## **Material Safety Data Sheet**

Section 1 : Chemical Product Company Identification	
Product Name	Rivaroxaban EP Impurity H
CAS No.	1770812-37-7
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	4,5-Dichloro-N-[[(5S)-2-oxo-3-[4-(3-oxomorpholin-4-yl)phenyl]-1,3-oxazolidin-5-yl]methyl]thiophene-2-carboxamide
CAS No.	1770812-37-7
Synonyms	Rivaroxaban USP Related Compound H
Molecular Weight	470.3
Molecular Formula	C19H17Cl2N3O5S

Section 3: Hazards Identification		
Emergency Overview:		
Appearance	Light Brown 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 Measure	es	
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 EP Impurity H 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	Light Brown 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

## **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** IATA: No ADR/RID: No IMDG Marine pollutant: 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.

