

This safety data sheet was created pursuant to the requirements of: Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

Revision Date 14-Nov-2022 Revision Number 3

73532 73534 - Vandetanib

Section 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Document Number DX21222

Product Name Vandetanib

Synonyms CH 331; Zactima; ZD 6474;

N-(4-bromo-2-fluorophenyl)-6-methoxy-7-[(1-methyl-4-piperidinyl)methoxy]-4-quinazolinami

ne;

Pure substance/mixture Substance

Contains N-(4-bromo-2-fluorophenyl)-6-methoxy-7-[(1-methylpiperidin-4-yl)methoxy]quinazolin-4-amine

Molecular weight 475.4

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

Recommended Use Laboratory chemicals

Uses advised against No information available

1.3. Details of the supplier of the safety data sheet

Manufacturer

STEMCELL Technologies SARL

40 Rue des Berges, Miniparc Polytec, Bâtiment Sirocco, 38000 Grenoble, France

+33 (0) 4 76 04 75 30

STEMCELL Technologies Germany GmbH

Stolberger Str. 200, 50933, Köln, Germany

+33 (0) 4 76 04 75 30

STEMCELL Technologies UK Ltd.

Building 7100, Cambridge Research Park, Beach Drive, Waterbeach, Cambridge, UK, CB25 9TL

+33 (0) 4 76 04 75 30

For further information, please contact

1.4. Emergency telephone number

Emergency Telephone No information available

Emergency Telephone - §45 - (EC)1272/2008 Europe | 112

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Section 2: HAZARDS IDENTIFICATION



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2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 4 - (H302)
Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 2 - (H319)
Reproductive toxicity	Category 1A - (H360)
Specific target organ toxicity (single exposure)	Category 3 - (H335)
Specific target organ toxicity (repeated exposure)	Category 2 - (H373)
Chronic aquatic toxicity	Category 1 - (H410)

2.2. Label elements

Contains N-(4-bromo-2-fluorophenyl)-6-methoxy-7-[(1-methylpiperidin-4-yl)methoxy]quinazolin-4-amine



Signal word Danger

Hazard statements

Hazard statements

- H302 Harmful if swallowed
- H315 Causes skin irritation
- H319 Causes serious eye irritation
- H335 May cause respiratory irritation
- H360 May damage fertility or the unborn child
- H373 May cause damage to organs through prolonged or repeated exposure
- H410 Very toxic to aquatic life with long lasting effects
- H303 May be harmful if swallowed

Precautionary Statements - EU (§28, 1272/2008)

- P201 Obtain special instructions before use
- P202 Do not handle until all safety precautions have been read and understood
- P280 Wear protective gloves/protective clothing/eye protection/face protection
- P308 + P313 IF exposed or concerned: Get medical advice/attention
- P260 Do not breathe dust/fume/gas/mist/vapors/spray
- P314 Get medical advice/attention if you feel unwell
- P501 Dispose of contents/container to industrial incineration plant

Additional information

This product requires tactile warnings if supplied to the general public

2.3. Other hazards

No information available



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Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Chemical name	EC No.	CAS No.	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
N-(4-bromo-2-fluorophenyl)-6-methox y-7-[(1-methylpiperidin-4-yl)methoxy] quinazolin-4-amine		443913-73-3	100	Repr. 1 (H360) STOT RE 2 (H373) Aquatic Chronic 1 (H410) Acute Tox. 4 (H302) Skin Irrit. 2 (H315) Eye Irrit. 2A (H319) STOT SE 3 (H335) Aquatic Acute 3 (H402)	No data available

Full text of H- and EUH-phrases: see section 16

Section 4: FIRST AID MEASURES

4.1. Description of first aid measures

General advice Show this safety data sheet to the doctor in attendance.

Inhalation IF exposed or concerned: Get medical advice/attention. Get medical attention immediately if

symptoms occur. Remove to fresh air.

Eye contact Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes.

Remove contact lenses, if present and easy to do. Continue rinsing. Keep eye wide open while rinsing. Do not rub affected area. Get medical attention if irritation develops and

persists.

Skin contact Wash off immediately with soap and plenty of water for at least 15 minutes. Get medical

attention if irritation develops and persists.

Ingestion Clean mouth with water and drink afterwards plenty of water. Never give anything by mouth

to an unconscious person. Do NOT induce vomiting. Call a physician.

Self-protection of the first aider Avoid contact with skin, eyes or clothing. Wear personal protective clothing (see section 8).

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



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Symptoms Burning sensation.

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

Note to physicians Treat symptomatically.

Section 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

surrounding environment.

Unsuitable Extinguishing Media No information available.

5.2. Special hazards arising from the substance or mixture

Specific hazards arising from the

chemical

No information available.

5.3. Advice for firefighters

Special protective equipment for

fire-fighters

Firefighters should wear self-contained breathing apparatus and full firefighting turnout

gear. Use personal protection equipment.

Section 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Evacuate personnel to safe areas. Ensure adequate ventilation. Avoid contact with skin,

eyes or clothing. Use personal protective equipment as required.

Other Information Refer to protective measures listed in Sections 7 and 8.

6.2. Environmental precautions

Environmental precautions Prevent further leakage or spillage if safe to do so.

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 upTake up mechanically, placing in appropriate containers for disposal.

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

6.4. Reference to other sections

Reference to other sectionsSee section 8 for more information. See section 13 for more information.

Section 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Advice on safe handling Remove contaminated clothing and shoes. Take off contaminated clothing and wash before

reuse. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation. Avoid breathing vapors or mists. In case of insufficient ventilation,

wear suitable respiratory equipment.

General hygiene considerations Wash hands before breaks and immediately after handling the product. Avoid contact with

skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or

smoke when using this product.

7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions Keep out of the reach of children. Store locked up. Store in accordance with information

listed on the Product Information Sheet (PIS).

7.3. Specific end use(s)

Identified Uses

Risk Management Methods (RMM) The information required is contained in this Material Safety Data Sheet.

Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Exposure Limits This product, as supplied, does not contain any hazardous materials with occupational

exposure limits established by the region specific regulatory bodies.

Derived No Effect Level (DNEL) No information available.

Predicted No Effect Concentration No information available.

(PNEC)

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8.2. Exposure controls

Personal protective equipment

Eye/face protection If splashes are likely to occur, wear safety glasses with side-shields.

Hand protection Impervious gloves. Wear suitable gloves.

Skin and body protectionLong sleeved clothing. Wear suitable protective clothing.

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 Wash hands before breaks and immediately after handling the product. Avoid contact with

skin, eyes or clothing. Wear suitable gloves and eye/face protection. Do not eat, drink or

smoke when using this product.

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

ColorNo information availableOdorNo data available.Odor thresholdNo data available

<u>Property</u> <u>Values</u> <u>Remarks • Method</u>

pHNo data availableNone knownMelting point / freezing pointNo data availableNone knownBoiling point / boiling rangeNo data availableNone knownFlash pointNo data availableNone knownEvaporation rateNo data availableNone known

Flammability (solid, gas) Product is not flammable.

Flammability Limit in Air None known

Upper flammability limit: No data available Lower flammability limit: No data available

Vapor pressureNo data availableNone knownVapor densityNo data availableNone knownRelative densityNo data availableNone knownWater solubilityNo data availableNone known

Solubility(ies) DMF: 2 mg/mL; DMF:PBS(pH



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7.2)(1:1): 0.5 mg/mL; DMSO: 2 mg/mL; None known

Partition coefficientNo data availableNone knownAutoignition temperatureNo data availableNone knownDecomposition temperatureNo data availableNone knownKinematic viscosityNo data availableNone knownDynamic viscosityNo data availableNone known

Explosive propertiesNo information available

Oxidizing properties No information available

9.2. Other information

Softening point No information available

Molecular weight 475.4

Molecular formulaC22H24BrFN4O2VOC Content (%)No information availableLiquid DensityNo information availableBulk densityNo information available

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity

Reactivity No information available.

10.2. Chemical stability

Stability Stable under recommended transport or storage conditions.

Explosion data

Sensitivity to Mechanical Impact None.

Sensitivity to Static Discharge None 10.3. Possibility of hazardous reactions

Possibility of hazardous reactions None under normal processing.

10.4. Conditions to avoid

Conditions to avoidNone known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

Hazardous decomposition products Carbon oxides. Nitrogen oxides (NOx). Hydrogen bromide gas. Hydrogen fluoride.

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Section 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

Information on likely routes of exposure

Product Information

Inhalation Specific test data for the substance or mixture is not available. May cause irritation of

respiratory tract.

Eye contact Irritating to eyes. Specific test data for the substance or mixture is not available. Causes

serious eye irritation. (based on components).

Skin contact Causes skin irritation. (based on components). Specific test data for the substance or

mixture is not available.

Ingestion Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. 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 Redness. May cause redness and tearing of the eyes.

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).

Product Information

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



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Skin corrosion/irritation	Classification based on data available for ingredients. Irritating to skin.			
Product Information				
Serious eye damage/eye irritation Product Information	Classification based on data available for ingredients. Irritating to eyes.			
Respiratory or skin sensitization Product Information	No information available.			
Germ cell mutagenicity Product Information	No information available.			
Carcinogenicity Product Information	No information available.			
Reproductive toxicity	Classification based on data available for ingredients.			
Product Information				
STOT - single exposure	May cause respiratory irritation.			
Product Information				
STOT - repeated exposure Product Information	May cause damage to organs.			
Aspiration hazard	No information available.			

Section 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecotoxicity Very toxic to aquatic life with long lasting effects.

Unknown aquatic toxicityContains 0 % of components with unknown hazards to the aquatic environment.

Product Information

12.2. Persistence and degradability

Persistence and degradability No information available.

12.3. Bioaccumulative potential

Bioaccumulation No information available.

12.4. Mobility in soil



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Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessmentNo information available.

12.6. Other adverse effects

Other adverse effects No information available.

Section 13: DISPOSAL CONSIDERATIONS

13.1. 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.

Section 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.

IMDG

14.1 UN Number UN3077

14.2 UN proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Vandetanib)

14.3 Transport hazard class(es) 9 Miscellaneous dangerous substances and articles

14.4 Packing Group

14.5 Marine pollutant Not applicable

14.6 Special Provisions None

14.7. Transport in bulk according to No information available

Annex II of MARPOL and the IBC

Code

RID

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated

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14.5 Environmental hazard Not applicable

14.6 Special Provisions None

ADR

14.1 UN NumberNot regulated14.2 UN proper shipping nameNot regulated14.3 Transport hazard class(es)Not regulated14.4 Packing GroupNot regulated14.5 Environmental hazardNot applicable

14.6 Special Provisions None

IATA

14.1 UN Number UN3077

14.2 UN proper shipping name Environmentally hazardous substance, solid, n.o.s. (Vandetanib)

14.3 Transport hazard class(es) 9 Miscellaneous dangerous substances and articles

14.4 Packing Group

14.5 Environmental hazard Not applicable

14.6 Special Provisions None

Section 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

European Union

Take note of Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work

Authorizations and/or restrictions on use:

This product does not contain substances subject to authorization (Regulation (EC) No. 1907/2006 (REACH), Annex XIV) This product does not contain substances subject to restriction (Regulation (EC) No. 1907/2006 (REACH), Annex XVII)

Persistent Organic Pollutants

Not applicable

Dangerous substance category per Seveso Directive (2012/18/EU)

E1 - Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1

Ozone-depleting substances (ODS) regulation (EC) 1005/2009 Not applicable

International Inventories

TSCA Does not comply



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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

15.2. Chemical safety assessment

Chemical Safety Report No information available

Section 16: OTHER INFORMATION

Key or legend to abbreviations and acronyms used in the safety data sheet

Full text of H-Statements referred to under section 3

H302 - Harmful if swallowed

H315 - Causes skin irritation

H319 - Causes serious eye irritation

H335 - May cause respiratory irritation

H360 - May damage fertility or the unborn child

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

H402 - Harmful to aquatic life

H410 - Very toxic to aquatic life with long lasting effects

Legend

SVHC: Substances of Very High Concern for Authorization:

Legend Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

TWA TWA (time-weighted average) STEL STEL (Short Term Exposure Limit)

Ceiling Maximum limit value * Skin designation

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