

Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013

**SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING**

**Product Identifier**

Perihalan Produk: **Dabigatran etexilate**  
Product Description: **Dabigatran etexilate**  
Cat No. : 469930000; 469930010; 469932500  
CAS No 211915-06-9  
Molecular Formula C34 H41 N7 O5

**Relevant identified uses of the substance or mixture and uses advised against**

Recommended Use Laboratory chemicals.  
Uses advised against No Information available

**Company** Thermo Fisher Scientific Fisher Scientific (M) Sdn Bhd  
Hap Seng Business Park, Lot 01-03, 01-04 Aras 1 Unity Square,  
No 12, Persiaran Perusahaan, Seksyen 23, 40300 Shah Alam,  
Selangor Darul Ehsan, Malaysia.  
Main line: +60 3-5525 7888

**Supplier**

**E-mail address** Enquiry.my@thermofisher.com

**Emergency Telephone Number** Tel: +03-5525 7888  
CHEMTREC Malaysia **1-800-815-308** (Malay)  
CHEMTREC Malaysia (Kuala Lumpur) **+(60)-327884561** (Malay)

**SECTION 2: HAZARDS IDENTIFICATION**

**Classification of the substance or mixture**

**Label Elements**

**Hazard Statements**

**Other Hazards**

No information available  
This product does not contain any known or suspected endocrine disruptors

# SAFETY DATA SHEET

Dabigatran etexilate

Revision Date 23-Mar-2025

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight %
beta-Alanine, N-[[2-[[[4-[[[(hexyloxy)carbonyl]amino]iminomethyl]phenyl]amino]methyl]-1-methyl-1H-benzimidazol-5-yl]carbonyl]-N-2-pyridinyl-, ethyl ester	211915-06-9	<=100

## SECTION 4: FIRST AID MEASURES

### Description of first aid measures

<b>Eye Contact</b>	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
<b>Skin Contact</b>	Wash off immediately with plenty of water for at least 15 minutes. Get medical attention immediately if symptoms occur.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
<b>Inhalation</b>	Remove to fresh air. Get medical attention immediately if symptoms occur.
<b>Self-Protection of the First Aider</b>	No special precautions required.

### Most important symptoms and effects, both acute and delayed

None reasonably foreseeable.

### Indication of any immediate medical attention and special treatment needed

**Notes to Physician** Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

### Extinguishing media

#### **Suitable Extinguishing Media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical, CO<sub>2</sub>, water spray or alcohol-resistant foam.

#### **Extinguishing media which must not be used for safety reasons**

No information available.

### Special hazards arising from the substance or mixture

Thermal decomposition can lead to release of irritating gases and vapors.

#### **Hazardous Combustion Products**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), Nitrogen oxides (NO<sub>x</sub>).

### Advice for fire-fighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

# SAFETY DATA SHEET

Dabigatran etexilate

Revision Date 23-Mar-2025

## SECTION 6: ACCIDENTAL RELEASE MEASURES

### Personal Precautions, Protective Equipment and Emergency Procedures

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

### Environmental precautions

Should not be released into the environment.

### Methods and Material for Containment and Cleaning Up

Sweep up and shovel into suitable containers for disposal. Avoid dust formation.

### Reference to Other Sections

Refer to protective measures listed in Sections 8 and 13.

## SECTION 7: HANDLING AND STORAGE

### Precautions for Safe Handling

Wear personal protective equipment/face protection. Ensure adequate ventilation. Avoid contact with skin, eyes or clothing. Avoid ingestion and inhalation. Avoid dust formation.

### Conditions for Safe Storage, Including any Incompatibilities

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

### Specific End Uses

Use in laboratories.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control Parameters

### Exposure Controls

#### Engineering Measures

None under normal use conditions.

### Personal protective equipment

#### **Eye Protection**

Wear safety glasses with side shields (or goggles)

#### **Hand Protection**

Protective gloves

#### **Skin and body protection**

Long sleeved clothing

Inspect gloves before use.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. (Refer to manufacturer/supplier for information)

Ensure gloves are suitable for the task: Chemical compatibility, Dexterity, Operational conditions, User susceptibility, e.g. sensitisation effects, also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion.

Remove gloves with care avoiding skin contamination.

# SAFETY DATA SHEET

Dabigatran etexilate

Revision Date 23-Mar-2025

<b>Respiratory Protection</b>	No protective equipment is needed under normal use conditions
<b>Recommended Filter type:</b>	Particle filter

**Hygiene Measures** Handle in accordance with good industrial hygiene and safety practice

**Environmental exposure controls** No information available

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

<b>Appearance</b>	White	
<b>Physical State</b>	Solid	
<b>Odor</b>	No information available	
<b>Odor Threshold</b>	No data available	
<b>pH</b>	No information available	
<b>Melting Point/Range</b>	128 - 129 °C / 262.4 - 264.2 °F	
<b>Softening Point</b>	No data available	
<b>Boiling Point/Range</b>	827 °C / 1520.6 °F	
<b>Flash Point</b>	No information available	<b>Method -</b> No information available
<b>Evaporation Rate</b>	Not applicable	Solid
<b>Flammability (solid,gas)</b>	No information available	
<b>Explosion Limits</b>	No data available	
<b>Vapor Pressure</b>	No data available	
<b>Vapor Density</b>	Not applicable	Solid
<b>Specific Gravity / Density</b>	No data available	
<b>Bulk Density</b>	No data available	
<b>Water Solubility</b>	No information available	
<b>Solubility in other solvents</b>	No information available	
<b>Partition Coefficient (n-octanol/water)</b>		
<b>Autoignition Temperature</b>	No data available	
<b>Decomposition Temperature</b>	No data available	
<b>Viscosity</b>	Not applicable	Solid
<b>Explosive Properties</b>	No information available	
<b>Oxidizing Properties</b>	No information available	
<b>Molecular Formula</b>	C34 H41 N7 O5	
<b>Molecular Weight</b>	627.74	

## SECTION 10: STABILITY AND REACTIVITY

### Reactivity

# SAFETY DATA SHEET

Dabigatran etexilate

Revision Date 23-Mar-2025

None known, based on information available.

## Chemical Stability

No information available.

## Possibility of Hazardous Reactions

### **Hazardous Polymerization**

No information available.

### **Hazardous Reactions**

None under normal processing.

## Conditions to Avoid

Incompatible products.

## Incompatible Materials

Strong oxidizing agents.

## Hazardous Decomposition Products

Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>). Nitrogen oxides (NO<sub>x</sub>).

## SECTION 11: TOXICOLOGICAL INFORMATION

### Information on Toxicological Effects

#### **Product Information**

The toxicological properties have not been fully investigated

#### **(a) acute toxicity;**

##### **Oral**

No data available

##### **Dermal**

No data available

##### **Inhalation**

No data available

#### **(b) skin corrosion/irritation;**

No data available

#### **(c) serious eye damage/irritation;**

No data available

#### **(d) respiratory or skin sensitization;**

##### **Respiratory**

No data available

##### **Skin**

No data available

#### **(e) germ cell mutagenicity;**

No data available

#### **(f) carcinogenicity;**

No data available

There are no known carcinogenic chemicals in this product

#### **(g) reproductive toxicity;**

No data available

#### **(h) STOT-single exposure;**

No data available

# SAFETY DATA SHEET

Dabigatran etexilate

Revision Date 23-Mar-2025

(i) STOT-repeated exposure; No data available

Target Organs None known.

(j) aspiration hazard; Not applicable  
Solid

Symptoms / effects, both acute and delayed No information available.

Endocrine Disrupting Properties Assess endocrine disrupting properties for human health. This product does not contain any known or suspected endocrine disruptors.

## SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity effects

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Persistence and degradability No information available

Bioaccumulative potential No information available

Mobility in soil No information available.

Endocrine Disruptor Information This product does not contain any known or suspected endocrine disruptors

Other adverse effects No information available

## SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

Waste from Residues/Unused Products Dispose of in accordance with local regulations

Contaminated Packaging Empty containers should be taken to an approved waste handling site for recycling or disposal

## SECTION 14: TRANSPORT INFORMATION

IMDG/IMO Not regulated

Road and Rail Transport Not regulated

IATA Not regulated

# SAFETY DATA SHEET

Dabigatran etexilate

Revision Date 23-Mar-2025

**Special Precautions for User** No special precautions required

## SECTION 15: REGULATORY INFORMATION

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

**International Inventories** X = listed

Component	EINECS	TSCA	DSL	PICCS	ENCS	ISHL	IECSC	AICS	KECL
beta-Alanine, N-[[2-[[[4-[[[(hexyloxy)carbonyl]amino]iminomethyl]phenyl]amino]methyl]-1-methyl-1H-benzimidazol-5-yl]carbonyl]-N-2-pyridinyl-, ethyl ester	-	-	-	-	-	X	-	-	-

### National Regulations

**Persistent Organic Pollutant** This product does not contain any known or suspected substance  
**Ozone Depletion Potential** This product does not contain any known or suspected substance

## SECTION 16: OTHER INFORMATION

### Legend

**CAS** - Chemical Abstracts Service

**EINECS/ELINCS** - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances

**PICCS** - Philippines Inventory of Chemicals and Chemical Substances

**IECSC** - Chinese Inventory of Existing Chemical Substances

**KECL** - Korean Existing and Evaluated Chemical Substances

**TSCA** - United States Toxic Substances Control Act Section 8(b) Inventory

**DSL/NDSL** - Canadian Domestic Substances List/Non-Domestic Substances List

**ENCS** - Japanese Existing and New Chemical Substances

**AICS** - Australian Inventory of Chemical Substances

**NZIoC** - New Zealand Inventory of Chemicals

**WEL** - Workplace Exposure Limit

**ACGIH** - American Conference of Governmental Industrial Hygienists

**RPE** - Respiratory Protective Equipment

**LC50** - Lethal Concentration 50%

**POW** - Partition coefficient Octanol:Water

**TWA** - Time Weighted Average

**IARC** - International Agency for Research on Cancer

**LD50** - Lethal Dose 50%

**EC50** - Effective Concentration 50%

**ADR** - European Agreement Concerning the International Carriage of Dangerous Goods by Road

**IMO/IMDG** - International Maritime Organization/International Maritime Dangerous Goods Code

**OECD** - Organisation for Economic Co-operation and Development

**BCF** - Bioconcentration factor

**ICAO/IATA** - International Civil Aviation Organization/International Air Transport Association

**MARPOL** - International Convention for the Prevention of Pollution from Ships

**ATE** - Acute Toxicity Estimate

**VOC** - (Volatile Organic Compound)

### Key literature references and sources for data

<https://echa.europa.eu/information-on-chemicals>

Suppliers safety data sheet, Chemadvisor - LOLI, Merck index, RTECS

**Revision Date** 23-Mar-2025  
**Revision Summary** Not applicable.

ACR46993

# SAFETY DATA SHEET

Dabigatran etexilate

Revision Date 23-Mar-2025

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**In accordance with local and national regulations: Occupational Safety and Health (Classification, Labelling and Safety Data Sheet of Hazardous Chemicals) Regulations 2013**

## **Disclaimer**

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**End of Safety Data Sheet**