

Registered Address: Chemicea Pharmaceuticals Pvt Ltd, Platinum Springs,  
Unit No- A- 205&206 Second floor, Plot No: G-6, G-20 to G 24, Talaja- MIDC, Opp. Dena Bank  
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## 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, Talaja MIDC, Navi Mumbai, Raigad, Maharashtra, 410208, Email- <a href="mailto:info@chemicea.com">info@chemicea.com</a> 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	
<b>Emergency Overview:</b>	
Appearance	White to Off White Solid
Target Organs	NA
<b>Potential Health Effects:</b>	
Eye	NIL
Skin	NIL
Ingestion	NIL
Inhalation	NIL
Chronic	NIL

<b>Section 4 : First Aid Measures</b>	
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

<b>Section 5 : Firefighting Measures</b>	
Extinguishing Media	Carbon dioxide, dry chemical powder, foam, water.
Unusual Fire and Explosion Hazards	None indicated

<b>Section 6 : Accidental Release Measures</b>	
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.

<b>Section 7 : Handlings and Storage</b>	
Handling	Work under hood. Do not inhale substance/mixture. Avoid generation of vapours/aerosols.
Storage	Can be stored at room temperature

<b>Section 8 : Exposure Controls, Personal Protection</b>	
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

<b>Section 9 : Physical and Chemical Properties</b>	
Appearance	White to Off 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
<b>Explosion Limits</b>	
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 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:
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#### 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:
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#### Packaging Group

ADR/RID:	IMDG: IATA:
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#### Environmental hazards

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