

**Safety Data Sheet (SDS)** According to the REACH Regulation (EC) No. 1907/2006

**Issuing Date:** 2015-01-15

**Revision Date:** 2018-03-26

**Version:** 3

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

**Product No** 12209  
**Product name** Nilotinib  
**Reach registration number** This substance/mixture contains only ingredients which have been registered, or are exempt from registration, according to Regulation (EC) No. 1907/2006.

### Contains

**Formula** C<sub>28</sub>H<sub>22</sub>F<sub>3</sub>N<sub>7</sub>O  
**Molecular Weight** 529.52 g/mol

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

**Identified uses** For research use only

### 1.3. Details of the supplier of the safety data sheet

<b>Importer (Applicable in EU only)</b>	<b>Manufacturer</b>
Cell Signaling Technology Europe B.V.	Cell Signaling Technology, Inc.
Schuttersveld 2	3 Trask Lane
2316 ZA Leiden	Danvers, MA 01923
The Netherlands	United States
TEL: +31 (0)71 7200 200	TEL: +1 978 867 2300
FAX: +31 (0)71 891 0098	FAX: +1 978 867 2400

**Website** www.cellsignal.com  
**E-mail Address** info@cellsignal.eu

### 1.4. Emergency telephone number

**CHEMTREC** 24 hours a day, 7 days a week, 365 days a year  
+1 703 527 3887 (INTERNATIONAL) +1 800 424 9300 (NORTH AMERICA)

**Europe** 112

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Regulation (EC) No. 1272/2008

Specific target organ toxicity - repeated exposure (STOT RE)	Category 1 - (H372)
Chronic aquatic toxicity	Category 4 - (H413)

### 2.2. Label elements

**Signal word**

Danger

**Hazard statement(s)**

H372 - Causes damage to organs through prolonged or repeated exposure if swallowed

H413 - May cause long lasting harmful effects to aquatic life

**Precautionary statement(s)**

P260 - Do not breathe dust/fume/gas/mist/vapors/spray

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

P273 - Avoid release to the environment

P314 - Get medical advice/attention if you feel unwell

P501 - Dispose of contents/container to an approved waste disposal plant

**2.3. Other hazards**

For the full text of the H-phrases & EUH-phrases mentioned in this Section, see Section 16

## SECTION 3: Composition/information on ingredients

**3.1 Substances****Synonyms**

Nilotinib;  
Tasigna®;  
AMN 107;  
Benzamide,  
4-methyl-N-[3-(4-methylimidazol-1-yl)-5-(trifluoromethyl)phenyl]-3-[(4-pyridin-3-yl)pyrimidin-2-yl]amino]benzamide

**Formula**C<sub>28</sub>H<sub>22</sub>F<sub>3</sub>N<sub>7</sub>O

Chemical Name	CAS No	Weight %	EC No	Classification (1272/2008)	REACH Registration Number
N-[3-[3-(1H-imidazolyl)propoxy]phenyl]-4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]benzamide	641571-10-0	100	-	Repr. 1B (H360D) Lact. (H362) STOT RE 1 (H372) Aquatic Chronic. 4 (H413)	no data available

For the full text of the R-phrases mentioned in this Section, see Section 16

## SECTION 4: First aid measures

**4.1. Description of first aid measures****General advice**

Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.

**Inhalation**

Immediate medical attention is required. Move to fresh air. If not breathing, give artificial respiration.

**Skin contact**

Immediate medical attention is required. Wash off immediately with soap and plenty of

<b>Eye contact</b>	water removing all contaminated clothes and shoes. Rinse thoroughly with plenty of water, also under the eyelids. Keep eye wide open while rinsing.
<b>Ingestion</b>	Do NOT induce vomiting. Immediate medical attention is required. Never give anything by mouth to an unconscious person. Drink plenty of water.
<b>Protection of first-aiders</b>	Use personal protective equipment. Avoid contact with skin, eyes and clothing.

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

Arthralgia. nasopharyngitis. Nausea. rash. Headache. Fatigue. Pruritus. Vomiting. Diarrhea. Shortness of breath or cough. Constipation. Pyrexia. thrombocytopenia. Neutropenia. anemia.

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

**Notes to physician** Treat symptomatically.

### **SECTION 5: Firefighting measures**

#### **5.1. Extinguishing media**

<b>Suitable Extinguishing Media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Unsuitable Extinguishing Media</b>	No information available.

#### **5.2. Special hazards arising from the substance or mixture**

Thermal decomposition can lead to release of irritating gases and vapors.

#### **5.3. Advice for firefighters**

Wear self-contained breathing apparatus and protective suit. Use personal protective equipment.

### **SECTION 6: Accidental release measures**

#### **6.1. Personal precautions, protective equipment and emergency procedures**

<b>For non-emergency personnel</b>	Evacuate personnel to safe areas. Ensure adequate ventilation.
<b>For emergency responders</b>	Use personal protection recommended in Section 8.

#### **6.2. Environmental precautions**

Do not flush into surface water or sanitary sewer system.

#### **6.3. Methods and material for containment and cleaning up**

<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	Use personal protective equipment. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid dust formation. Clean contaminated surface thoroughly.

#### **6.4. Reference to other sections**

See Sections 8 & 13 for additional information.

### **SECTION 7: Handling and storage**

#### **7.1. Precautions for safe handling**

When using, do not eat, drink or smoke. Provide regular cleaning of equipment, work area and clothing. Avoid contact with skin, eyes and clothing. Wash hands before breaks and immediately after handling the product. Keep away from food, drink and animal feeding stuffs.

**7.2. Conditions for safe storage, including any incompatibilities**

Keep container tightly closed in a dry and well-ventilated place.

**7.3. Specific end use(s)**

Use as a laboratory reagent.

## SECTION 8: Exposure controls/personal protection

**8.1. Control parameters****8.2. Exposure controls****Appropriate engineering controls**

Showers, eyewash stations, and ventilation systems.

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

<b>Eye/face protection</b>	Tightly fitting safety goggles
<b>Skin protection</b>	
<b>Hand protection</b>	Impervious gloves.
<b>Other</b>	Impervious gloves. Impervious clothing.
<b>Respiratory protection</b>	In case of inadequate ventilation wear respiratory protection.

**Environmental Exposure Controls**

No information available.

## SECTION 9: Physical and chemical properties

**9.1. Information on basic physical and chemical properties**

<b>Physical state</b>	Solid
<b>Appearance</b>	Powder
<b>Color</b>	Off-white - Yellow
<b>Odor</b>	No information available
<b>Odor Threshold</b>	No information available

<u>Property</u>	<u>Values</u>	<u>Remarks • Method</u>
<b>pH</b>		No information available
<b>Melting point/freezing point</b>	230 - 242 °C	
<b>Initial boiling point and boiling range</b>		No information available
<b>Flash point</b>		No information available.
<b>Evaporation rate</b>		No information available
<b>Flammability (solid, gas)</b>		No information available
<b>Upper flammability limit</b>		No information available
<b>Lower flammability limit</b>		No information available
<b>Vapor pressure</b>		No information available
<b>Vapor density</b>		No information available
<b>Relative density</b>		No information available
<b>Solubility</b>	Practically insoluble	
<b>Partition coefficient: n-octanol/water</b>		No information available
<b>Autoignition temperature</b>		No information available
<b>Decomposition temperature</b>		No information available.
<b>Viscosity</b>		No information available
<b>Explosive properties</b>		No information available
<b>Oxidizing properties</b>		No information available

**9.2. Other information**

<b>Softening point</b>	No information available
<b>Molecular Weight</b>	529.52 g/mol
<b>Solubility in other solvents</b>	Soluble in dimethyl sulfoxide (DMSO) @ 50 mg/mL
<b>VOC content</b>	No information available
<b>Density</b>	No information available.

## SECTION 10: Stability and reactivity

**10.1. Reactivity**

No information available.

**10.2. Chemical stability**

Stable under normal conditions.

**10.3. Possibility of hazardous reactions**

<b>Hazardous polymerization</b>	Hazardous polymerization does not occur.
<b>Hazardous reactions</b>	None under normal processing.

**10.4. Conditions to avoid**

None known based on information supplied.

**10.5. Incompatible materials**

No information available.

**10.6. Hazardous decomposition products**

None under normal use conditions.

## SECTION 11: Toxicological information

**11.1. Information on toxicological effects**

This material should only be handled by, or under the close supervision of, those properly qualified in the handling and use of potentially hazardous chemicals. It should be borne in mind that the toxicological and physiological properties of this compound is not well defined.

**Information on likely routes of exposure**

<b>Inhalation</b>	May cause irritation of respiratory tract.
<b>Eye contact</b>	Contact with eyes may cause irritation.
<b>Skin contact</b>	May cause irritation.
<b>Ingestion</b>	May be harmful if swallowed: Target Organ Effects.
<b>Symptoms</b>	Arthralgia. nasopharyngitis. Nausea. rash. Headache. Fatigue. Pruritus. Vomiting. Diarrhea. Shortness of breath or cough. Constipation. Pyrexia. thrombocytopenia. Neutropenia. anemia.
<b>Skin corrosion/irritation</b>	No information available.
<b>Serious eye damage/eye irritation</b>	No information available.
<b>Sensitization</b>	No information available.
<b>Mutagenic effects</b>	Did not show mutagenic effects in animal experiments: Negative in the chromosomal aberration assay, Negative in the Ames test, Negative in an in vivo rat micronucleus test.
<b>Carcinogenic effects</b>	A 2-year carcinogenicity study was conducted orally in rats at nilotinib doses of 5, 15, and 40 mg/kg/day. The study was negative for carcinogenic findings.
<b>Reproductive toxicity</b>	This material is classified as a Pregnancy Category D: Positive evidence of risk. In rats,

	nilotinib at doses of 100 mg/kg/day was associated with maternal toxicity (decreased gestation weight, gravid uterine weight, net weight gain, and food consumption). Nilotinib at doses =30 mg/kg/day resulted in embryo-fetal toxicity as shown by increased resorption and post-implantation loss, and at 100 mg/kg/day, a decrease in viable fetuses. In rabbits, maternal toxicity at 300 mg/kg/day was associated with mortality, abortion, decreased gestation weights and decreased food consumption. Embryonic toxicity (increased resorption) and minor skeletal anomalies were observed at a dose of 300 mg/kg/day. One study in lactating rats demonstrates that nilotinib is excreted into milk.
<b>STOT - single exposure</b>	No information available.
<b>STOT - repeated exposure</b>	Causes damage to organs through prolonged or repeated exposure if swallowed: Heart. Liver. Gastrointestinal tract (GI).
<b>Target Organ Effects</b>	Heart, Liver, Gastrointestinal tract (GI), Reproductive system.
<b>Other adverse effects</b>	Tasigna prolongs the QT interval. Sudden deaths have been reported in patients receiving nilotinib.
<b>Aspiration Hazard</b>	No information available.
<b>Other information</b>	No information available.

## SECTION 12: Ecological information

### 12.1. Toxicity

May cause long lasting harmful effects to aquatic life

### 12.2. Persistence and degradability

Not readily biodegradable.

### 12.3. Bioaccumulative potential

<b>Bioaccumulation</b>	No information available.
<b>Bioconcentration factor (BCF)</b>	No information available.

Chemical Name	Octanol-Water Partition Coefficient
N-[3-[3-(1H-imidazolyl)propoxy]phenyl]-4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]benzamide	5.01

### 12.4. Mobility in soil

Is not likely mobile in the environment due its low water solubility.

### 12.5. Results of PBT and vPvB assessment

No information available.

### 12.6. Other adverse effects

No information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

<b>Waste from residues / unused products</b>	Dispose of in accordance with local regulations.
<b>Contaminated packaging</b>	Empty containers should be taken to an approved waste handling site for recycling or disposal.
<b>Other information</b>	According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

## SECTION 14: Transport information

**IMDG/IMO**

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 hazards	None
14.6 Special precautions for user	None
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not regulated

**ADR/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 hazards	None
14.6 Special precautions for user	None

**IATA**

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 hazards	None
14.6 Special precautions for user	None

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Candidate List of Substances of Very High Concern for Authorization Information**

This product does not contain Substances of Very High Concern (SVHC).

**SEVESO Directive Information**

This product does not contain substances identified in the SEVESO Directive.

**International inventories**

TSCA 8(b)	-
DSL/NDL	-
EINECS/ELINCS	-
ENCS	-
IECSC	-
KECL	-
PICCS	-
AICS	-

**International inventories 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 Commercial Chemical Substances/EU 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**

For this substance a chemical safety assessment has not been carried out

## SECTION 16: Other information

### Full text of H-Statements referred to under Sections 2 and 3

H372 - Causes damage to organs through prolonged or repeated exposure if swallowed

H413 - May cause long lasting harmful effects to aquatic life

**Classification procedure:** Expert judgment and weight of evidence determination.

**Issuing Date:** 2015-01-15

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### 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.