

# Material Safety Data Sheet

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| Section 1 : Chemical Product Company Identification |   |
| Product Name  | Apixaban Impurity 104   |
| CAS No.   | NA  |
| Identified uses                                     | Pharmaceutical Reference Standard   |
| Details of the Supplier Company                     | SynZeal Research Pvt Ltd<br>Plot No. F, Ganesh Industrial Estate<br>423/24/8, MahagujaratInd Estate<br>Sarkhej-Bavla Road,<br>Ahmedabad-382 213.<br>Gujarat, India. |
| Telephone   | +91-7969225400  |

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| Section 2 : Chemical Information |   |
| Chemical Name                    | Ethyl<br>6-(4-aminophenyl)-1-(4-methoxyphenyl)-7a-morpholino-7-oxo-3a,4,5<br>,6,7,7a-hexahydro-1H-pyrazolo[3,4-c]pyridine-3-carboxylate |
| CAS No.                          | NA  |
| Molecular Weight                 | 493.6   |
| Molecular Formula                | C26H31N5O5  |

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| Section 3 : Hazards Identification |             |
| Emergency Overview:                |             |
| Appearance                         | Beige Solid |
| Target Organs                      | NA          |
| Potential Health Effects:          |             |
| Eye                                | NIL         |
| Skin                               | NIL         |
| Ingestion                          | NIL         |
| Inhalation                         | NIL         |
| Chronic                            | NIL         |

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| Hazard Statement:          |
| H302:Harmful if swallowed. |

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| <b>H312:</b> Harmful in contact with skin.   |
| <b>H315:</b> Causes skin irritation.   |
| <b>H319:</b> Causes serious eye irritation.  |
| <b>H332:</b> Harmful if inhaled.   |
| <b>H335:</b> May cause respiratory irritation.   |
| Precautionary Statement:   |
| <b>P261:</b> Avoid breathing dust/fume/gas/mist/vapours/spray.   |
| <b>P262:</b> Do not get in eyes, on skin, or on clothing.  |
| <b>P271:</b> Use only outdoors or in a well-ventilated area.   |
| <b>P280:</b> Wear protective gloves/protective clothing/eye protection/face protection.  |
| <b>P302 + P352:</b> IF ON SKIN: Wash with plenty of water  |
| <b>P304 + P340:</b> IF INHALED: Remove person to fresh air and keep comfortable for breathing.   |
| <b>P305 + P351 +P338:</b> IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| <b>P308 + P313:</b> IF exposed or concerned: Get medical advice/attention.   |

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| Section 4 : First Aid Measures |  |
| Eye                            | Wash with plenty of water  |
| Skin                           | Wash with plenty of water  |
| Ingestion                      | Medical assistance for gastric lavage.   |
| Inhalation                     | Remove to fresh air, artificial respiration or oxygen if necessary.              |
| Notes to Physician             | Apixaban Impurity 104 can be washed with plenty of water in case of any exposure |

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| Section 5 : Firefighting Measures  |   |
| Extinguishing Media                | Carbon dioxide, dry chemical powder, foam, water. |
| Unusual Fire and Explosion Hazards | None indicated                                    |

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| Section 6 : Accidental Release Measures |  |
| Personal Precautions                    | Wear self-contained breathing apparatus, avoid dust formation. |
| Spills/Leaks                            | Wash with plenty of water, provide adequate ventilation.       |

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| Section 7 : Handlings and Storage |                      |
| Handling                          | Wear surgical gloves |

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| Storage | Can be stored at room temperature |
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| Section 8 : Exposure Controls, Personal Protection |                                    |
| Respiratory Protection                             | Self-contained breathing apparatus |
| Exposure Limits                                    | NA                                 |
| Eye Protection                                     | Wear safety goggles                |
| Other Protective Equipment                         | Protective clothing                |
| Skin   | Full sleeves apron                 |
| Clothing   | Cotton                             |

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| Section 9 : Physical and Chemical Properties |                      |
| Appearance                                   | Beige Solid          |
| Odor   | Odor less            |
| Melting Point                                | NA                   |
| pH   | Basic                |
| Vapor Pressure                               | NA                   |
| Vapor Density                                | NA                   |
| Evaporation Rate                             | NA                   |
| Viscosity                                    | NA                   |
| Boiling Point                                | NA                   |
| Decomposition Temp                           | NA                   |
| Auto ignition Temp.                          | NA                   |
| Flash Point                                  | NA                   |
| NFPA Rating                                  | NA                   |
| <b>Explosion Limits</b>                      |                      |
| Lower  | NA                   |
| Upper  | NA                   |
| Solubility                                   | Chloroform, Methanol |
| Specific Gravity/Density                     | NA                   |

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| Section 10 : Stability and Reactivity |                         |
| Chemical Stability                    | Stable                  |
| Conditions to avoid                   | Direct contract to skin |

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| Incompatibilities with other Materials | Keep away |
| Hazardous Decomposition Products       | NIL       |
| Hazardous Polymerization               | NIL       |

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| Section 11 : Toxicological Information |     |
| CAS                                    | NA  |
| LD50/LC50                              | NA  |
| Carcinogenicity                        | NIL |
| Epidemiology                           | NIL |
| Teratogenicity                         | NIL |
| Reproductive Effects                   | NIL |
| Neurotoxicity                          | NIL |
| Mutagencity                            | NIL |
| Other Studies                          | NA  |

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| Section 12 : Ecological Information |  |
| Data not available                  |  |

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| Section 13 : Disposal Consideration |                    |
| RCRA P-Series                       | Can be incinerated |
| RCRA U-Series                       | NA                 |

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| Section 14 : Transport Consideration   |             |
| <b>UN-Number</b>   |             |
| ADR/RID:   | IMDG: IATA: |
| <b>UN proper shipping name</b>   |             |
| ADR/RID: Not dangerous goods<br>IMDG: Not dangerous goods<br>IATA: Not dangerous goods |             |
| <b>Transport hazard class(es)</b>  |             |
| ADR/RID:   | IMDG: IATA: |
| <b>Packaging Group</b>   |             |
| ADR/RID:   | IMDG: IATA: |
| <b>Environmental hazards</b>   |             |

|                                      |                           |          |
|--------------------------------------|---------------------------|----------|
| ADR/RID: No                          | IMDG Marine pollutant: No | IATA: No |
| <b>Special precautions for users</b> |                           |          |
| <b>Further information</b>           |                           |          |

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| Section 15 : Regulatory Information   |                                      |
| TSCA  | Attached the letter                  |
| Health and Safety Reporting List  | No data available                    |
| Chemical Test Rules   | Chemical analysis report is attached |
| Section 16 : Additional Information   |                                      |
| <p>This product is not bioactive, non-radioactive. It is for R and D use only. Not for drug, household or other uses.</p> <p>The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge. It does not represent any guarantee of the product.</p> |                                      |