Material Safety Data Sheet

| Section 1 : Chemical Product Company Identification | |
|---|---|
| Product Name | Dabigatran Impurity M |
| CAS No. | 1422435-41-3 |
| Identified uses | Pharmaceutical Reference Standard |
| Details of the Supplier Company | SynZeal Research Pvt Ltd Plot No. F, Ganesh Industrial Estate 423/24/8, MahagujaratInd Estate Sarkhej-Bavla Road, Ahmedabad-382 213. Gujarat, India. |
| Telephone | +91-7969225400 |

| Section 2 : Chemical Information | |
|----------------------------------|---|
| Chemical Name | Ethyl 3-(2-(((4-carbamoylphenyl)amino)methyl)-1-methyl- N-(pyridin-2-yl)-1H-benzo[d]imidazole-5- carboxamido)propanoate |
| CAS No. | 1422435-41-3 |
| Molecular Weight | 500.6 |
| Molecular Formula | C27H28N6O4 |
| | |

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

| Hazard Statement: |
|--------------------------------------|
| H302: Harmful if swallowed. |
| H312: Harmful in contact with skin. |
| H315: Causes skin irritation. |
| H319: Causes serious eye irritation. |
| H332: Harmful if inhaled. |

H335: May cause respiratory irritation.

Precautionary Statement:

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P262: Do not get in eyes, on skin, or on clothing.

P271: Use only outdoors or in a well-ventilated area.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P302 + P352: IF ON SKIN: Wash with plenty of water

P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305 + P351 +P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P308 + P313: IF exposed or concerned: Get medical advice/attention.

| 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 | Dabigatran Impurity M can be washed with plenty of water in case of any exposure |
| | 7 |

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

| 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. |

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

| 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 |

| Section 9 : Physical and Chemical Properties | |
|--|----------------------|
| Appearance | Light Yellow Solid |
| Odor | Odor less |
| Melting Point | NA |
| рН | 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 |
| Explosion Limits | |
| Lower | NA |
| Upper | NA |
| Solubility | Chloroform, Methanol |
| Specific Gravity/Density | NA |

| Section 10 : Stability and Reactivity | |
|--|-------------------------|
| Chemical Stability | |
| Conditions to avoid | Direct contract to skin |
| Incompatibilities with other Materials | Keep away |
| Hazardous Decomposition Products | NIL |
| Hazardous Polymerization | NIL |

| 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 |

Section 12 : Ecological Information

Data not available

| Section 13 : Disposal Consideration | | |
|--|--------------------|--|
| RCRA P-Series | Can be incinerated | |
| RCRA U-Series | NA | |
| | 60 | |
| Section 14 : Transport Consideration | | |
| UN-Number | | |
| ADR/RID: IMDG: IATA: | | |
| UN proper shipping name | | |
| ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods | | |
| Transport hazard class(es) | | |
| ADR/RID: IMDG: IATA: | | |
| Packaging Group | | |
| ADR/RID: IMDG: IATA: | | |
| Environmental hazards | | |
| ADR/RID: No IMDG Marine pollutant: No IATA | A: No | |
| Special precautions for users | | |
| Further information | | |

| Section 15 : Regulatory Information | | |
|--|--------------------------------------|--|
| TSCA | Attached the letter | |
| Health & Safety Reporting List | No data available | |
| Chemical Test Rules | Chemical analysis report is attached | |
| Section 16 : Additional Information | | |
| This product is not bioactive, non-radioactive. It is for R&D use only. Not for drug, household or other uses. | | |

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.