



# SAFETY DATA SHEET

73072 73074 - Dabrafenib

Revision Date 26-Mar-2024

Revision Number 3.1

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

### Product identifier

Product Name Dabrafenib

### Other means of identification

Catalog Number 73072 73074

UN/ID no. UN3077

Document Number DX21176

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

### Recommended use of the chemical and restrictions on use

Recommended Use Laboratory chemicals

### 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)

Reproductive toxicity	Category 2
Specific target organ toxicity (repeated exposure)	Category 2

### Hazards not otherwise classified (HNOC)

Not applicable




# SAFETY DATA SHEET

73072 73074 - Dabrafenib

Revision Date 26-Mar-2024

Revision Number 3.1

## Label elements

<b>Warning</b>		
<b>Hazard statements</b> Suspected of damaging fertility or the unborn child May cause damage to organs through prolonged or repeated exposure		
		
<b>Appearance</b> Crystalline	<b>Physical state</b> Solid	<b>Odor</b> No data available

### Precautionary Statements - Prevention

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Wear protective gloves/protective clothing/eye protection/face protection  
Do not breathe dust/fume/gas/mist/vapors/spray

### Precautionary statements - Response

IF exposed or concerned: Get medical advice/attention

### Precautionary Statements - Storage

Store locked up

### Precautionary Statements - Disposal

Dispose of contents/container to an approved waste disposal plant

### Other Information

Toxic to aquatic life with long lasting effects

**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)

## 3. COMPOSITION/INFORMATION ON INGREDIENTS

### Substance



# SAFETY DATA SHEET

73072 73074 - Dabrafenib

Revision Date 26-Mar-2024

Revision Number 3.1

## Synonym

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

Chemical name	CAS No.	Weight-%
N-[3-[5-(2-aminopyrimidin-4-yl)-2-tert-butyl-1,3-thiazol-4-yl]-2-fluorophenyl]-2,6-difluorobenzenesulfonamide	1195765-45-7	100

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

## 4. FIRST AID MEASURES

### Description of first aid measures

<b>General advice</b>	Show this safety data sheet to the doctor in attendance.
<b>Inhalation</b>	Remove to fresh air.
<b>Eye contact</b>	Rinse thoroughly with plenty of water for at least 15 minutes, lifting lower and upper eyelids. Consult a physician.
<b>Skin contact</b>	Wash skin with soap and water.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water.

### 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

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable extinguishing media</b>	CAUTION: Use of water spray when fighting fire may be inefficient.
<b>Specific hazards arising from the chemical</b>	No information available.



# SAFETY DATA SHEET

73072 73074 - Dabrafenib

Revision Date 26-Mar-2024

Revision Number 3.1

## 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.

## 6. ACCIDENTAL RELEASE MEASURES

### 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.

### 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

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.

### Conditions for safe storage, including any incompatibilities

#### Storage Conditions

Store locked up. Store in accordance with information listed on the Product Information Sheet (PIS).



# SAFETY DATA SHEET

73072 73074 - Dabrafenib

Revision Date 26-Mar-2024

Revision Number 3.1

## 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**

**Engineering controls**                      Showers  
 Eyewash stations  
 Ventilation systems.

**Individual protection measures, such as 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.

## 9. PHYSICAL AND CHEMICAL PROPERTIES

**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

<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



# SAFETY DATA SHEET

Revision Date 26-Mar-2024

Revision Number 3.1

73072 73074 - Dabrafenib

<b>Flash point</b>	No data available	None known
<b>Evaporation rate</b>	No data available	None known
<b>Flammability (solid, gas)</b>	Product is not flammable.	None known
<b>Flammability Limit in Air</b>		None known
<b>Upper flammability limit:</b>	No data available	
<b>Lower flammability limit:</b>	No data available	
<b>Vapor pressure</b>	No data available	None known
<b>Vapor density</b>	No data available	None known
<b>Relative density</b>	No data available	None known
<b>Water solubility</b>	No data available	None known
<b>Solubility in other solvents</b>	DMF: 30 mg/mL; DMSO: 30 mg/mL; DMSO: PBS (pH 7.2) (1:1): 0.5 mg/mL; Ethanol: 1 mg/mL	
<b>Partition coefficient</b>	No data available	None known
<b>Autoignition temperature</b>	No data available	None known
<b>Decomposition temperature</b>	No data available	None known
<b>Kinematic viscosity</b>	No data available	None known
<b>Dynamic viscosity</b>	No data available	None known
<b>Explosive properties</b>	No data available	
<b>Oxidizing properties</b>	No information available	
<b><u>Other Information</u></b>		
<b>Softening point</b>	No information available	
<b>Molecular weight</b>	519.6	
<b>Molecular formula</b>	C23H20F3N5O2S2	
<b>VOC Content (%)</b>	No information available	
<b>Liquid Density</b>	No information available	
<b>Bulk density</b>	No information available	

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	No information available.
<b>Chemical stability</b>	Stable under recommended transport or storage conditions.
<b>Possibility of hazardous reactions</b>	None under normal processing.
<b>Conditions to avoid</b>	None known based on information supplied.
<b>Incompatible materials</b>	Strong oxidizing agents.
<b>Hazardous decomposition products</b>	Carbon oxides. Hydrogen fluoride. Hydrogen sulfide. Nitrogen oxides (NOx).

## 11. TOXICOLOGICAL INFORMATION

### Information on likely routes of exposure



# SAFETY DATA SHEET

Revision Date 26-Mar-2024

Revision Number 3.1

73072 73074 - Dabrafenib

## Product Information

<b>Inhalation</b>	Specific test data for the substance or mixture is not available.
<b>Eye contact</b>	Specific test data for the substance or mixture is not available.
<b>Skin contact</b>	Specific test data for the substance or mixture is not available.
<b>Ingestion</b>	Specific test data for the substance or mixture is not available.

## Symptoms related to the physical, chemical and toxicological characteristics

**Symptoms** No information available.

## 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.

**Reproductive toxicity** Classification based on data available for ingredients.

Product Information

**STOT - single exposure** No information available.



# SAFETY DATA SHEET

73072 73074 - Dabrafenib

Revision Date 26-Mar-2024

Revision Number 3.1

**Product Information**

**STOT - repeated exposure** May cause damage to organs.

**Product Information**

**Aspiration hazard** No information available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity** The environmental impact of this product has not been fully investigated.

**Product Information**

**Persistence and degradability** No information available.

**Bioaccumulation** There is no data for this product.

**Other adverse effects** No information available.

**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:** 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, per IATA 2.6.10. Therefore packaging does not have to be labeled as Dangerous Goods/Excepted Quantity.

**DOT**

<b>UN/ID no.</b>	UN3077
<b>Proper shipping name</b>	Environmentally hazardous substance, solid, n.o.s.(Dabrafenib);
<b>Hazard class</b>	9 Miscellaneous dangerous substances and articles
<b>Packing Group</b>	III





# SAFETY DATA SHEET

Revision Date 26-Mar-2024

Revision Number 3.1

**73072 73074 - Dabrafenib**

**TDG** Not regulated

**MEX** Not regulated

**ICAO (air)** Not regulated

**IATA**

**UN Number** UN3077  
**UN proper shipping name** Environmentally hazardous substance, solid, n.o.s.(Dabrafenib);  
**Transport hazard class(es)** 9 Miscellaneous dangerous substances and articles  
**Packing Group** III

**IMDG**

**UN Number** UN3077  
**UN proper shipping name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE,SOLID, N.O.S. (Dabrafenib);  
**Transport hazard class(es)** 9 Miscellaneous dangerous substances and articles  
**Packing Group** III

**RID** Not regulated

**ADR** Not regulated

**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**



# SAFETY DATA SHEET

Revision Date 26-Mar-2024

Revision Number 3.1

**73072 73074 - Dabrafenib**

## **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

## **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 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**

This product does not contain any substances regulated under applicable 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** 26-Mar-2024

**Revision Note** No information available.

### **Disclaimer**



# SAFETY DATA SHEET

73072 73074 - Dabrafenib

Revision Date 26-Mar-2024

Revision Number 3.1

---

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**