

Material Safety Data Sheet

Section 1: Chemical Product Company Identification	
Product Name	Dabigatran Etxilate EP Impurity B (HCl salt)
CAS No.	211914-50-0
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	Ethyl 3-(2-(((4-carbamimidoylphenyl)amino)methyl)-1-methyl-N-(pyridin-2-yl)-1H-benzo[d]imidazole-5-carboxamido)propanoate hydrochloride
CAS No.	211914-50-0
Synonyms	Dabigatran Ethyl Ester (HCl)
Molecular Weight	499.6 : 36.5
Molecular Formula	C27H29N7O3 : HCl

Section 3: Hazards Identification	
Emergency Overview:	
Appearance	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	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 Etexilate EP Impurity B (HCl salt) 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	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
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.	