Material Safety Data Sheet

Effective Date: Due Date:

Section 1 : Chemical Product Company Identification	
Product Name	Dabigatran Nitroso Impurity 16
CAT No.	KMD029125
CAS No.	NA
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	(E)-3-(2-(((4-(N'- ((Hexyloxy)carbonyl)carbamimidoyl)phenyl)(nitroso)amino)methy l)-1-methyl-N-(pyridin-2-yl)-1H-benzo[d]imidazole-5- carboxamido)propanoic acid
CAS No.	NA
Molecular Weight	628.7
Molecular Formula	C32H36N8O6

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 Nitroso Impurity 16 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



рН	NA
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
Flash Point NA NFPA Rating NA Explosion Limits Lower NA	
Lower	NA
Upper	NA
Solubility	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	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	
RCRA U-Series	NA	2

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: IATA: IMDG:

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.



