

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

SECTION 1. Identification

Product identifier

Product No 12121
Product name Lapatin
Other means of identification 12121S

Recommended use of the chemical and restrictions on use

Identified usesThis 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 www.cellsignal.com

Website www.cellsignal.com 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)

Reproductive toxicity	Category 1B
Specific target organ toxicity - repeated exposure (STOT RE)	Category 1

GHS Label elements, including precautionary statements



Signal Word Danger

Hazard statement(s)

May damage fertility or the unborn child. Causes 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.

Store locked up.

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

Supplementary Hazard Information

No information available.

Hazards not otherwise classified (HNOC)

May cause long lasting harmful effects to aquatic life.

SECTION 3. Composition/information on ingredients

Formula C29H26CIFN4O4S (C7H8O3S)2

Molecular Weight 925.46 g/mol

Chemical nature Monoconstituent substance Synonyms Lapatinib Ditosylate;

Tykerb:

4-Quinazolinamine.

N-(3-chloro-4-((3-fluorophenyl)methoxy)phenyl)-6-(5-(((2-(methylsulfonyl)ethyl)amino)methyllograms and the state of the

I)-2-furanyl), bis(4-methylbenzenesulfonate), monohydrate

Chemical Name	CAS No	Weight %
N-[3-chloro-4-{ [3-(fluorophenyl)methl]oxy}	388082-78-8	100
phenyl)-6-[5-({ [2-(methylsufonyl)ethyl]amino}		
methyl)-2-furanyl]-4-quinazolinamine		
bis(4-methylbenzenesulfonate)		

SECTION 4. First-aid measures

Eye contact Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids.

Consult a physician.

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

Diarrhea. Nausea. rash. Vomiting. tiredness. Loss of appetite. Headache. Dry skin. infection. mouth sores. indigestion. hair loss. nose bleeds.

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

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 Other information

Ensure adequate ventilation. No information available.

Environmental precautions

See Section 12 for additional information.

Methods and material for containment and cleaning up

Methods for containment Methods for cleaning up Prevent further leakage or spillage if safe to do so. Pick up and transfer to properly labeled containers.

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

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 Skin and body protection Safety glasses with side-shields Wear protective gloves/clothing.

Respiratory protection 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

> > Remarks Method

provided in accordance with current local regulations.

Handle in accordance with good industrial hygiene and safety practice. Hygiene measures

SECTION 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state Solid

Appearance Powder Color Yellow

Odor No information available **Odor Threshold** No information available

Property

No information available рH

241-252 °C Melting point/freezing point

Initial boiling point and boiling

range

Flash point **Evaporation rate** No information available

Flammability (solid, gas) No information available Upper flammability limit No information available Lower flammability limit No information available Vapor pressure No information available Vapor density No information available Relative density No information available Practically insoluble Solubility Solubility in other solvents No information available. Partition coefficient: n-octanol/waterNo information available No information available **Autoignition temperature Decomposition temperature** No information available No information available

Viscosity Viscosity, dynamic No information available No information available **Explosive properties** No information available **Oxidizing properties**

Other information

Softening point No information available

Molecular Weight 925.46 a/mol

VOC content No information available **Density** No information available. No information available. **Bulk Density VALUE**

SECTION 10. Stability and reactivity

Reactivity

No information available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

None under normal processing. **Hazardous reactions** 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

InhalationMay cause irritation of respiratory tract.Eye contactContact with eyes may cause irritation.

Skin contact May cause irritation.

Ingestion May cause adverse liver effects. May cause adverse cardiac effects. May cause

gastrointestinal discomfort if consumed in large amounts.

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

Symptoms Diarrhea. Nausea. rash. Vomiting. tiredness. Loss of appetite. Headache. Dry skin.

infection. mouth sores. indigestion. hair loss. nose bleeds.

Sensitization No information available.

Mutagenic effects Did not show mutagenic effects in animal experiments.

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

Developmental toxicity

This material is classified as a Pregnancy Category D: Positive evidence of risk.

Lapatinib was studied for effects on embryo-fetal development in pregnant rats and rabbits given oral doses of 30, 60, and 120 mg/kg/day. Minor anomalies (left-sided umbilical artery, cervical rib, and precocious ossification) occurred in rats at the maternally toxic dose of 120

mg/kg/day. In rabbits, lapatinib was associated with decreased fetal body weights and

minor skeletal variations at 60 and 120 mg/kg/day.

Teratogenicity In a study where pregnant rats were dosed with lapatinib during organogenesis and through

lactation, at a dose of 120 mg/kg/day, 91% of the pups had died by the fourth day after

birth, while 34% of the 60 mg/kg/day pups were dead.

STOT - single exposure No information available.

STOT - repeated exposure May cause disorder and damage to the: Liver, Heart, Respiratory system, Gastrointestinal

tract (GI), Skin.

Neurological effectsNo information available.Aspiration HazardNo information available.

SECTION 12. Ecological information

Ecotoxicity

Mobility

May cause long lasting harmful effects to aquatic life

Persistence and degradability

Bioaccumulation

e and degradability

Not readily biodegradable. 32% 28 day period. Material may have some potential to bioaccumulate.

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

Chemical Name	Octanol-Water Partition Coefficient
N-[3-chloro-4-{ [3-(fluorophenyl)methl]oxy} phenyl)-6-[5-({ [2-(methylsufonyl)ethyl]amino} methyl)-2-furanyl]-4-quinazolinamine bis(4-methylbenzenesulfonate)	4.65 - 6.12

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

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-chloro-4-{	Not Listed	Not Listed	Not Listed	Not Listed
[3-(fluorophenyl)methl]oxy}				
phenyl)-6-[5-({				
[2-(methylsufonyl)ethyl]amino}				
methyl)-2-furanyl]-4-quinazolina				
mine				
bis(4-methylbenzenesulfonate)				

Canadian Workplace Hazardous Materials Information System (WHMIS) Classification

T)	Class D2A - Very Toxic Material at >= 0.1%
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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	No
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

Issuing Date: 2015-01-14 **Revision Date:** 2018-03-23

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