MATERIAL SAFETY DATA SHEETS

DATE: 05-11-2026

1.IDENTIFICATION

1.1 GHS PRODUCT IDENTIFIER

Product Name	**Dabigatran Isopropyl Ester Impurity / Dabigatran Impurity 16**

1.2 OTHER MEANS OF IDENTIFICATION

Product Name	**Dabigatran Isopropyl Ester Impurity / Dabigatran Impurity 16**
Other names	3-({2-[(4-Carbamimidoyl-phenylamino)-methyl]-1-methyl-1H-benzoimidazole-5-carbonyl}-pyridin-2-yl-amino)-propionic acid isopropyl ester

1.3 RECOMMENDED USE OF THE CHEMICAL AND RESTRICTIONS ON USE

Identified uses	Industrial and scientific research uses
Uses advised against	No data available

1.4 SUPPLIER'S DETAILS

Company	Cleanchem Laboratories LLP
Address	Plot No.R-80, 2nd Floor, Prama Instruments,TTC Industrial area, Rabale, Navi Mumbai, Maharashtra- 400 701
Telephone	022-27601987

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2. HAZARD IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

NO DATA AVAILABLE

2.2 GHS LABEL ELEMENTS, INCLUDING PRECAUTIONARY STATEMENTS

Pictogram(s)	No data available
Signal word	No data available
Hazard statement(s)	No data available
Precautionary statement(s)	
Prevention	No data available
Response	No data available
Storage	No data available
Disposal	No data available
Hazard(s) not otherwise classified (HNOC)	None known
Supplemental information	Pharmaceutical related compound of unknown potency.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES

NO DATA AVAILABLE

MOLECULAR FORMULA: C28H31N7O3 **MOLECULAR WEIGHT:** 513.6

Chemical name	Common names and synonyms	CAS number
3-({2-[(4-Carbamimidoyl-phenylamino)-methyl]-1-methyl-1H-benzoimidazole-5-carbonyl}-pyridin-2-yl-amino)-propionic acid isopropyl ester	NA	1610758-17-2

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4. FIRST-AID MEASURES

4.1 DESCRIPTION OF NECESSARY FIRST-AID MEASURES

General advice

Medical attention is required. Consult a doctor. Show this safety data sheet (SDS) to the doctor in attendance

Inhalation

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing.
Call a physician if symptoms develop or persist.

Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

Following ingestion

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person.
Call a doctor or Poison Control Center immediately.

4.2 MOST IMPORTANT SYMPTOMS/EFFECTS, ACUTE AND DELAYED

may cause physiological effects

4.3 INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED, IF NECESSARY

Treat symptomatically

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5. FIRE-FIGHTING MEASURES

5.1 EXTINGUISHING MEDIA

Suitable extinguishing media

Water, use dry chemical, carbon dioxide or alcohol-resistant foam.

5.2 SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Carbon oxides, Nitrogen oxides, Hydrogen fluoride, Sulphur oxides

5.3 SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS

Wear self-contained breathing apparatus for fire fighting if necessary.

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6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid

Inhalation of dust from the spilled material. Do not touch damaged containers or spilled material

Unless wearing appropriate protective clothing. Ensure adequate ventilation.

6.2 ENVIRONMENTAL PRECAUTIONS

Avoid discharge into drains, water courses or onto the ground.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in

Suitable container for disposal. Clean surface thoroughly to remove residual contamination. For

Waste disposal

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7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Provide appropriate exhaust ventilation at places where dust is formed

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep container tightly closed in a dry and well-ventilated place

Keep in a dry place.

Storage conditions: Refrigernator

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8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parametersg

Occupational Exposure limit values

No exposure limits noted for ingredient

8.2 Appropriate engineering controls

A laboratory fume hood or other appropriate form of local exhaust ventilations

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flame resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves

Respiratory protection

Recommended respirators are NIOSH-approved N100 or CEN-approved FFP3 particulate respirators. These are to be only used as

a backup to local exhaust ventilation or other engineering controls. If the respirator is the only means of protection, a full-face

supplied air respirator must be used

Thermal hazards

Wear appropriate thermal protective clothing, when necessary

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9. PHYSICAL AND CHEMICAL PROPERTIES

Physical state	
Colour	
Odour	
Melting point/ freezing point	

Boiling point or initial boiling point and boiling range	
Flammability	
Lower and upper explosion limit / flammability limit	
Flash point	NA
Auto-ignition temperature	NA
Decomposition temperature	NA
pH	
Kinematic viscosity	
Solubility	
Partition coefficient n-octanol/water	
Vapour pressure	NA
Density and/or relative density	NA
Relative vapour density	NA
Particle characteristics	NA

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10. STABILITY AND REACTIVITY

10.1 Reactivity

The product is stable and non-reactive under normal conditions of use, storage and transport

10.2 Chemical stability

Material is stable under normal conditions

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use

10.4 Conditions to avoid

Contact with incompatible materials

10.5 Incompatible materials

Strong oxidizing agents

10.6 Hazardous decomposition products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

- ORAL LD50: NO DATA AVAILABLE
- INHALATION: NO DATA AVAILABLE
- DERMAL: NO DATA AVAILABLE

Skin corrosion/irritation

No data available

Serious eye damage/irritation

No data available

Respiratory or skin sensitization

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

No data available

STOT-single exposure

No data available

STOT-repeated exposure

No data available

Aspiration hazard

Based on available data, the classification criteria are not met

12. ECOLOGICAL INFORMATION

12.1 Ecotoxicity

There are no data on the ecotoxicity of this product.

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Other adverse effects

No data available

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13. DISPOSAL CONSIDERATIONS

13.1 Disposal methods
Product

Product may be burned in an incinerator equipped with afterburner and scrubber. Excess and expired materials are to be offered to a licensed hazardous material disposal company. Ensure that all Federal and Local regulations regarding the disposal and destruction of this material are followed.

Contaminated packaging Dispose of as above.

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14. TRANSPORT INFORMATION

14.1 DOT: Not regulated as dangerous goods

IATA: Not regulated as dangerous goods

14.2 UN Proper Shipping Name

ADR/RID: No data available	IMDG: No data available	IATA: No data available

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ADR/RID: No data available	IMDG: No data available	IATA: No data available

14.3 Transport hazard class(es)

ADR/RID: No data available	IMDG: No data available	IATA: No data available

14.4 Packing group, if applicable

ADR/RID: No data available IMDG: No data available IATA: No data available

14.5 Environmental hazards

ADR/RID: No IMDG: No IATA: No

14.6 Special precautions for user

No data available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

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It is the shipper's responsibility to determine the correct transport classification at the time of shipment

15. Regulatory information

US federal regulations	This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

European Union

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1052)

Not regulated.

16. OTHER INFORMATION

Abbreviations and acronyms

- CAS: CHEMICAL ABSTRACTS SERVICE
- IATA: INTERNATIONAL AIR TRANSPORTATION ASSOCIATION
- LD50: LETHAL DOSE 50%

Disclaimer: 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 and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. We as supplier shall not be held liable for any damage resulting from handling or from contact with the above product