## Material Safety Data Sheet

| Section 1 : Chemical Product Company Identification |   |
|---|---|
| Product Name  | Rivaroxaban Impurity 42   |
| CAS No.   | 1403383-55-0  |
| 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  |

| Section 2 : Chemical Information |  |
|----------------------------------|--|
| Chemical Name                    | (S)-4-(4-((3-amino-2-<br>hydroxypropyl)amino)phenyl)morpholin-3-one<br>hydrochloride |
| CAS No.                          | 1403383-55-0   |
| Molecular Weight                 | 265.3 : 36.5   |
| Molecular Formula                | C13H19N3O3 : HCI   |
|                                  |  |

| Section 3 : Hazards Identification |            |  |
|------------------------------------|------------|--|
| Emergency Overview:                |            |  |
| Appearance                         | Grey 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             | Rivaroxaban Impurity 42 can be washed with plenty of water in case of any exposure |
|                                |  |

| 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                                   | Grey 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<br>IMDG: Not dangerous goods<br>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.