# Material Safety Data Sheet

#### Effective Date:

#### Due Date:

Section 1 : Chemical Product Company Identification	
Product Name	Dabigatran Impurity 19
CAT No.	KMD029056
CAS No.	2096992-14-0
Identified uses	Pharmaceutical Reference Standard
Details of the Supplier Company	K. M. PHARMA SOLUTION PRIVATE LIMITED Unit No.101, Shivam Industrial park, Sarkhej-bavala NH=8A, At-Moraiya, Changodar, Ahmedabad (Gujarat), India-382213
Telephone	+91 9898822121

Section 2 : Chemical Information	
Chemical Name	Ethyl (Z)-3-(1-methyl-2-(((4-(N'-(((3- methylpentyl)oxy)carbonyl)carbamimidoyl)phenyl)amino)methyl) -N-(pyridin-2-yl)-1H-benzo[d]imidazole-5- carboxamido)propanoate
CAS No.	2096992-14-0
Molecular Weight	627.8
Molecular Formula	C34H41N7O5
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Section 3 : Hazards Identification		
Emergency Overview:		
Appearance	NA	
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	Dabigatran Impurity 19 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	~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	NA
Odor	NA
Melting Point	NA



nH	ΝΑ
рН	
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 NA NA
Upper	NA
Solubility	NA NA NA
Specific Gravity/Density	NA

# Section 10 : Stability and Reactivity

Chemical Stability	~ChemicalStability
Conditions to avoid	Direct contract to skin
Incompatibilities with other Materials	Кеер аway
Hazardous Decomposition Products	NIL
Hazardous Polymerization	NIL

# Section 11 : Toxicological Information

CAS	NA
LD50/LC50	>10,000 mg/kg Remarks: Behavioral:Somnolence (general depressed activity)
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

NA

**RCRA U-Series** 

### Section 14 : Transport Consideration

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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 & 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.

K.M. Pharma Solution Privato Limited

Pharma Control