



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

Issuing Date: 2014-03-18

Revision Date: 2017-08-30

Version: 2

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

1.1. Product identifier

Product No 12616
Product name Vandetanib
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

Formula $C_{22}H_{24}BrFN_4O_2$
Molecular Weight 475.35
Other means of identification 12616S

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) 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	Manufacturer Cell Signaling Technology, Inc. 3 Trask Lane Danvers, MA 01923 United States TEL: +1 978 867 2300 FAX: +1 978 867 2400
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Website www.cellsignal.com
E-mail Address 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

Acute oral toxicity	Category 4 - (H302)
Reproductive toxicity	Category 1B - (H360Df)
Specific target organ toxicity - repeated exposure (STOT RE)	Category 2 - (H373)
Acute aquatic toxicity	Category 1 - (H400)
Chronic aquatic toxicity	Category 1 - (H410)

2.2. Label elements

**Signal word**

Danger

Hazard statement(s)

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

H410 - Very toxic to aquatic life with long lasting effects

H302 - Harmful if swallowed

H360Df - May damage the unborn child. Suspected of damaging fertility

Precautionary statement(s)

P202 - Do not handle until all safety precautions have been read and understood

P260 - Do not breathe dust

P273 - Avoid release to the environment

P281 - Use personal protective equipment as required

P314 - Get medical advice/attention if you feel unwell

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

2.3. Other hazards

None under normal use conditions.

SECTION 3: Composition/information on ingredients

3.1 Substances**Synonyms**

Vandetanib; Caprelsa; Zactima; ZD6474

FormulaC22H24BrFN4O2**Chemical nature**

Monoconstituent substance.

Chemical Name	CAS No	Weight %	EC No	Classification (1272/2008)	REACH Registration Number
N-(4-bromo-2-fluorophenyl)-6-methoxy-7-[(1-methylpiperidin-4-yl)methoxy]quinazolin-4-amine	443913-73-3	100	-	Acute Tox. 1 (H302) Repr. 1B (H360Df) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 1 (H410)	no data available

For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16

SECTION 4: First aid measures

4.1. Description of first aid measures**General advice**

Use first aid treatment according to the nature of the injury. When symptoms persist or in all cases of doubt seek medical advice.

Inhalation

Move to fresh air.

Skin contact

Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.

Eye contact

Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.

Ingestion Rinse mouth. Never give anything by mouth to an unconscious person.

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

Diarrhea, Nausea, Headache, rash, tiredness, Abdominal pain.

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

Notes to physician Exposure may cause a serious skin reaction, called Stevens-Johnson syndrome or other serious skin reactions which may be life threatening. May cause a breathing problem called interstitial lung disease that can lead to death. Torsades de pointes, ventricular tachycardia and sudden deaths have been reported in patients administered vandetanib.

SECTION 5: Firefighting 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

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

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

6.2. Environmental precautions

Do not flush into surface water or sanitary sewer system.

6.3. 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.

6.4. Reference to other sections

See Sections 8 & 13 for additional information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Do not eat, drink or smoke when using this product.

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

Physical state	Solid
Appearance	Crystalline Powder
Color	White to off-white
Odor	No information available
Odor Threshold	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
pH		No information available
Melting point/freezing point	221-234 °C	
Initial boiling point and boiling range		No information available
Flash point		No information available.
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
Solubility	Practically insoluble	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
Explosive properties		No information available
Oxidizing properties		No information available

9.2. Other information

Softening point	No information available
Molecular Weight	475.35
Solubility in other solvents	No information available
VOC content	No information available
Density	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

Hazardous polymerization
Hazardous reactions

Hazardous polymerization does not occur.
None under normal processing.

10.4. Conditions to avoid

Dust formation.

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-(4-bromo-2-fluorophenyl)-6-methoxy-7-[(1-methylpiperidin-4-yl)methoxy]quinazolin-4-amine	= LD 2000 mg/kg (Rat)	-	-

Information on likely routes of exposure

Inhalation

There is no data available for this product.

Eye contact

There is no data available for this product.

Skin contact

There is no data available for this product.

Ingestion

Harmful if swallowed. Target Organ Effects.

Symptoms

Diarrhea. Nausea. Headache. rash. tiredness. Abdominal pain.

Skin corrosion/irritation

No information available.

Serious eye damage/eye irritation

No information available.

Sensitization

No information available.

Mutagenic effects

Not mutagenic in AMES Test.

Carcinogenic effects

No information available.

Reproductive toxicity

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

Developmental toxicity

Doses of 1, 10 and 25 mg/kg/day (Rats): Caused malformations of the heart vessels and delayed ossification of the skull, vertebrae and sternum, indicating delayed fetal development.

Teratogenicity

Caused total litter loss when administered at a dose of 25 mg/kg/day during organogenesis until expected parturition.

STOT - single exposure

No information available.

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STOT - repeated exposure Kidney. Liver. Gastrointestinal tract (GI). Skin.
Aspiration Hazard No information available.
Other information No information available.

SECTION 12: Ecological information

12.1. Toxicity

Very toxic to aquatic life with long lasting effects

Chemical Name	Toxicity to algae	Toxicity to fish	Toxicity to daphnia and other aquatic invertebrates
N-(4-bromo-2-fluorophenyl)-6-methoxy-7-[(1-methylpiperidin-4-yl)methoxy]quinazolin-4-amine	ErC50 0.303 mg/l (Green algae) 72 h	LC50 2.5 mg/l (Rainbow trout) 96 h	-

12.2. Persistence and degradability

Not readily biodegradable.

12.3. Bioaccumulative potential

Bioaccumulation Not likely to bioaccumulate.
Bioconcentration factor (BCF) No information available.

12.4. Mobility in soil

Mobility in soil.

12.5. Results of PBT and vPvB assessment

No information available.

12.6. Other adverse effects

Evidence of inhibition to aerobic process at 10-100mg/l (EC20)

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

SECTION 14: Transport information

IMDG/IMO

14.1 UN number UN3077
14.2 UN proper shipping name (Vandetanib)
14.3 Transport hazard class(es) 9
14.4 Packing group III
14.5 Environmental hazards Yes
14.6 Special precautions for user None
EmS No. F-A, S-F
14.7 Transport in bulk according to Not regulated

Annex II of MARPOL 73/78 and the IBC Code**ADR/RID**

14.1 UN number	UN3077
14.2 UN proper shipping name	(Vandetanib)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
14.5 Environmental hazards	Yes
14.6 Special precautions for user	None
Classification Code	M7
Tunnel Restriction Code	(E)

IATA

14.1 UN number	UN3077
14.2 UN proper shipping name	(Vandetanib)
14.3 Transport hazard class(es)	9
14.4 Packing group	III
14.5 Environmental hazards	Yes
14.6 Special precautions for user	None
Special provisions	A158, A179, A97

SECTION 15: Regulatory information**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

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

H302 - Harmful if swallowed

H360Df - May damage the unborn child. Suspected of damaging fertility
H373 - May cause damage to organs through prolonged or repeated exposure
H400 - Very toxic to aquatic life
H410 - Very toxic to aquatic life with long lasting effects

Classification procedure: Expert judgment and weight of evidence determination.

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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.