

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: **Varenicline tartrate**  
 Product Description: **Varenicline tartrate**  
 Cat No. : 470080000; 470080010; 470082500  
 CAS No 375815-87-5  
 Molecular Formula C13 H13 N3 · C4 H6 O6

**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,  
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 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**

Acute oral toxicity	Category 4 (H302)
Acute aquatic toxicity	Category 1 (H400)

**Label Elements**

**Signal Word**
**Warning**
**Hazard Statements**

H302 - Harmful if swallowed

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H400 - Very toxic to aquatic life

## Precautionary Statements

### Prevention

P264 - Wash face, hands and any exposed skin thoroughly after handling

P270 - Do not eat, drink or smoke when using this product

### Response

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell

P330 - Rinse mouth

### Storage

P403 - Store in a well-ventilated place

### Disposal

P501 - Dispose of contents/ container to an approved waste disposal plant

## Other Hazards

No information available

This product does not contain any known or suspected endocrine disruptors

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No	Weight %
Varenicline tartrate	375815-87-5	<=100

## SECTION 4: FIRST AID MEASURES

### Description of first aid measures

#### General Advice

If symptoms persist, call a physician.

#### Eye Contact

Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.

#### Skin Contact

Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.

#### Ingestion

Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.

#### Inhalation

Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.

#### Self-Protection of the First Aider

Ensure that medical personnel are aware of the material(s) involved, take precautions to protect themselves and prevent spread of contamination.

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

No information available.

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

#### Notes to Physician

Treat symptomatically.

## SECTION 5: FIREFIGHTING MEASURES

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## 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

Do not allow run-off from fire-fighting to enter drains or water courses.

## **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.

## **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

Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system. Prevent product from entering drains. Local authorities should be advised if significant spillages cannot be contained.

### Methods and Material for Containment and Cleaning Up

Sweep up and shovel into suitable containers for disposal. Keep in suitable, closed containers for disposal.

### 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. Do not get in eyes, on skin, or on 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 under an inert atmosphere.

### Specific End Uses

Use in laboratories.

## **SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

### Control Parameters

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## Exposure Controls

### Engineering Measures

Ensure adequate ventilation, especially in confined areas.

Wherever possible, engineering control measures such as the isolation or enclosure of the process, the introduction of process or equipment changes to minimise release or contact, and the use of properly designed ventilation systems, should be adopted to control hazardous materials at source

### 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 compatability, 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.

#### **Respiratory Protection**

When workers are facing concentrations above the exposure limit they must use appropriate certified respirators

#### **Recommended Filter type:**

Particulates filter conforming to EN 143

To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained properly

When RPE is used a face piece Fit Test should be conducted

### Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice

### Environmental exposure controls

Prevent product from entering drains Do not allow material to contaminate ground water system Local authorities should be advised if significant spillages cannot be contained

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### Information on basic physical and chemical properties

#### **Appearance**

Light yellow

#### **Physical State**

Solid

#### **Odor**

No information available

#### **Odor Threshold**

No data available

#### **pH**

No information available

#### **Melting Point/Range**

No data available

#### **Softening Point**

No data available

#### **Boiling Point/Range**

206 - 208 °C / 402.8 - 406.4 °F

#### **Flash Point**

No information available

**Method -** No information available

#### **Evaporation Rate**

Not applicable

Solid

#### **Flammability (solid,gas)**

No information available

#### **Explosion Limits**

No data available

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Vapor Pressure	No data available	
Vapor Density	Not applicable	Solid
Specific Gravity / Density	No data available	
Bulk Density	No data available	
Water Solubility	No information available	
Solubility in other solvents	No information available	

## Partition Coefficient (n-octanol/water)

Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
Viscosity	Not applicable	Solid
Explosive Properties	No information available	
Oxidizing Properties	No information available	

Molecular Formula	C13 H13 N3 · C4 H6 O6
Molecular Weight	361.35

## SECTION 10: STABILITY AND REACTIVITY

### Reactivity

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
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**(a) acute toxicity;**

Oral Category 4  
Dermal No data available  
Inhalation No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Varenicline tartrate	500,1 mg/kg (Rat)	-	-

**(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

**(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** Very toxic to aquatic organisms. The product contains following substances which are hazardous for the environment.

**Persistence and degradability** No information available  
**Degradation in sewage treatment plant** Contains substances known to be hazardous to the environment or not degradable in waste water treatment plants.

**Bioaccumulative potential** No information available

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**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**

Should not be released into the environment Waste is classified as hazardous Dispose of in accordance with the European Directives on waste and hazardous waste Dispose of in accordance with local regulations

#### **Contaminated Packaging**

Dispose of this container to hazardous or special waste collection point.

#### **Other Information**

Do not flush to sewer Waste codes should be assigned by the user based on the application for which the product was used Do not empty into drains Do not let this chemical enter the environment

## SECTION 14: TRANSPORT INFORMATION

### IMDG/IMO

**UN-No** UN3077  
**Hazard Class** 9  
**Packing Group** III  
**Proper Shipping Name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Varenicline tartrate

### Road and Rail Transport

**UN-No** UN3077  
**Hazard Class** 9  
**Packing Group** III  
**Proper Shipping Name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Varenicline tartrate

### IATA

**UN-No** UN3077  
**Hazard Class** 9  
**Packing Group** III  
**Proper Shipping Name** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. Varenicline tartrate

**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
Varenicline tartrate	-	-	-	-	-	X	-	-	-

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## National Regulations

**Persistent Organic Pollutant**  
**Ozone Depletion Potential**

This product does not contain any known or suspected substance  
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.

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

### **Disclaimer**

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text

**End of Safety Data Sheet**