



SAFETY DATA SHEET

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

Revision Date 26-Mar-2024

Revision Number 3.1

73072 73074 - Dabrafenib

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

1.1. Product identifier

Document Number DX21176

Product Name Dabrafenib

Synonym Dabarefenib; GSK 2118436;
N-[3-[5-(2-amino-4-pyrimidinyl)-2-(1,1-dimethylethyl)-4-thiazolyl]-2-fluorophenyl]-2,6-difluorobenzenesulfonamide;

Pure substance/mixture Substance

Contains N-[3-[5-(2-aminopyrimidin-4-yl)-2-tert-butyl-1,3-thiazol-4-yl]-2-fluorophenyl]-2,6-difluorobenzenesulfonamide

Molecular weight 519.6

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 |

Section 2: HAZARDS IDENTIFICATION



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2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

| | |
|--|---------------------|
| Reproductive toxicity | Category 2 - (H361) |
| Specific target organ toxicity (repeated exposure) | Category 2 - (H373) |
| Chronic aquatic toxicity | Category 2 - (H411) |

2.2. Label elements

Contains N-[3-[5-(2-aminopyrimidin-4-yl)-2-tert-butyl-1,3-thiazol-4-yl]-2-fluorophenyl]-2,6-difluorobenzenesulfonamide



Signal word

Warning

Hazard statements

Hazard statements

H361 - Suspected of damaging fertility or the unborn child

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

H411 - Toxic to aquatic life with long lasting effects

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

Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Synonym

| Chemical name | EC No. | CAS No. | Weight-% | Classification according to | REACH |
|---------------|--------|---------|----------|-----------------------------|-------|
|---------------|--------|---------|----------|-----------------------------|-------|



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| | | | | Regulation (EC) No. 1272/2008 [CLP] | Registration Number |
|---|---|--------------|-----|--|------------------------|
| N-[3-[5-(2-aminopyrimidin-4-yl)-2-tert-butyl-1,3-thiazol-4-yl]-2-fluorophenyl]-2,6-difluorobenzenesulfonamide | - | 1195765-45-7 | 100 | Repr. 2 (H361) STOT RE 2 (H373) Aquatic Acute 1 (H400) Aquatic Chronic 2 (H411) | 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 | 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. In the case of skin irritation or allergic reactions see a physician. |
| Ingestion | Clean mouth with water and drink afterwards plenty of water. |

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

| | |
|-----------------|---------------------------|
| Symptoms | No information available. |
|-----------------|---------------------------|

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

| | |
|---------------------------------------|---|
| 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



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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 Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.

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

For emergency responders Use personal protection recommended in Section 8.

6.2. Environmental precautions

Environmental precautions See Section 12 for additional Ecological Information.

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 Take up mechanically, placing in appropriate containers for disposal.

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

6.4. Reference to other sections

Reference to other sections See 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 Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes. Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation.

General hygiene considerations Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.



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7.2. Conditions for safe storage, including any incompatibilities

Storage Conditions 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 (PNEC) No information available.

8.2. Exposure controls

Personal protective equipment

Eye/face protection No special protective equipment required.

Hand protection Wear suitable gloves.

Skin and body protection 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 Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

Environmental exposure controls No information available.



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Section 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

| | |
|----------------|--------------------------|
| Physical state | Solid |
| Appearance | Crystalline |
| Color | No information available |
| Odor | No data available. |
| Odor threshold | No data available |

| Property | Values | Remarks • Method |
|--------------------------------|--|------------------|
| 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) | Product is not flammable. | 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(ies) | DMF: 30 mg/mL; DMSO: 30 mg/mL; DMSO: PBS (pH 7.2) (1:1): 0.5 mg/mL; Ethanol: 1 mg/mL | |
| Partition coefficient | No data available | None known |
| Autoignition temperature | No data available | None known |
| Decomposition temperature | No data available | None known |
| Kinematic viscosity | No data available | None known |
| Dynamic viscosity | No data available | None known |
| Explosive properties | No information available | |

Oxidizing properties No information available

9.2. Other information

| | |
|-------------------|--------------------------|
| Softening point | No information available |
| Molecular weight | 519.6 |
| Molecular formula | C23H20F3N5O2S2 |
| VOC Content (%) | No information available |
| Liquid Density | No information available |
| Bulk density | No information available |

Section 10: STABILITY AND REACTIVITY

10.1. Reactivity



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Reactivity No information available.

10.2. Chemical stability

Stability Stable under normal 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 avoid None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.

10.6. Hazardous decomposition products

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

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.

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.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms No information available.



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Numerical measures of toxicity

Acute toxicity

Unknown acute toxicity 100 % of the mixture consists of ingredient(s) of unknown toxicity.
100 % 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

Skin corrosion/irritation No information available.

Product Information

Serious eye damage/eye irritation No information available.

Product Information

Respiratory or skin sensitization No information available.

Product Information

Germ cell mutagenicity No information available.

Product Information

Carcinogenicity No information available.

Product Information

Reproductive toxicity Classification based on data available for ingredients.

Product Information

STOT - single exposure No information available.

Product Information

STOT - repeated exposure May cause damage to organs.

Product Information

Aspiration hazard No information available.

Section 12: ECOLOGICAL INFORMATION



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12.1. Toxicity

Ecotoxicity Toxic to aquatic life with long lasting effects.

Unknown aquatic toxicity Contains 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

Mobility in soil No information available.

12.5. Results of PBT and vPvB assessment

PBT and vPvB assessment No 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: IATA - When sold in quantities of less than or equal to 1mL, or 1g, with an Excepted Quantity Code of E1, E2, E4, or E5, this item meets the De Minimis Quantities exemption,



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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. (Dabrafenib); |
| 14.3 Transport hazard class(es) | 9 Miscellaneous dangerous substances and articles |
| 14.4 Packing Group | III |
| 14.5 Marine pollutant | Not applicable |
| 14.6 Special Provisions | None |
| 14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code | No information available |

RID

| | |
|---------------------------------|----------------|
| 14.1 UN Number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing Group | Not regulated |
| 14.5 Environmental hazard | Not applicable |
| 14.6 Special Provisions | None |

ADR

| | |
|---------------------------------|----------------|
| 14.1 UN Number | Not regulated |
| 14.2 UN proper shipping name | Not regulated |
| 14.3 Transport hazard class(es) | Not regulated |
| 14.4 Packing Group | Not regulated |
| 14.5 Environmental hazard | Not 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.(Dabrafenib); |
| 14.3 Transport hazard class(es) | 9 Miscellaneous dangerous substances and articles |
| 14.4 Packing Group | III |
| 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



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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)

E2 - Hazardous to the Aquatic Environment in Category Chronic 2

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

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

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

H361 - Suspected of damaging fertility or the unborn child



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

H400 - Very toxic to aquatic life

H411 - 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

Revision Date

26-Mar-2024

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006

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.