



SAFETY DATA SHEET

73162 - Gefitinib

Revision Date 28-Mar-2018

Revision Number 2

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier

Product Name Gefitinib

Other means of identification

Catalog Number 73162

UN/ID no. UN3077

Document Number DX21185

Synonyms Gefonib; ZD1839;

Recommended use of the chemical and restrictions on use

Recommended Use Laboratory chemicals

STEMCELL TECHNOLOGIES INC.'S QUALITY MANAGEMENT SYSTEM IS CERTIFIED TO ISO 13485. PRODUCTS ARE FOR RESEARCH USE ONLY AND NOT INTENDED FOR HUMAN OR ANIMAL DIAGNOSTIC OR THERAPEUTIC USES UNLESS OTHERWISE STATED.

Details of the supplier of the safety data sheet

Manufacturer/Supplier

STEMCELL Technologies Canada Inc.
Suite 500 - 1618 Station Street
Vancouver, British Columbia V6A 1B6 Canada

Emergency telephone number

Emergency Telephone 1-800-667-0322

2. HAZARDS IDENTIFICATION

Classification

This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral

Category 4

Hazards not otherwise classified (HNOC)

Not applicable

Label elements



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Warning

Hazard statements

Harmful if swallowed



Appearance Crystalline

Physical state Solid

Odor No information available

Precautionary Statements - Prevention

Wash face, hands and any exposed skin thoroughly after handling
Do not eat, drink or smoke when using this product

Precautionary statements - Response

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell
Rinse mouth

Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

Other Information

Very toxic to aquatic life

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)

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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance

Synonyms Gefonib;. ZD1839;.

Chemical name	CAS No.	Weight-%
N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine	184475-35-2	100



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*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

Description of first aid measures

General advice	Show this safety data sheet to the doctor in attendance.
Inhalation	Remove to fresh air.
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.
Ingestion	Do NOT induce vomiting. Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth to an unconscious person. Call a physician.

Most important symptoms and effects, both acute and delayed

Symptoms No information available.

Indication of any immediate medical attention and special treatment needed

Note to physicians Treat symptomatically.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the 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.
Special protective equipment for fire-fighters	Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear. Use personal protection equipment.



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6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Personal precautions Ensure adequate ventilation.

Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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 Pick up and transfer to properly labeled containers.

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

7. HANDLING AND STORAGE

Precautions for safe handling

Advice on safe handling Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Limits The following ingredients are the only ingredients of the product above the cut-off level (or level that contributes to the hazard classification of the mixture) which have an exposure limit applicable in the region for which this safety data sheet is intended or other recommended limit. At this time, the other relevant constituents have no known exposure limits from the sources listed here.

Appropriate engineering controls



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Engineering controls Showers
 Eyewash stations
 Ventilation systems.

Individual protection measures, such as personal protective equipment

Eye/face protection No special protective equipment required.

Skin and body protection No special protective equipment required.

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 Handle in accordance with good industrial hygiene and safety practice.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

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

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
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)	No data available	None known
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
Water solubility	No data available	None known
Solubility in other solvents	~0.5 mg/mL in 1:1 DMSO:PBS (pH 7.2); ~0.3 mg/mL in EtOH; ~20 mg/mL in DMF & DMSO;	None known
Partition coefficient	No data available	None known
Autoignition temperature	No data available	None known
Decomposition temperature	No data available	None known



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Kinematic viscosity	No data available	None known
Dynamic viscosity	No data available	None known
Explosive properties	No information available	
Oxidizing properties	No information available	

Other Information

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

10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Hazardous polymerization	Hazardous polymerization does not occur.
Conditions to avoid	None known based on information supplied.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon monoxide. Carbon dioxide (CO ₂). Hydrogen fluoride. Nitrogen oxides (NO _x). Hydrogen chloride gas.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	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	No information available.
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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)
 100 % of the mixture consists of ingredient(s) of unknown acute inhalation toxicity (dust/mist)

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

- Skin corrosion/irritation** No information available.
Serious eye damage/eye irritation No information available.
Respiratory or skin sensitization No information available.
Germ cell mutagenicity No information available.
Carcinogenicity No information available.
Reproductive toxicity No information available.
STOT - single exposure No information available.
STOT - repeated exposure No information available.
Aspiration hazard No information available.
RTECS # VA0952000

12. ECOLOGICAL INFORMATION

- Ecotoxicity** The environmental impact of this product has not been fully investigated.
Persistence and degradability No information available.
Bioaccumulation There is no data for this product.
Other adverse effects No information available.



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13. DISPOSAL CONSIDERATIONS

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.

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.

DOT

UN/ID no. UN3077
Proper shipping name Environmentally hazardous substances, solid, n.o.s. (Gefitinib)
Hazard class 9 CLASS 9
Packing Group III

TDG

Not regulated

MEX

Not regulated

ICAO (air)

UN/ID no. 3077
Proper shipping name Environmentally hazardous substances, solid, n.o.s. (Gefitinib)
Hazard class 9 - CLASS 9
Packing Group III

IATA

UN Number 3077
Transport hazard class(es) 9 - CLASS 9
Packing Group III

IMDG

Not regulated

RID

UN Number 3077



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UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Gefitinib)
Transport hazard class(es) 9 - CLASS 9
Packing Group III

ADR

UN Number 3077
UN proper shipping name Environmentally hazardous substances, solid, n.o.s. (Gefitinib)
Transport hazard class(es) 9 - CLASS 9
Packing Group III

ADN

Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Does not comply
DSL/NDSL	Does not comply
EINECS/ELINCS	Does not comply
ENCS	Does not comply
IECSC	Does not comply
KECL	Does not comply
PICCS	Does not comply
AICS	Does not comply

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 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

US Federal Regulations

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

CWA (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



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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.

US State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals.

U.S. State Right-to-Know Regulations

US State Regulations

This product does not contain any substances regulated by state right-to-know regulations

U.S. EPA Label Information

EPA Pesticide Registration Number Not applicable

16. OTHER INFORMATION, INCLUDING DATE OF PREPARATION OF THE LAST REVISION

Prepared By, Quality Control. STEMCELL Technologies Canada Inc.

Revision Date 28-Mar-2018

Revision Note No information available.

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.

End of Safety Data Sheet