



MSN Laboratories Private Limited
R&D Center, Formulation Division.

SAFETY DATA SHEET		Page No. 1 of 5
* Product Name	Nilotinib Capsules 50 mg, 150 mg and 200 mg/ Nilotinib 50 mg, 150 mg and 200 mg Hard Capsules	

1. Product Information

Product Name: Nilotinib Capsules 50 mg, 150 mg and 200 mg/
Nilotinib 50 mg, 150 mg and 200 mg Hard Capsules

Chemical Family: Mixture

Intended use: Pharmaceutical product used as Antineoplastic drug

Details of the manufacturer:

MSN Laboratories Private Limited.

Formulation Division, Unit - II,

Sy No 1277 & 1319 to 1324

Nandigama Village & Mandal

Ranga Reddy Dist

Telangana State, India.

PIN 509228

Phone: +91 40 3044 9200

2. Information on Ingredient

C.A.S. No : 641571-10-0
Molecular Formula : $C_{28}H_{23}ClF_3N_7O \cdot 1.5 H_2O$
Formula Weight : 593
Chemical Name : 4-methyl-N-(3-(4-methyl-1H-imidazol-1-yl)-5-(trifluoromethyl)phenyl)-3-((4-(pyridin-3-yl)pyrimidin-2-yl)amino)benzamide hydrochloride sesquihydrate.

3. Hazards Identification

Classification of the Substance or Mixture

GHS - Classification

Germ Cell Mutagenicity: Category 2

Reproductive Toxicity: Category 1B

Flammable liquids- Category 2

Label Elements

Signal Word: Danger

Hazard Statements: H225 - Highly flammable liquid and vapor

H360FD - May damage fertility. May damage the unborn child.

H341 - Suspected of causing genetic defects

Precautionary Statements: P201 - Obtain special instructions before use

P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking

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P233 - Keep container tightly closed P260 - Do not breathe dust/fume/gas/mist/vapors/spray
 P303 + P361 + P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing.
 Rinse skin with water/shower
 P308 + P313 - IF exposed or concerned: Get medical attention/advice
 P403 + P235 - Store in a well-ventilated place. Keep cool
 P405 - Store locked up
 P501 - Dispose of contents/container in accordance with all local and national regulations
CLP/GHS hazard pictogram

Other Hazards No data available



Note: This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. First Aid Measures

In case of inhalation:

Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Seek medical attention.

In case of contact with skin:

Immediately wash skin with soap and copious amounts of water for at least 15 minutes. If irritation persists, seek medical attention.

In case of contact with eyes:

Immediately flush eyes with copious amounts of water for at least 15 minutes. Seek medical advice.

In case of ingestion:

If swallowed, wash out mouth with water, provided person is conscious. Seek medical advice.

Remove and wash/discard of contaminated clothing promptly.

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5. Emergency Overview

Major Health Hazards: No major health hazards are known.

6. Fire Fighting Measures

Extinguishing Media:

Carbon dioxide, dry chemical powder or appropriate foam. Water spray.

Unusual fire and explosion hazards:

Emits toxic fumes under fire conditions

Special fire fighting procedures:

Wear self-contained breathing apparatus and protective clothing to prevent contact with the skin and eyes.

7. Accidental Release Measures

Ensuring personal safety, mark out contaminated area with signs and prevent unauthorised access. Turn leaking containers up to prevent further Evacuate area. Wear self-contained breathing apparatus, rubber boots & heavy rubber gloves. Sweep-up/absorb in suitable material, place in a container and hold for disposal. Avoid raising dust. Ventilate area and wash spill site after pick-up complete

8. Handling and Storage

US: Store at 25°C (77°F); excursions permitted between 15°C to 30°C (59°F to 86°F) [see USP Controlled Room Temperature]

EU: Do not store above 30°C. Store in the original package in order to protect from moisture.

9. Exposure Controls/Personal Protection

Respiratory protection:

required when dusts are generated.

Eye protection: Required.

Hand protection: Required.

Industrial hygiene:

Immediately change contaminated clothing. Wash hands and face after working with substance.

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10. Physical Properties

50 mg: Light yellow colored blend filled in Size "4" hard gelatin capsules with Light yellow opaque colour body and Red opaque colour cap imprinted with "MN5" with black ink, free from physical defects

150 mg: Light yellow colored blend filled in Size "1" hard gelatin capsules with Red opaque colour body and Red opaque colour cap imprinted with "MN4" with black ink, free from physical defects

200 mg: Light yellow colored blend filled in Size "0" hard gelatin capsules with Light yellow opaque colour body and Light yellow opaque colour cap imprinted with "MN3" with black ink, free from physical defects

11. Stability and Reactivity

Conditions to be avoided: Unknown

Substances to be avoided: Unknown

Hazardous decomposition products: Unknown

12. Toxicological Information

Not listed by ACGIH, IARC, NIOSH, NTP, or OSHA.

13. Ecological Information

Do not allow product to enter drinking water supplies, waste water or soil.

14. Disposal Considerations

Dissolve or mix material with a suitable combustible solvent and incinerate in a chemical incinerator equipped with an afterburner and scrubber.

Material should be disposed of in keeping with all local and national legislation. Packaging should be disposed of in keeping with all local and national legislation. Handle contaminated containers as product.

15. Transport Information

Transport information: Transport in accordance with local, state, federal regulations.

16. Regulatory Information

European/International Regulations

European Labeling in Accordance with EC Directives

Hazard Symbols: XN

Risk Phrases:

Safety Phrases:

WGK (Water Danger/Protection)

CAS# United Kingdom Occupational Exposure Limits

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United Kingdom Maximum Exposure Limits

Canada

CAS# is listed on Canada's DSL List.

CAS# is not listed on Canada's Ingredient Disclosure List.

Exposure Limits

US FEDERAL

TSCA

CAS# is listed on the TSCA inventory.

17. Other Information

While the information herein is believed to be reliable, it is furnished without warranty of any kind. It shall be used only as a guide. We assume no liabilities from the use of this product or information contained herein.

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