufacturer
Cell Signaling Technology Europe B.V. Schuttersveld 2 2316 ZA Leiden The Netherlands TEL: +31 (0)71 7200 200 FAX: +31 (0)71 891 0098	Cell Signaling Technology, Inc. 3 Trask Lane Danvers, MA 01923 United States TEL: +1 978 867 2300 FAX: +1 978 867 2400

<b>Website</b>	www.cellsignal.com
<b>E-mail Address</b>	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

<b>Acute oral toxicity</b>	Category 4 - (H302)
<b>Reproductive toxicity</b>	Category 2 - (H361)

Specific target organ toxicity - repeated exposure (STOT RE)	Category 2 - (H373)
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**2.2. Label elements****Signal word**

Warning

**Hazard statement(s)**

H302 - Harmful if swallowed

H361 - Suspected of damaging fertility or the unborn child if swallowed

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

**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

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

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

P330 - Rinse mouth

P405 - Store locked up

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

**2.3. Other hazards**

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**

Erlotinib;  
 TARCEVA®;  
 UNII-J4T82NDH7E;  
 4-Quinazolinamine, N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)-  
 C<sub>22</sub>H<sub>23</sub>N<sub>3</sub>O<sub>4</sub>

**Formula**

Chemical Name	CAS No	Weight %	EC No	Classification (1272/2008)	REACH Registration Number
N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)quinazolin-4-amine	183321-74-6	100	-	Acute Tox. 4 (H302) Repr. 2 (H361) STOT RE 2 (H373)	no data available

For the full text of the R-phrases mentioned in this Section, see Section 16

## SECTION 4: First aid measures

**4.1. Description of first aid measures**

<b>General advice</b>	Use first aid treatment according to the nature of the injury. When symptoms persist or in all cases of doubt seek medical advice.
<b>Inhalation</b>	Move to fresh air.
<b>Skin contact</b>	Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Ingestion</b>	Clean mouth with water and afterwards drink plenty of water.

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

Diarrhea. Dry skin. hirsutism. rash. Liver transaminase elevation. Shortness of breath or cough.

**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**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable Extinguishing Media</b>	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**

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

**6.2. Environmental precautions**

Do not flush into surface water or sanitary sewer system. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas.

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

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	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**

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Handle in accordance with good industrial hygiene and safety practice.

### 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

### 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

**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.

## SECTION 9: Physical and chemical properties

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

<b>Physical state</b>	Solid
<b>Appearance</b>	Crystalline Powder
<b>Color</b>	White
<b>Odor</b>	No information available
<b>Odor Threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>		No information available
<b>Melting point/freezing point</b>	167-180 °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>	Partly soluble	
<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>Viscosity</b>		No information available
<b>Explosive properties</b>		No information available
<b>Oxidizing properties</b>		No information available

**9.2. Other information**

<b>Softening point</b>	No information available
<b>Molecular Weight</b>	393.44 g/mol
<b>Solubility in other solvents</b>	Soluble in dimethyl sulfoxide (DMSO) @ 100 mg/mL
<b>VOC content</b>	No information available
<b>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 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.

Chemical Name	LD50 Oral	LD50 Dermal	LC50 Inhalation
N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)quinazolin-4-amine	1000 - 2000 mg/kg ( Rat )	-	-

**Information on likely routes of exposure**

<b>Inhalation</b>	May cause irritation of respiratory tract.
<b>Eye contact</b>	Contact with eyes may cause irritation.
<b>Skin contact</b>	May cause irritation.
<b>Ingestion</b>	May be harmful if swallowed. Reproductive Toxicity. Target Organ Effects.
<b>Symptoms</b>	Diarrhea. Dry skin. hirsutism. rash. Liver transaminase elevation. Shortness of breath or cough.
<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Sensitization</b>	No information available.
<b>Mutagenic effects</b>	The weight of evidence demonstrates that this material is not genotoxic.
<b>Carcinogenic effects</b>	Did not show carcinogenic effects in animal experiments.

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<b>Reproductive toxicity</b>	This material is classified as a Pregnancy Category D: Positive evidence of risk. Erlotinib has been shown to cause maternal toxicity resulting in embryo-fetal lethality and abortion in rabbits when given during the period of organogenesis. Femal rats treated with 30 mg/kg/day of erlotinib had an increase in early resorptions that resulted in a decrease in the number of live fetuses.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	Skin. Eyes. Respiratory system. Reproductive system. Liver.
<b>Aspiration Hazard</b>	No information available.
<b>Other information</b>	No information available.

## SECTION 12: Ecological information

### 12.1. Toxicity

Product does not present an aquatic toxicity hazard based on known or supplied information.

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)quinazolin-4-amine	EC50 >100 mg/L (Selenastrum capricornutum)72H NOEC 1.39 mg/L (Selenastrum capricornutum)72H	LC50 > 100 mg/L (Danio rerio) 96 H	-

### 12.2. Persistence and degradability

Not readily biodegradable. 0% 28 day period: OECD 301C.

### 12.3. Bioaccumulative potential

<b>Bioaccumulation</b>	Not likely to bioaccumulate.
<b>Bioconcentration factor (BCF)</b>	7.8 - 10.1

Chemical Name	Octanol-Water Partition Coefficient
N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)quinazolin-4-amine	2.7

### 12.4. Mobility in soil

Is not likely mobile in the environment due its low water solubility.

### 12.5. Results of PBT and vPvB assessment

No information available.

### 12.6. Other adverse effects

No information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal.
<b>Other information</b>	Waste codes should be assigned by the user based on the application for which the product was used.

## SECTION 14: Transport information

### IMDG/IMO

<b>14.1 UN number</b>	Not regulated
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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 hazards	None
14.6 Special precautions for user	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not regulated

**ADR/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 hazards	None
14.6 Special precautions for user	None

**IATA**

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 hazards	None
14.6 Special precautions for user	None

<b>SECTION 15: Regulatory information</b>
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**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Candidate List of Substances of Very High Concern for Authorization Information**

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

**SEVESO Directive Information**

This product does not contain substances identified in the SEVESO Directive.

**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

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

H302 - Harmful if swallowed

H361 - Suspected of damaging fertility or the unborn child if swallowed

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

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

**Issuing Date:** 2015-03-27

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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.**