

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

Issuing Date: 2015-03-27

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Version: 4

SECTION 1. Identification

Product identifier

Product No 5083
Product name Erlotinib

Recommended use of the chemical and restrictions on use

Identified uses This product is intended for research purposes only.

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
Reproductive toxicity	Category 2
Specific target organ toxicity - repeated exposure (STOT RE)	Category 2

GHS Label elements, including precautionary statements



Signal Word
 Warning.

Hazard statement(s)
 Harmful if swallowed.

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.
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.
IF exposed or concerned: Get medical advice/attention
IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth.
Store locked up.
Dispose of contents/container to an approved waste disposal plant.

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

Not applicable.

SECTION 3. Composition/information on ingredients

Formula $C_{22}H_{23}N_3O_4$
Molecular Weight 393.44 g/mol
Synonyms Erlotinib;
TARCEVA®;
UNII-J4T82NDH7E;
4-Quinazolinamine, N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)-

Chemical name	CAS No	Weight-%
N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)quinazolin-4-amine	183321-74-6	100

SECTION 4. First-aid measures

Eye contact Rinse thoroughly with plenty of water, also under the eyelids.
Skin contact Wash skin with soap and water.
Inhalation Move to fresh air.
Ingestion Clean mouth with water and afterwards drink plenty of water.

Most important symptoms and effects, both acute and delayed

Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.

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.

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. Beware of vapors accumulating to form explosive concentrations. Vapors can accumulate in low areas.

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**

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.

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	Color	White
Appearance	Crystalline Powder	Odor Threshold	No information available
Odor	No information available		
<u>Property</u>	<u>Values</u>	<u>Remarks</u>	<u>Method</u>
pH	No information available		
Melting point/freezing point	167-180 °C		
Boiling point or initial boiling point and boiling range			
Flash point		-	
Evaporation rate	No information available		
Flammability	No information available		
Upper flammability limit	No information available		
Lower flammability limit	No information available		
Vapor pressure	No information available		
Relative vapor density	No information available		
Density and/or relative density	No information available		
Solubility	Partly soluble		
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		
Explosive properties	No information available		
Oxidizing properties	No information available		
<u>Other information</u>			
Softening point	No information available		
Molecular Weight	393.44		
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	Contact with eyes may cause irritation.
Skin contact	May cause irritation.
Ingestion	May be harmful if swallowed. Reproductive Toxicity. Target Organ Effects.

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)	-	-

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

Symptoms	Symptoms of overexposure may be headache, dizziness, tiredness, nausea and vomiting.
Sensitization	No information available.
Mutagenic effects	The weight of evidence demonstrates that this material is not genotoxic.
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	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.
STOT - single exposure	No information available.
STOT - repeated exposure	Skin. Eyes. Respiratory system. Reproductive system. Liver.
Neurological effects	No information available.
Aspiration Hazard	No information available.

SECTION 12. Ecological information

Ecotoxicity

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	-

Persistence and degradability

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

Mobility

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

Bioaccumulation

Not likely to bioaccumulate.

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

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. Dispose of wastes in an approved waste disposal facility.

SECTION 14. Transport information

This material is not subject to regulation as a hazardous material for shipping.

SECTION 15. Regulatory information

North American Inventory Listing

Chemical name	TSCA 8(b)	TSCA 12(b)	DSL	NDSL
N-(3-ethynylphenyl)-6,7-bis(2-methoxyethoxy)quinazolin-4-amine	Not Listed	Not Listed	Not Listed	Not Listed

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

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