Material Safety Data Sheet (MSDS)

Effective Date: **Due Date:**

Section 1: Chemical Product and Company Identification

Product Name	Dabigatran Etexilate EP Impurity E
CAT No.	KMD029035
CAS No.	212321-78-3
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	3-[2-[[4-[N′-[(hexyloxy)carbonyl]carbamimidoyl]anilino]methyl]-1-methyl-N-(pyridin-2-yl)-1H-benzimidazole-5-carboxamido]propanoic acid (as per EP)
CAS No.	212321-78-3
Molecular Weight	599.7
Molecular Formula	C32H37N7O5

Section 3: Hazards Identification

Emergency Overview:	
Appearance	NA
Target Organs	NA
Potential Health Effects:	
Eye (Hazard)	NIL
Skin (Hazard)	NIL
Ingestion (Hazard)	NIL
Inhalation (Hazard)	NIL
Chronic (Hazard)	NIL

Section 4: First Aid Measures

Eye	Wash with plenty of water
Skin	Wash with plenty of water

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Ingestion	Medical assistance for gastric lavage.
Inhalation	Remove to fresh air, artificial respiration or oxygen if necessary.
Notes to Physician	Dabigatran Etexilate EP Impurity E 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: Handling 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
pH	NA
Vapor Pressure	NA
Vapor Density	NA
Evaporation Rate	NA
Viscosity	NA
Boiling Point	NA

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Decomposition Temp	NA
Auto ignition Temp.	NA
Flash Point	NA
NFPA Rating	NA
Explosion Limits	
Lower	NA
Upper	NA
Solubility	NA
Specific Gravity/Density	NA

Section 10: Stability and Reactivity

Chemical Stability	~ChemicalStability
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	>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

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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.

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