









Registered Address: Chemicea Pharmaceuticals Pvt Ltd, Platinum Springs, Unit No- A- 205&206 Second floor, Plot No: G-6, G-20 to G 24, Taloja- MIDC, Opp. Dena Bank Navi Mumbai 410208, MH, INDIA. Email- <u>info@chemicea.com</u> Mob- +91 9284897978

## **Material Safety Data Sheet**

Section 1 : Chemical Product and Company information	
Product Name	Rivaroxaban EP Impurity D
CAS No.	1365267-35-1
Identified uses	Pharmaceutical Reference Standard
Details of the Supplier Company	Chemicea Pharmaceuticals Pvt Ltd, 2nd floor, A-205 Plot Number G-6, G-20 to G-24, Platinum Spring, Vavanje Panvel Road, Taloja MIDC, Navi Mumbai, Raigad, Maharashtra, 410208, Email- info@chemicea.com Mob- +91-92848979789
Telephone	+91-9284897978

Section 2 : Chemical Information	
Chemical Name	N,N'-bis[[(5S)-2-oxo-3-[4-(3-oxomorpholin-4-yl)phenyl]-1,3-oxazolidin-5-yl]methyl]urea (as per EP)
CAS No.	1365267-35-1
CAT No.	CP-R17004
Synonyms	Rivaroxaban USP Related Compound D ; Rivaroxaban Urea Dimer
Molecular Weight	608.61
Molecular Formula	C29H32N6O9

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

Section 4 : First Aid Measures	
Eye	After eye contact: rinse out with plenty of water. Immediately call in ophthalmologist. Remove contact lenses.
Skin	Take off immediately all contaminated clothing. Rinse skin with water/ shower. Call a physician immediately
Swallowed	After swallowing: make victim drink water (two glasses at most), avoid vomiting (risk of perforation). Call a physician immediately. Do not attempt to neutralise.
Inhalation	Remove to fresh air, artificial respiration or oxygen if necessary.
Notes to Physician	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	Advice for non-emergency personnel: Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.
Spills/Leaks	Wash with plenty of water, provide adequate ventilation.
Environmental precautions	Do not let product enter drains.

Section 7 : Handlings and Storage	
Handling	Work under hood. Do not inhale substance/mixture. Avoid generation of vapours/aerosols.
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 to Off White 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	Soluble in Methanol/DMSO
Specific Gravity/Density	NA

Section 10 : Stability and Reactivity	
Chemical Stability	Stable
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		
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.