

Safety Data Sheet (SDS) According to the OSHA Hazard Communication Standard 29 CFR 1910.1200

Issuing Date: 2015-01-15

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Version: 3

SECTION 1. Identification

Product identifier

Product No 12209
Product name Nilotinib

Recommended use of the chemical and restrictions on use

Identified uses This product is intended for research purposes only.
Manufacturer, importer, supplier

Manufacturer address Cell Signaling Technology, Inc.
 3 Trask Lane
 Danvers, MA 01923
 United States
 TEL: +1 978 867 2300
 FAX: +1 978 867 2400
Website www.cellsignal.com
Email address support@cellsignal.com
Emergency telephone number In case of emergency call CHEMTREC 1-800-424-9300

SECTION 2. Hazard(s) identification

Classification

This substance/mixture is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Specific target organ toxicity - repeated exposure (STOT RE)	Category 1
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GHS Label elements, including precautionary statements



Signal Word
 Danger

Hazard statement(s)
 Causes damage to organs through prolonged or repeated exposure.

Precautionary Statement(s)
 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.
 Get medical advice/attention if you feel unwell.

Dispose of contents/container to an approved waste disposal plant.

Supplementary Hazard Information

No information available.

Hazards not otherwise classified (HNOC)

May cause long lasting harmful effects to aquatic life.

SECTION 3. Composition/information on ingredients

Formula	C ₂₆ H ₂₂ F ₃ N ₇ O
Molecular Weight	529.52 g/mol
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

Chemical Name	CAS No	Weight %
N-[3-[3-(1H-imidazolyl)propoxy]phenyl]-4-methyl-3-[4-(3-pyridinyl)-2-pyrimidinyl]amino]benzamide	641571-10-0	100

SECTION 4. First-aid measures

Eye contact	Rinse thoroughly with plenty of water, also under the eyelids. Keep eye wide open while rinsing.
Skin contact	Immediate medical attention is required. Wash off immediately with soap and plenty of water removing all contaminated clothes and shoes.
Inhalation	Immediate medical attention is required. Move to fresh air. If not breathing, give artificial respiration.
Ingestion	Do NOT induce vomiting. Immediate medical attention is required. Never give anything by mouth to an unconscious person. Drink plenty of water.

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.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

Advice for emergency responders

General advice	Immediate medical attention is required. Show this safety data sheet to the doctor in attendance.
Protection of first-aiders	Use personal protective equipment. Avoid contact with skin, eyes and clothing.

SECTION 5. Fire-fighting measures

Extinguishing media

Suitable Extinguishing Media	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable Extinguishing Media	CAUTION: Use of water spray when fighting fire may be inefficient.

Specific hazards arising from the chemical

No information available.

Explosion Data

Sensitivity to Mechanical Impact None.
Sensitivity to Static Discharge None.

Protective Equipment and Precautions for Firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel Ensure adequate ventilation.
Other information No information available.

Environmental precautions

Do not flush into surface water or sanitary sewer system.

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 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.

SECTION 7. Handling and storage

Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

Conditions for safe storage, including any incompatibilities

Technical measures/Storage conditions Keep containers tightly closed in a dry, cool and well-ventilated place.
Packaging material No information available.
Incompatible products None known based on information supplied.

SECTION 8. Exposure controls/personal protection

Control parameters

Appropriate engineering controls

Showers, eyewash stations, and ventilation systems.

Individual protection measures, such as personal protective equipment

Personal protective equipment (PPE) needs to be selected depending on the implemented engineering controls, frequency/duration of work activities and the concentrations of the hazardous substance.

Eye/face protection Tightly fitting safety goggles
Skin and body protection Wear protective gloves/clothing.
Respiratory protection If exposure limits are exceeded or irritation is experienced, NIOSH/MSHA approved

Hygiene measures

respiratory protection should be worn. Positive-pressure supplied air respirators may be required for high airborne contaminant concentrations. Respiratory protection must be provided in accordance with current local regulations.

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.

SECTION 9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state	Solid	Color	Off-white - Yellow
Appearance	Powder	Odor Threshold	No information available
Odor	No information available		
Property	Values	Remarks	Method
pH	No information available		
Melting point/freezing point	230 - 242 °C		
Initial boiling point and boiling range			
Flash point		-	
Evaporation rate	No information available		
Flammability (solid, gas)	No information available		
Upper flammability limit	No information available		
Lower flammability limit	No information available		
Vapor pressure	No information available		
Vapor density	No information available		
Relative density	No information available		
Solubility	Practically insoluble		
Solubility in other solvents	No information available.		
Partition coefficient: n-octanol/water	No information available		
Autoignition temperature	No information available		
Decomposition temperature	No information available		
Viscosity	No information available		
Viscosity, dynamic	No information available		
Explosive properties	No information available		
Oxidizing properties	No information available		
Other information			
Softening point	No information available		
Molecular Weight	529.52 g/mol		
VOC content	No information available		
Density	No information available.		
Bulk Density VALUE	No information available.		

SECTION 10. Stability and reactivity

Reactivity

No information available.

Chemical stability

Stable under recommended storage conditions.

Possibility of hazardous reactions

Hazardous reactions	None under normal processing.
Hazardous polymerization	None under normal processing.

Conditions to Avoid

No information available.

Incompatible Materials

None known based on information supplied.

Hazardous Decomposition Products

None known based on information supplied.

SECTION 11. Toxicological information

Information on likely routes of exposure

Inhalation	May cause irritation of respiratory tract.
Eye contact	Contact with eyes may cause irritation.
Skin contact	May cause irritation.
Ingestion	May be harmful if swallowed: Target Organ Effects.

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.

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

Symptoms	Arthralgia. nasopharyngitis. Nausea. rash. Headache. Fatigue. Pruritus. Vomiting. Diarrhea. Shortness of breath or cough. Constipation. Pyrexia. thrombocytopenia. Neutropenia. anemia.
Sensitization	No information available.
Mutagenic effects	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.
Carcinogenicity	No component of this product present at levels greater than or equal to 0.1% is identifiable as probable, possible or confirmed carcinogen by IARC, ACGIH, NTP, or OSHA. 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.
Reproductive toxicity	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.
STOT - single exposure	No information available.
STOT - repeated exposure	Causes damage to organs through prolonged or repeated exposure if swallowed: Heart. Liver. Gastrointestinal tract (GI).
Target Organ Effects	Heart, Liver, Gastrointestinal tract (GI), Reproductive system.
Neurological effects	No information available.
Other adverse effects	Tasigna prolongs the QT interval. Sudden deaths have been reported in patients receiving nilotinib.
Aspiration Hazard	No information available.

SECTION 12. Ecological information

Ecotoxicity

Persistence and degradability Not readily biodegradable.
Bioaccumulation No information available.
Mobility Is not likely mobile in the environment due its low water solubility

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

Other adverse effects

No information available.

SECTION 13. Disposal considerations**Waste Disposal Methods**

Should not be released into the environment.

Disposal considerations

Do not empty into drains; dispose of this material and its container in a safe way.


SECTION 14. Transport information

This material is not subject to regulation as a hazardous material for shipping.

SECTION 15. Regulatory information**North American Inventory Listing**

Chemical Name	TSCA 8(b)	TSCA 12(b)	DSL	NDSL
N-[3-[3-(1H-imidazolyl)propoxy]phenyl]-4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]benzamide	Not Listed	Not Listed	Not Listed	Not Listed

Canadian Workplace Hazardous Materials Information System (WHMIS) Classification

	Class D2A - Very Toxic Material at >= 0.1%
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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

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.

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. FIFRA Label Information

This product does not contain any substances regulated as pesticides.

US Commerce Department - Export Administration Regulations Information

This product does not contain any substances regulated under the Chemical Weapons Convention (CWC).

U.S. Drug Enforcement Administration Information

This product does not contain any substances regulated under the DEA.

SECTION 16. Other information

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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.

End of Safety Data Sheet