



# SAFETY DATA SHEET

73302 73304 - Nilotinib

Revision Date 16-Dec-2020

Revision Number 2

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

### Product identifier

Product Name Nilotinib

### Other means of identification

Catalog Number 73302 73304

Document Number DX21199

Synonyms AMN107; Tasigna

### 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)

Specific target organ toxicity (repeated exposure)	Category 1
--	------------

### Hazards not otherwise classified (HNOC)

Not applicable

### Label elements

Danger

Hazard statements



# SAFETY DATA SHEET

**73302 73304 - Nilotinib**

Revision Date 16-Dec-2020

Revision Number 2

Causes damage to organs through prolonged or repeated exposure



**Appearance** Crystalline

**Physical state** Solid

**Odor** No information available

**Precautionary Statements - Prevention**

Do not breathe dust/fume/gas/mist/vapors/spray  
 Wash face, hands and any exposed skin thoroughly after handling  
 Do not eat, drink or smoke when using this product

**Precautionary statements - Response**

Get medical advice/attention if you feel unwell

**Precautionary Statements - Disposal**

Dispose of contents/container to an approved waste disposal plant

**Other Information**

May cause long lasting harmful effects to aquatic life

**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**

**Synonyms** AMN107;. Tasigna.

Chemical name	CAS No.	Weight-%
4-methyl-N-[3-(4-methylimidazol-1-yl)-5-(trifluoromethyl)phenyl]-3-[(4-pyridin-3-yl)pyrimidin-2-yl]amino]benzamide	641571-10-0	100

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



# SAFETY DATA SHEET

73302 73304 - Nilotinib

Revision Date 16-Dec-2020

Revision Number 2

## 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.
<b>Explosion data</b>	
<b>Sensitivity to Mechanical Impact</b>	None.
<b>Sensitivity to Static Discharge</b>	None.
<b>Special protective equipment for fire-fighters</b>	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



# SAFETY DATA SHEET

73302 73304 - Nilotinib

Revision Date 16-Dec-2020

Revision Number 2

<b>Personal precautions</b>	Ensure adequate ventilation. Use personal protective equipment as required. Evacuate personnel to safe areas.
<b>Other Information</b>	Refer to protective measures listed in Sections 7 and 8.
<b><u>Environmental precautions</u></b>	
<b>Environmental precautions</b>	See Section 12 for additional Ecological Information.
<b><u>Methods and material for containment and cleaning up</u></b>	
<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Pick up and transfer to properly labeled containers.
<b>Prevention of secondary hazards</b>	Clean contaminated objects and areas thoroughly observing environmental regulations.

## 7. HANDLING AND STORAGE

### **Precautions for safe handling**

**Advice on safe handling** Handle in accordance with good industrial hygiene and safety practice. Ensure adequate ventilation.

### **Conditions for safe storage, including any incompatibilities**

**Storage Conditions** Store in accordance with information listed on the Product Information Sheet (PIS).

## 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



# SAFETY DATA SHEET

73302 73304 - Nilotinib

Revision Date 16-Dec-2020

Revision Number 2

Eyewash stations  
Ventilation systems.

**Individual protection measures, such as personal protective equipment**

- Eye/face protection** No special protective equipment required.
- Skin and body protection** No special protective equipment required.
- 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** Handle in accordance with good industrial hygiene and safety practice.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**Information on basic physical and chemical properties**

**Physical state** Solid  
**Appearance** Crystalline  
**Color** No information available  
**Odor** No information available  
**Odor threshold** No information 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
Flash point	No data available	None known
Evaporation rate	No data available	None known
Flammability (solid, gas)	No data available	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 in other solvents	~3 mg/mL in DMF; ~10 mg/mL in DMSO;	None known
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



# SAFETY DATA SHEET

Revision Date 16-Dec-2020

Revision Number 2

73302 73304 - Nilotinib

Dynamic viscosity	No data available	None known
Explosive properties	No information available	
Oxidizing properties	No information available	

**Other Information**

Softening point	No information available
Molecular weight	529.5
Molecular formula	C <sub>28</sub> H <sub>22</sub> F <sub>3</sub> N <sub>7</sub> O
VOC Content (%)	No information available
Liquid Density	No information available
Bulk density	No information available

## 10. STABILITY AND REACTIVITY

Reactivity	No information available.
Chemical stability	Stable under normal conditions.
Possibility of hazardous reactions	None under normal processing.
Conditions to avoid	None known based on information supplied.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	Carbon monoxide. Carbon dioxide (CO <sub>2</sub> ). Hydrogen fluoride. Nitrogen oxides (NO <sub>x</sub> ).

## 11. TOXICOLOGICAL INFORMATION

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.
----------	---------------------------

Numerical measures of toxicity



# SAFETY DATA SHEET

**73302 73304 - Nilotinib**

Revision Date 16-Dec-2020

Revision Number 2

**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** No information available.  
 Product Information

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

**STOT - repeated exposure** Causes damage to organs through prolonged or repeated exposure.  
 Product Information

**Aspiration hazard** No information available.  
**RTECS #** CV5581770

**12. ECOLOGICAL INFORMATION**

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

**Persistence and degradability** No information available.



# SAFETY DATA SHEET

**73302 73304 - Nilotinib**

**Revision Date** 16-Dec-2020  
**Revision Number** 2

**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

**DOT** Not regulated

**TDG** Not regulated

**MEX** Not regulated

**ICAO (air)** Not regulated

**IATA** Not regulated

**IMDG** Not regulated

**RID** Not regulated

**ADR** Not regulated

**ADN** Not regulated

## 15. REGULATORY INFORMATION

**International Inventories**

<b>TSCA</b>	Does not comply
<b>DSL/NDSL</b>	Does not comply
<b>EINECS/ELINCS</b>	Does not comply
<b>ENCS</b>	Does not comply





# SAFETY DATA SHEET

Revision Date 16-Dec-2020

Revision Number 2

**73302 73304 - Nilotinib**

**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/NDL** - 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**

**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**

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	Yes
<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	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**



# SAFETY DATA SHEET

73302 73304 - Nilotinib

Revision Date 16-Dec-2020

Revision Number 2

**US State Regulations** This product does not contain any substances regulated by 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** 16-Dec-2020

**Revision Note** No information available.

### 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.

**End of Safety Data Sheet**