

May damage fertility or the unborn child
 May cause harm to breast-fed children
 Causes damage to organs through prolonged or repeated exposure

Precautionary Statement(s)

Obtain special instructions before use
 Do not handle until all safety precautions have been read and understood
 Use personal protective equipment as required
 Do not breathe dust/fume/gas/mist/vapors/spray
 Avoid contact during pregnancy/while nursing
 Wash face, hands and any exposed skin thoroughly after handling
 Do not eat, drink or smoke when using this product
 IF exposed or concerned: Get medical advice/attention
 Store locked up
 Dispose of contents/container to an approved waste disposal plant

Supplementary Hazard Information

Hazards not otherwise classified (HNOC) May cause long lasting harmful effects to aquatic life

SECTION 3. Composition/information on ingredients

Formula	C ₂₈ 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

Commonly reported symptoms include: nausea, rash, headache, fatigue, pruritus, vomiting, diarrhea, cough, constipation, arthralgia, nasopharyngitis, pyrexia, night sweats and myelosuppression: thrombocytopenia, neutropenia and 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 and collect in suitable container 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

This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

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 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.
Hygiene measures	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
Appearance	Powder
Odor	No information available
Color	Off-white to pale yellow
Odor Threshold	No information available
pH	No information available
Melting point/freezing point	230 - 242 °C
Initial boiling point and boiling range	No information available
Flash point	No information available.
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.
Explosive properties	No information available
Oxidizing properties	No information available
Molecular Weight	529.52 g/mol
VOC content	No information available
Viscosity	No information available.
Density	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	Inhalation of particulates may cause mechanical irritation to upper respiratory tract.
Eye contact	Contact with eyes may cause mechanical irritation.
Skin contact	Contact with skin may cause mechanical 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	Commonly reported symptoms include: nausea, rash, headache, fatigue, pruritus, vomiting, diarrhea, cough, constipation, arthralgia, nasopharyngitis, pyrexia, night sweats and myelosuppression: thrombocytopenia, neutropenia and 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.
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

Product does not present an aquatic toxicity hazard based on known or supplied information.

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