

SECTION-1: Identification of the substance / mixture and the company / undertaking

Catalogue Number	CS-O-59205
Product Name	Dabigatran Impurity 8
CAS No.	429659-01-8
Category	Impurity
Synonyms	ethyl 3-(4-(methylamino)-3-nitro-N-(pyridin-2-yl)benzamido)propanoate
Brand	Clearsynth Labs Ltd.
Identified uses	Laboratory Chemicals
Uses advised against	Not available
Company	Clearsynth Labs Ltd. Mumbai, India
Emergency Phone #	+91-22-245045900
REACH No.	Not available

SECTION 2: Hazards identification

Disclaimer: This is sample MSDS. Please email sales@clearsynth.com for more details.

2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Not available

2.2 Label Elements

Signal Word: Warning

Not available

Hazard Statement(s)

Code	Statement
H412	Not available

Precautionary Statement(s)

Code	Statement
P273	Not available
P501	Dispose of contents/container in accordance with local/regional/national/international regulation

SECTION 3: Composition / information on ingredients

3.1 Substance

Component : Dabigatran Impurity 8

CAS Number : 429659-01-8

Molecular Formula : C₁₈H₂₀N₄O₅

Molecular Weight : 372.38

Parent Chemical : Dabigatran

Synonyms : ethyl 3-(4-(methylamino)-3-nitro-N-(pyridin-2-yl)benzamido)propanoate

Concentration : Not available

SECTION 4: First aid measures

SECTION 4: First-aid measures

4.1 Description of first aid measures

General advice:

- Seek medical attention if symptoms occur or persist.
- Show this Safety Data Sheet to the physician in attendance.

Inhalation:

- Move person to fresh air.
- If breathing is difficult, seek medical attention.

Skin contact:

- Remove contaminated clothing and shoes.
- Wash skin with plenty of water and soap.
- Seek medical attention if irritation develops.

Eye contact:

- Rinse cautiously with water for several minutes.
- Remove contact lenses if present and easy to do; continue rinsing.
- Seek medical attention if irritation persists.

Ingestion:

- Rinse mouth with water.
- Do not induce vomiting unless directed by medical personnel.
- Seek medical attention.

4.2 Most important symptoms and effects, both acute and delayed

- Not available.

4.3 Indication of any immediate medical attention and special treatment needed

- Treat symptomatically.
- No data available.

SECTION 5: Firefighting measures

SECTION 5: Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media:

- Use extinguishing measures appropriate to local circumstances and surrounding environment (e.g., water spray, dry chemical, foam, carbon dioxide).

Unsuitable extinguishing media:

- Not available.

5.2 Special hazards arising from the substance or mixture

- No data available.

- Combustion may produce carbon oxides, nitrogen oxides, and other irritating/toxic fumes.

5.3 Advice for firefighters

- Wear self-contained breathing apparatus (SCBA) and full protective gear.

- Avoid inhalation of combustion products.

- Cool containers with water spray if exposed to fire.

SECTION 6: Accidental release measures

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- Avoid breathing dust.

- Avoid contact with skin and eyes.

- Use appropriate personal protective equipment (see Section 8).

- Ensure adequate ventilation.

6.2 Environmental precautions

- Avoid release to the environment.

- Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

- Avoid generating dust.

- Collect spilled material using suitable means (e.g., dampened absorbent or HEPA-filtered vacuum) and place in a suitable, labeled container for disposal.

- Clean contaminated area with water and detergent as appropriate.

6.4 Reference to other sections

- See Section 8 for personal protective equipment.

- See Section 13 for disposal considerations.

SECTION-7: Handling and storage

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Handle in accordance with good industrial hygiene and safety practice.

- Avoid formation of dust and aerosols.

- Avoid contact with skin, eyes, and clothing.

- Do not breathe dust.

- Use with adequate ventilation; use local exhaust where appropriate.

7.2 Conditions for safe storage, including any incompatibilities

- Store in a tightly closed container.

- Store in a cool, dry, well-ventilated place.
- Protect from moisture.
- Incompatibilities: Not available.

7.3 Specific end use(s)

- Laboratory/research use: Not available.

SECTION 8: Exposure controls / personal protection

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limits:

- No data available.

8.2 Exposure controls

Engineering controls:

- Provide adequate general and/or local exhaust ventilation to control airborne levels.

Personal protective equipment (PPE):

Eye/face protection:

- Safety glasses with side shields or chemical splash goggles.

Skin protection:

- Wear protective gloves (material selection dependent on use conditions).
- Wear protective clothing to prevent skin contact.

Respiratory protection:

- If ventilation is inadequate or dust is generated, use a properly fitted particulate respirator in accordance with applicable regulations.

Hygiene measures:

- Wash hands after handling.
- Remove contaminated clothing and wash before reuse.

Environmental exposure controls:

- Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Test	Result
Appearance	No data available
IR spectrum	No data available
pH	No data available
Solubility	No data available

Property	Value
a) Physical State	No data available
b) Color	No data available
c) Odor	No data available
d) pH	No data available
e) Vapour Pressure	No data available
f) Viscosity	No data available
g) Initial Boiling Point and boiling range	No data available
h) Melting Point / Freezing Point	No data available
i) Auto Ignition Temperature	No data available
j) Flash Point	No data available
k) Explosion Limit, Lower	No data available
l) Explosion Limit, Upper	No data available
m) Decomposition Temperature	No data available
n) Loss on Drying	No data available
o) Relative Density	No data available
p) Solubility (in DMSO)	No data available
q) Oxidizing Properties	No data available

SECTION 10: Stability and reactivity

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10.1 Reactivity

- No data available.

10.2 Chemical stability

- Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

- No data available.

10.4 Conditions to avoid

- Avoid excessive heat.

- Avoid dust generation.

- Other: Not available.

10.5 Incompatible materials

- Not available.

10.6 Hazardous decomposition products

- Under fire conditions: carbon oxides, nitrogen oxides, and other irritating/toxic fumes.
- Other: Not available.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

- Acute toxicity: No data available.
- Skin corrosion/irritation: No data available.
- Serious eye damage/eye 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: No data available.

Likely routes of exposure

- No data available.

Symptoms related to the physical, chemical and toxicological characteristics

- Not available.

SECTION 12: Ecological information

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12.1 Toxicity

- No data available.

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 Results of PBT and vPvB assessment

- No data available.

12.6 Endocrine disrupting properties

- No data available.

12.7 Other adverse effects

- No data available.

SECTION 13: Disposal considerations

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product:

- Dispose of contents/container in accordance with local/regional/national/international regulations.
- Treat as hazardous waste unless determined otherwise by applicable regulations.

Contaminated packaging:

- Dispose of as unused product.

Waste code:

- Not available.

SECTION 14: Transport information

SECTION 14: Transport information

14.1 UN number

- Not available.

14.2 UN proper shipping name

- Not available.

14.3 Transport hazard class(es)

- Not available.

14.4 Packing group

- Not available.

14.5 Environmental hazards

- Not available.

14.6 Special precautions for user

- Not available.

14.7 Maritime transport in bulk according to IMO instruments

- Not available.

SECTION 15: Regulatory information

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15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

- Regulatory status: Not available.
- Inventory listing (e.g., TSCA/REACH/DSL/ENCS/AICS/IECSC/K-REACH): Not available.

15.2 Chemical safety assessment

- No data available.

SECTION 16: Other information

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- Parent chemical: Dabigatran
- Category: Impurity
- Molecular weight: 372.38

Supplier:

- Clearsynth Labs Ltd., Mumbai, India

Emergency telephone:

- +91-22-245045900

Disclaimer:

- The information provided is believed to be correct based on available data; however, no warranty is expressed or implied. Users should determine suitability for their particular purpose and comply with all applicable laws and regulations.

Revision information:

- Not available.

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