

Nilotinib (AMN-107) SDS/MSDS (Safety Data Sheet)

1. PRODUCT AND COMPANY IDENTIFICATION

Product identifier

* Product Name: Nilotinib (AMN-107)

* Catalog Number: S1033

* CAS Number: 641571-10-0

* IUPAC Name: 4-methyl-N-(3-(4-methyl-1H-imidazol-1-yl)-5-(trifluoromethyl)phenyl)-3-(4-(pyridin-3-yl)pyrimidin-2-yl amino)benzamide

Relevant identified uses and uses advised against

* Identified uses: For research and development use only; laboratory chemicals; manufacture of substances.

* Uses advised against: Not for pharmaceutical, household, or other unapproved uses.

Details of the supplier

* Company: Selleck Chemicals

* TollFree: +1 877 796-6397

* Tel: +1 832 582-8158

* Fax: +1 832 582-8590

Emergency telephone number

* Emergency phone #: +1 832 582-8158

2. HAZARDS IDENTIFICATION

2.1 GHS classification in accordance with 29 CFR 1910 (OSHA HCS):

Reproductive toxicity: Category 2. H361

Specific target organ toxicity (repeated exposure): Category 1. H372

Specific target organ toxicity (repeated exposure): Category 2. H373

Acute aquatic toxicity: Category 1. H400

Chronic aquatic toxicity: Category 1. H410

Chronic aquatic toxicity: Category 4. H413

2.2 GHS Label elements, including precautionary statements

Hazard Pictogram(s)



Signal Word

Danger

Hazard statement(s)

H361: Suspected of damaging fertility or the unborn child

H372: Causes damage to organs through prolonged or repeated exposure

H373: May causes damage to organs through prolonged or repeated exposure

H400: Very toxic to aquatic life

H410: Very toxic to aquatic life with long lasting effects

H413: May cause long lasting harmful effects to aquatic life

Precautionary statement(s)	None.
Prevention	P203: Obtain, read and follow all safety instructions before use. P260: Do not breathe dust/fume/gas/mist/vapors/spray. P264: Wash hands thoroughly after handling. P270: Do not eat, drink or smoke when using this product. P273: Avoid release to the environment. P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection.
Response	P318: if exposed or concerned, get medical advice. P319: Get medical help if you feel unwell. P391: Collect spillage.
Storage	P405: Store locked up.
Disposal	P501: P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Other hazards

None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Nilotinib (AMN-107)

CAS Number: 641571-10-0

PubChem CID: 644241

Molecular formula: C₂₈H₂₂F₃N₇O

Molecular weight: 529.5 g/mol

IUPAC name:

4-methyl-N-[3-(4-methylimidazol-1-yl)-5-(trifluoromethyl)phenyl]-3-[(4-pyridin-3-yl)pyrimidin-2-yl]amino]benzamide

3.2 Mixtures

Not applicable (pure substance).

4. FIRST-AID MEASURES

4.1 Description of first aid measures

Inhalation: Move to fresh air. Keep at rest in a position comfortable for breathing. Seek medical attention if symptoms persist.

Skin contact: Wash with plenty of soap and water. Remove contaminated clothing. Seek medical attention if irritation develops.

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. Seek medical attention.

Ingestion: Rinse mouth. Do NOT induce vomiting unless directed by medical personnel. Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

See Section 11 (Toxicological Information).

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically. Contact a poison control center or physician for severe exposure.

5. FIRE-FIGHTING MEASURES**5.1 Extinguishing media**

Suitable: Water spray, dry chemical, carbon dioxide (CO₂), alcohol-resistant foam.

Unsuitable: None known.

5.2 Specific hazards arising from the substance or mixture

Combustible. Heating may produce toxic fumes.

5.3 Advice for firefighters

Wear self-contained breathing apparatus (SCBA) and full protective clothing.

Fight fire from upwind. Cool containers with water spray until fire is extinguished.

6. ACCIDENTAL RELEASE MEASURES**6.1 Personal precautions, protective equipment and emergency procedures**

Wear appropriate personal protective equipment (see Section 8).

Avoid breathing dust/vapor. Ensure adequate ventilation.

Evacuate personnel to safe areas. Keep people away from and upwind of spill.

6.2 Environmental precautions

Prevent product from entering drains, waterways, or soil.

Contain spill with inert absorbent material.

6.3 Methods and materials for containment and cleaning up

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Spill kits containing all materials needed to clean up spills of hazardous drugs should be assembled or purchased. These kits should be readily available in all areas where hazardous drugs are routinely handled. If hazardous drugs are being prepared or administered in a nonroutine area (home setting or unusual patient-care area), a spill kit should be obtained by the drug handler. The kit should include two pairs of disposable gloves (one outer pair of utility gloves and one inner latex pair); low-permeability, disposable protective garments (coveralls or gown and shoe covers); safety glasses or splash goggles; respirator; absorbent, plastic-backed sheets or spill pads; disposable toweling; at least 2 sealable thick plastic hazardous waste disposal bags (prelabeled with an appropriate warning label); a disposable scoop for collecting glass fragments; and a puncture-resistant container for glass fragments. All individuals who routinely handle hazardous drugs must be trained in proper spill management and cleanup procedures. Spills and breakages must be cleaned up immediately according to the following procedures. If the spill is not located in a confined space, the spill area should be identified and other people should be prevented from approaching and spreading the contamination. Wearing protective apparel from the spill kit, workers should remove any broken glass fragments and place them in the puncture-resistant container. Liquids should be absorbed with a spill pad; powder should be removed with damp disposable gauze pads or soft toweling. The hazardous material should be completely removed and the area rinsed with water and then cleaned with detergent. The spill cleanup should proceed progressively from areas of lesser to greater contamination. The detergent should be thoroughly rinsed and removed. All contaminated materials should be placed in the disposal bags provided and sealed and transported to a designated containment receptacle. Spills occurring in the biohazard cabinet should be cleaned up immediately; a spill kit should be used if the volume exceeds 150 ml or the contents of one drug vial or ampule. If there is broken glass, utility gloves should be worn to

remove it and place it in the puncture-resistant container located in the biohazard cabinet. The biological safety cabinet, including the drain spillage trough, should be thoroughly cleaned. If the spill is not easily and thoroughly contained, the biological safety cabinet should be decontaminated after cleanup. If the spill contaminates the high efficiency particulate air filter, use of the biological safety cabinet should be suspended until the cabinet has been decontaminated and the high efficiency particulate air filter replaced. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ If hazardous drugs are routinely prepared or administered in carpeted areas, special equipment is necessary to remove the spill. Absorbent powder should be substituted for pads or sheets and left in place on the spill for the time recommended by the manufacturer. The powder should then be picked up with a small vacuum unit reserved for hazardous drug cleanup. The carpet should then be cleaned according to usual procedures. The vacuum bag should be removed and discarded or cleaned, and the exterior of the vacuum cleaner should be washed with detergent and rinsed before being covered and stored. The contaminated powder should be discarded into a sealable plastic bag and segregated with other contaminated waste materials. Alternatively, inexpensive wet or dry vacuum units may be purchased for this express use and used with appropriate cleaners. All such units are contaminated, once used, and must be cleaned, stored, and ultimately discarded /properly/ ... The circumstances and handling of spills should be documented. Health-care personnel exposed during spill management should also complete an incident report or exposure form. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ All contaminated disposables should be contained in sealable bags for transfer to larger waste containers. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ If the biological safety cabinets is equipped with a drainpipe and valve, it may be used to collect rinse water. The collection vessel used must fit well around the drain valve and not allow splashing. Gauze may be used around the connection to prevent aerosol from escaping. The collection vessel must have a tight fitting cover, and all rinse water (gauze, if used) must be disposed of as contaminated waste. /Antineoplastic agents/

SRP: Expired or waste pharmaceuticals shall carefully take into consideration applicable DEA, EPA, and FDA regulations. It is not appropriate to dispose by flushing the pharmaceutical down the toilet or discarding to trash. If possible return the pharmaceutical to the manufacturer for proper disposal being careful to properly label and securely package the material. Alternatively, the waste pharmaceutical shall be labeled, securely packaged and transported by a state licensed medical waste contractor to dispose by burial in a licensed hazardous or toxic waste landfill or incinerator.

SRP: At the time of review, regulatory criteria for small quantity disposal are subject to significant revision, however, household quantities of waste pharmaceuticals may be managed as follows: Mix with wet cat litter or coffee grounds, double bag in plastic, discard in trash.

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ All bottles must be discarded as contaminated waste after decontamination of the biohazard cabinet. All protective apparel (gown, gloves, goggles, and respirator) should be discarded as contaminated waste. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ The contaminated filters must be removed, bagged in thick plastic and prepared for disposal in a hazardous waste dump site or incinerator licensed by the Environmental Protection Agency (EPA). /Antineoplastic agents/

For more Disposal Methods (Complete) data for Nilotinib (7 total), please visit the HSDB record page.

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Accidental contamination of the health-care environment, resulting in exposure of personnel, patients, visitors, and family members to hazardous substances, is prevented by maintaining the physical integrity and security of packages of hazardous drugs. 1. Access to all areas where hazardous drugs are stored is limited to specified authorized staff. 2. A method should be present for identifying to personnel those drugs that require special precautions (eg, cytotoxics). One way to accomplish this is to apply appropriate warning labels to all hazardous drug containers, shelves, and bins where the drug products are stored. ... 3. A method of identifying, for patients and family members, those drugs that require special precautions in the home should be in place. This may be accomplished in the health-care setting, by providing specific labeling for discharge medications, along with written instructions. 4. Methods for identifying shipping cartons of hazardous drugs should be required from manufacturers and distributors of these drugs. 5. Written procedures for handling

damaged packages of hazardous drugs should be maintained. Personnel involved in shipping and receiving hazardous drugs should be trained in these procedures, including the proper use of protective garments and equipment. Damaged shipping cartons of hazardous drugs should be received and opened in an isolated area (eg, in a laboratory fume hood, if available, not in a vertical laminar airflow biological safety cabinet used for preparing sterile products). /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Facilities (eg, shelves, carts, counters, and trays) for storing hazardous drugs are designed to prevent breakage and to limit contamination in the event of leakage. Bins, shelves with barriers at the front, or other design features that reduce the chance of drug containers falling to the floor should be used. Hazardous drugs requiring refrigeration should be stored separately from nonhazardous drugs in individual bins designed to prevent breakage and to contain leakage. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ Until the reproductive risks (or lack thereof) associated with handling hazardous drugs within a safety program have been substantiated, staff who are pregnant or breast-feeding should be allowed to avoid contact with these drugs. Policies should be in effect that provide these individuals with alternative tasks or responsibilities if they so desire. /Antineoplastic agents/

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ The pharmacy should provide access to information on toxicity, treatment of acute exposure (if available), chemical inactivators, solubility and stability of hazardous drugs (including investigational agents) used in the workplace. /Antineoplastic agents/

For more Preventive Measures (Complete) data for Nilotinib (19 total), please visit the HSDB record page.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practices.

Wear appropriate PPE (see Section 8). Avoid contact with skin, eyes, and clothing.

Wash hands thoroughly after handling. Do not eat, drink, or smoke in work area.

Avoid dust formation. Use only in a chemical fume hood or well-ventilated area.

7.2 Conditions for safe storage, including any incompatibilities

Store in a cool, dry, well-ventilated area. Keep container tightly closed.

Store away from incompatible materials (see Section 10).

Protect from light and moisture.

Recommended storage (industry convention for research compounds): -20°C for long-term storage; 2-8°C for short-term use and transport.

[Note: This is a general industry recommendation. Always verify exact storage conditions with the supplier Certificate of Analysis (COA).]

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Exposure controls

8.1.1 Occupational exposure limits (OEL)

OSHA PEL: Not established.

ACGIH TLV: Not established.

NIOSH REL: Not established.

No occupational exposure limit values are established for this substance.

Use the lowest feasible exposure level (ALARA principle).

8.1.2 Appropriate engineering controls

Use in a well-ventilated area. Chemical fume hood recommended for powder handling.

8.2 Individual protection measures

8.2.1 Eye/face protection

Wear safety glasses with side shields.

8.2.2 Skin protection

Wear protective gloves. Recommended material: Nitrile rubber.

Wear suitable protective clothing (lab coat).

8.2.3 Respiratory protection

Respiratory protection usually not required under normal use with adequate ventilation.

Use N95 respirator for large-scale powder handling.

8.2.4 Thermal hazards

Not applicable.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- a) Appearance: Solid
- b) Odor: No data available
- c) Odor threshold: No data available
- d) pH: No data available
- e) Melting point/freezing point: No data available
- f) Initial boiling point and boiling range: No data available
- g) Flash point: No data available
- h) Evaporation rate: No data available
- i) Flammability (solid, gas): No data available
- j) Upper/lower flammability or explosive limits: No data available
- k) Vapor pressure: No data available
- l) Vapor density: No data available
- m) Relative density: No data available
- n) Water solubility: The solubility ... in aqueous solutions decreases with increasing pH
- o) Partition coefficient: n-octanol/water: Log P (n-octanol/water): 4.9
- p) Auto-ignition temperature: No data available
- q) Decomposition temperature: No data available
- r) Viscosity: No data available
- s) Explosive properties: No data available
- t) Oxidizing properties: No data available

9.2 Other information

Topological Polar Surface Area (TPSA): 97.6 Å²

Complexity: 817

10. STABILITY AND REACTIVITY

10.1 Reactivity

No specific reactivity hazards identified under normal handling conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions under normal conditions.

10.4 Conditions to avoid

Avoid heat, sparks, open flames, direct sunlight, and moisture.

Avoid strong oxidizing agents, strong acids, and strong bases.

10.5 Incompatible materials

Strong oxidizing agents, strong acids, strong bases.

10.6 Hazardous decomposition products

Thermal decomposition may produce: Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NO_x), Hydrogen fluoride (HF).

See also Section 5 (Fire-fighting measures) for combustion products.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:

No acute toxicity data available.

Skin corrosion/irritation:

No data available.

Serious eye damage/eye irritation:

No data available.

Respiratory or skin sensitization:

No data available.

Germ cell mutagenicity:

No data available.

Carcinogenicity:

No data available.

Reproductive toxicity:

Suspected of damaging fertility or the unborn child (H361).

Specific target organ toxicity (single exposure):

H372, H373

Specific target organ toxicity (repeated exposure):

No data available.

Aspiration hazard:

No data available.

11.2 Additional information

No additional toxicological information available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

/PRECAUTIONS FOR ANTINEOPLASTIC AGENTS:/ The danger to health-care personnel from handling a hazardous drug stems from a combination of its inherent toxicity and the extent to which workers are exposed to the drug in the course of carrying out their duties. This exposure may be through inadvertent ingestion of the drug on foodstuffs (eg, workers' lunches), inhalation of drug dusts or droplets or direct skin contact. /Antineoplastic agents/

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

Log P (n-octanol/water): 4.9

Potential for bioaccumulation exists (Log P > 3).

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available.

12.6 Other adverse effects

This substance is classified as hazardous to the aquatic environment.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste Treatment Methods: Waste material must be disposed of in accordance with national and local regulations. Leave chemicals in original containers and do not mix with other waste. Handle uncleaned containers in the same manner as the product itself.

14. TRANSPORT INFORMATION

14.1 UN number

Not regulated as dangerous goods (research quantities typically exempt).

14.2 UN proper shipping name

Not subject to transport regulations (small quantities for research use).

14.3 Transport hazard class(es)

Not classified as dangerous goods for transport (research quantities).

14.4 Packing group

Not applicable (not regulated as dangerous goods in typical research quantities).

14.5 Environmental hazards

Marine pollutant: Yes (classified as environmentally hazardous per GHS).

14.6 Special precautions for user

Transport in original packaging. Ensure containers are tightly sealed.

For bulk or commercial quantities, consult applicable transport regulations (DOT, IATA, IMDG).

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

15. REGULATORY INFORMATION**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

US EPA / TSCA: Not available in public databases.

EU ECHA / REACH: Registered (REACH Active)

SARA 302 Components:

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards:

Chronic (long-term) health hazard

Environmental hazard

Massachusetts Right To Know Components:

This material contains components subject to the Massachusetts Right to Know Act. See Section 2 for hazard classification.

Pennsylvania Right To Know Components:

This material contains components subject to the Pennsylvania Right to Know Act. See Section 2 for hazard classification.

New Jersey Right To Know Components:

This material contains components subject to the New Jersey Right to Know Act. See Section 2 for hazard classification.

California Prop. 65 Components:

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive harm.

Other regulatory listings:

- FDA Requirements: The Approved Drug Products with Therapeutic Equivalence Evaluations List identifies currently marketed prescription drug products, including nilotinib hydrochloride monohydrate, approved on the basis of safety and effectiveness by FDA under sections 505 of the Federal Food, Drug, and Cosmetic Act. /

15.2 Chemical safety assessment

A chemical safety assessment has not been carried out for this substance.

For research-use-only compounds, no CSA is required under REACH Annex I.

16. OTHER INFORMATION

Revision Date: 2026/09/08

Further Information: The information provided is believed to be correct but is not exhaustive and should be used only as a guideline based on current knowledge. It does not represent a guarantee of the properties of the product. Selleck Chemicals Corporation and its Affiliates shall not be held liable for any damage resulting from handling or contact with the product.