

# Material Safety Data Sheet

## Section 1 : Chemical Product Company Identification

Product Name	Dabigatran Etexilate 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

### 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 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	

**Section 8 : Exposure Controls, Personal Protection**

Respiratory Protection	Self-contained breathing apparatus
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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
<b>Explosion Limits</b>	
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
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 & 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.

SynZeal