

Material Safety Data Sheet

| | |
|---|---|
| Section 1: Chemical Product Company Identification | |
| Product Name | Rivaroxaban Impurity 2 |
| CAS No. | 85-41-6 |
| 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 | Isoindoline-1,3-dione |
| CAS No. | 85-41-6 |
| Synonyms | Phthalimide Impurity |
| Molecular Weight | 147.1 |
| Molecular Formula | C8H5NO2 |

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

| | |
|--------------------------------------|---------------------------|
| 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 2 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 | Can be stored at room temperature |

| | |
|---|------------------------------------|
| 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 | White 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 |
| Explosion Limits | |
| Lower | NA |
| Upper | NA |
| Solubility | Chloroform, Methanol |
| Specific Gravity/Density | NA |

| | |
|--|------------------------|
| Section 10: Stability and Reactivity | |
| Chemical Stability | Stable |
| Conditions to avoid | Direct contact 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 |
| Mutagenicity | 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 |

| | |
|--|--|
| 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: No | |
| Special precautions for users | |
| Further information | |

| | |
|------------------------------------|--------------------------------------|
| 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 | |
| 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. | |