

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

Revision Date 16-Nov-2022 Revision Number 3

# 73082 73084 - Dasatinib

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

1.1. Product identifier

**Document Number** DX21177

Product Name Dasatinib

Synonyms BMS 354825; Sprycel;

N-(2-chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]

amino]-5-thiazolecarboxamide;

Pure substance/mixture Substance

Contains N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine

Molecular weight 488.0

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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### 2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Acute toxicity - Oral	Category 3 - (H301)
Skin corrosion/irritation	Category 2 - (H315)
Serious eye damage/eye irritation	Category 1 - (H318)
Carcinogenicity	Category 2 - (H351)
Reproductive toxicity	Category 2 - (H361)
Specific target organ toxicity (repeated exposure)	Category 1 - (H372)
Chronic aquatic toxicity	Category 1 - (H410)

#### 2.2. Label elements

Contains N-(3-chloro-4-fluorophenyl)-7-methoxy-6-(3-morpholin-4-ylpropoxy)quinazolin-4-amine



### Signal word Danger

### **Hazard statements**

# Hazard statements

- H301 Toxic if swallowed
- H315 Causes skin irritation
- H318 Causes serious eye damage
- H351 Suspected of causing cancer
- H361 Suspected of damaging fertility or the unborn child
- H372 Causes damage to organs through prolonged or repeated exposure
- H410 Very toxic to aquatic life with long lasting effects

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

- P301 + P310 IF SWALLOWED: Immediately call a POISON CENTER or doctor
- P280 Wear eye protection/ face protection
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- P310 Immediately call a POISON CENTER or doctor
- P280 Wear protective gloves/protective clothing/eye protection/face protection
- P201 Obtain special instructions before use
- P202 Do not handle until all safety precautions have been read and understood
- 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**



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This product requires child resistant fastenings if supplied to the general public 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 Substances

Chemical name	EC No.	CAS No.	Weight-%	Classification according to Regulation (EC) No. 1272/2008 [CLP]	REACH Registration Number
N-(3-chloro-4-fluorophenyl)-7-methox y-6-(3-morpholin-4-ylpropoxy)quinaz olin-4-amine		302962-49-8	100	Acute Tox. 3 (H301) Skin Irrit. 2 (H315) Eye Dam. 1 (H318) Carc. 2 (H351) Repr. 2 (H361) STOT RE 1 (H372) Aquatic Chronic 1 (H410)	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 Immediate medical attention is required. IF exposed or concerned: Get medical

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

**Inhalation** Remove to fresh air. Get medical attention immediately if symptoms occur.

Eye contact Get immediate medical advice/attention. Do not rub affected area. Rinse immediately with

plenty of water, also under the eyelids, for at least 15 minutes. Keep eye wide open while

rinsing. Remove contact lenses, if present and easy to do. Continue rinsing.

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. Get medical attention.

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



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

**Symptoms** Burning sensation.

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

**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. Avoid contact with skin, eyes or clothing. Ensure

adequate ventilation. 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.

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**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 Remove contaminated clothing and shoes. Ensure adequate ventilation. Handle in

accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Take off contaminated

clothing and wash before reuse.

General hygiene considerations Avoid contact with skin, eyes or clothing. Wash hands before breaks and immediately after

handling the product. 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.



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(PNEC)

8.2. Exposure controls

Personal protective equipment

**Eye/face protection** Tight sealing safety goggles.

**Hand protection** Wear suitable gloves. Impervious gloves.

**Skin and body protection** Wear suitable protective clothing. Long sleeved 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 Avoid contact with skin, eyes or clothing. Wash hands before breaks and immediately after

handling the product. 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>

No data available рΗ None known No data available None known Melting point / freezing point 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 None known

Flammability Limit in Air
Upper flammability limit:
No data available

Lower flammability limit: No data available

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

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None known Water solubility No data available Solubility(ies) DMSO: 200 mg/mL; None known Partition coefficient No data available None known **Autoignition temperature** No data available None known No data available **Decomposition temperature** None known No data available Kinematic viscosity None known No data available None known Dynamic viscosity

**Explosive properties**No information available

Oxidizing properties No information available

9.2. Other information

Softening point No information available

Molecular weight 488.0

Molecular formulaC22H26CIN7O2SVOC 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.

Hazardous polymerization Hazardous polymerization does not occur.

10.4. Conditions to avoid

**Conditions to avoid**None known based on information supplied.

10.5. Incompatible materials

Incompatible materials Strong oxidizing agents.



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10.6. Hazardous decomposition products

Hazardous decomposition products Carbon dioxide (CO2). Carbon monoxide. Hydrogen sulfide. Nitrogen oxides (NOx). Phosgene.

# 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** Severely irritating to eyes. Causes serious eye damage. May cause burns. May cause

irreversible damage to eyes. Specific test data for the substance or mixture is not available.

(based on components).

**Skin contact** Specific test data for the substance or mixture is not available. Causes skin irritation. (based

on components).

**Ingestion** Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea. Specific test

data for the substance or mixture is not available. Toxic if swallowed. (based on

components).

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms Burning. May cause blindness. 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) 100.00 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).

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

Skin corrosion/irritation Classification based on data available for ingredients. Irritating to skin. **Product Information** Serious eye damage/eye irritation Classification based on data available for ingredients. Causes burns. Risk of serious damage to eyes. **Product Information** Respiratory or skin sensitization No information available. Product Information Germ cell mutagenicity No information available. **Product Information** Carcinogenicity Classification based on data available for ingredients. Product Information Classification based on data available for ingredients. Reproductive toxicity **Product Information** STOT - single exposure No information available. Product Information STOT - repeated exposure Causes damage to organs through prolonged or repeated exposure. Product Information

Section 12: ECOLOGICAL INFORMATION
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12.1. Toxicity

**Aspiration hazard** 

**Ecotoxicity** Very toxic to aquatic life with long lasting effects.

No information available.

**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.

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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:** 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** UN2811

**14.2 UN proper shipping name** TOXIC SOLID, ORGANIC, N.O.S. (Dasatinib)

14.3 Transport hazard class(es) 6.1 Toxic substances

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

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RID

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

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** 2811

**14.2 UN proper shipping name** Toxic solid, organic, n.o.s. (Dasatinib)

**14.3 Transport hazard class(es)** 6.1 Toxic substances

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



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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

#### Leaend:

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

H301 - Toxic if swallowed

H315 - Causes skin irritation

H318 - Causes serious eye damage

H351 - Suspected of causing cancer

H361 - Suspected of damaging fertility or the unborn child

H372 - Causes damage to organs through prolonged or repeated exposure

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

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