

Australian statement of hazardous nature : Classified as hazardous according to criteria of Safe Work Australia

Section 1 - Identification

Product Name Varenicline tartrate

CAS No 375815-87-5

Product Code 470080000; 470080010; 470082500

Address ThermoFisher Scientific Australia Pty Ltd
5 Caribbean Drive, Scoresby
VICTORIA 3179, Australia

Emergency Tel. **CHEMTREC®**
03 9757 4559 or +613 9757 4559

Telephone / Fax Numbers Tel: 1300 735 292
Fax: 1800 067 639

E-mail address ANZinfo@thermofisher.com

Recommended Use Laboratory chemicals.

Uses advised against This product does not contain any substance(s) on the Illicit Drug Precursors/Reagents list.
This product does not contain any substance(s) subject to Prohibition, Authorization or Restriction. This product does not contain any substance(s) listed on the voluntary National Code of Practice for Chemicals of Security Concern.

Section 2 - Hazard(s) Identification

Classification under Safe Work Australia

Classified as hazardous according to criteria of Safe Work Australia

Physical hazards
No hazards identified

Health hazards

Acute Oral Toxicity Category 4

Environmental hazards

Acute aquatic toxicity Category 1

Label Elements



Exclamation Mark



Environment

Signal Word**Danger****Hazard Statements**

H302 - Harmful if swallowed

H400 - Very toxic to aquatic life

Precautionary Statements

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

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

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

P330 - Rinse mouth

P403 - Store in a well-ventilated place

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

Other information

No information available

Section 3 - Composition and Information on Ingredients

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

Section 4 - First Aid Measures

Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
Ingestion	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
Skin Contact	Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists, call a physician.
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
General Advice	If symptoms persist, call a physician.
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.
First Aid Facilities	Eyewash, safety shower and washroom.
Most important symptoms and effects	No information available.
Notes to Physician	Treat symptomatically.

Section 5 - Fire Fighting Measures**Suitable Extinguishing Media**

Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Dry chemical, CO₂, water spray or alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

No information available.

Hazardous Decomposition Products

Carbon monoxide (CO), Carbon dioxide (CO₂), Nitrogen oxides (NO_x).

Specific Hazards Arising from the Chemical

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

Special protective equipment and precautions 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

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 for Containment and Clean Up**Clean-up methods - small spillage**

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

Clean-up methods - large spillage

Typically only supplied in small quantities as packaged goods.

If extremely toxic or used in larger quantities ensure a spillage action plan is in place. Evacuate area. Control the source and/or contain the spill if safe and able to do so. Use temporary diking, sand bags, dry sand, earth or proprietary booms/absorbent pads if available. Obtain advice on containment, neutralisation and clean-up from local emergency responders.

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.

AS/NZS 2243.10:2004, Safety in laboratories - Storage of chemicals

Section 8 - Exposure Controls and Personal Protection

Exposure limits

The product does not contain any hazardous materials with occupational exposure limits established.

Biological limit values

This product, as supplied, does not contain any hazardous materials with biological limits established by the region specific regulatory bodies

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) (Australian/New Zealand Standard AS/NZS 1337 - Eye protectors for Industrial applications)

Hand Protection

Protective gloves

Glove material	Breakthrough time	Glove thickness	AUS/NZ Standard	Glove comments
Nitrile rubber	See manufacturers	-	AS/NZS 2161	(minimum requirement)
Neoprene	recommendations			
Natural rubber				
PVC				

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.

Skin and body protection

Long sleeved clothing

Respiratory Protection

Use an AS/NZS 1716 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. To protect the wearer, respiratory protective equipment must be the correct fit and be used and maintained in line with AS/NZS 1715 on the use and maintenance of respiratory protective devices

**Recommended Filter type:
Recommended half mask:-**

Particulates filter conforming to EN 143 (or AUS/NZ equivalent)
Particle filtering: EN149:2001 (or AUS/NZ equivalent)
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	
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	

Other information

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

Section 10 - Stability and Reactivity

Reactivity	None known, based on information available
Stability	No information available.
Conditions to Avoid	Incompatible products.
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Carbon monoxide (CO). Carbon dioxide (CO ₂). Nitrogen oxides (NO _x).
Hazardous Polymerization	No information available.

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
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(c) serious eye damage/irritation;	No data available
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(d) respiratory or skin sensitization;

Respiratory	No data available
Skin	No data available

(e) germ cell mutagenicity;	No data available
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(f) carcinogenicity;	No data available
	There are no known carcinogenic chemicals in this product

(g) reproductive toxicity;	No data available
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(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

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
Mobility	No information available.
Endocrine Disruptor Information	This product does not contain any known or suspected endocrine disruptors
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 13 - Disposal Considerations

Waste from Residues/Unused Products	Do not allow into drains or watercourses or dispose of where ground or surface waters may be affected. Wastes, including emptied containers, are controlled wastes and should be disposed of in accordance with all federal, E.P.A., state and local regulations. Assure conformity with all applicable regulations.
Contaminated Packaging	Dispose of this container to hazardous or special waste collection point.
Other Information	Chemical wastes should be disposed through a licensed commercial waste collection service. 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
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Technical Shipping Name	Varenicline tartrate
Hazard Class	9
Packing Group	III

ADG

UN-No	UN3077
Proper Shipping Name	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
Technical Shipping Name	Varenicline tartrate

Hazard Class 9
Packing Group III

IATA

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

Environmental hazards Dangerous for the environment
Product is a marine pollutant according to the criteria set by IMDG/IMO

Special Precautions No special precautions required

Additional information None known

Section 15 - Regulatory Information

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

National Regulations Australia

See section 8 for national exposure control parameters.

Standard for the Uniform Scheduling of Medicines and Poisons

No poison schedule number allocated.

Australian - Illicit Drug Precursors/Reagents Substance List

This product does not contain any substance(s) on the Illicit Drug Precursors/Reagents list.

Chemicals of Security Concern

This product does not contain any substance(s) listed on the voluntary National Code of Practice for Chemicals of Security Concern

National pollutant inventory Not applicable

Prohibition or notification/licensing requirements

Shown below are details of specific prohibition/notifications or licensing requirements when they apply.

This product does not contain any substance(s) subject to Prohibition, Authorization or Restriction.

International Inventories

Component	AICS	NZIoC	EINECS	ELINCS	TSCA	DSL	NDSL	PICCS	ENCs	ISHL	IECSC	KECL
Varenicline tartrate	-	-	-	-	-	-	-	-	-	X	-	-

Legend: X - Listed. '-' - Not Listed. **KECL** - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

International Regulations

Ozone Depletion Potential This product does not contain any known or suspected substance

Persistent Organic Pollutant This product does not contain any known or suspected substance

Rotterdam Convention (PIC) Not applicable

Basel convention on the control of transboundary movements of hazardous wastes and their disposal
Not applicable.

Component	CAS No	OECD HPV	Restriction of Hazardous Substances (RoHS)	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Major Accident Notification	Seveso III Directive (2012/18/EC) - Qualifying Quantities for Safety Report Requirements
Varenicline tartrate	375815-87-5	Not applicable	Not applicable	Not applicable	Not applicable

Authorisation/Restrictions according to EU REACH Not applicable

Section 16 - Other Information

Legend

AICS - Australian Inventory of Chemical Substances	NZIoC - New Zealand Inventory of Chemicals
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory	EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List	ENCS - Japanese Existing and New Chemical Substances
IECSC - Chinese Inventory of Existing Chemical Substances	KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances	CAS - Chemical Abstracts Service
TWA - Time Weighted Average	ACGIH - American Conference of Governmental Industrial Hygienists
IARC - International Agency for Research on Cancer	Predicted No Effect Concentration (PNEC)
ICAO/IATA - International Civil Aviation Organization/International Air Transport Association	IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code
MARPOL - International Convention for the Prevention of Pollution from Ships	
NZS 5433:2012 - Transport of Dangerous Goods on Land	OECD - Organisation for Economic Co-operation and Development
LD50 - Lethal Dose 50%	LC50 - Lethal Concentration 50%
EC50 - Effective Concentration 50%	ATE - Acute Toxicity Estimate
WEL - Workplace Exposure Limit	RPE - Respiratory Protective Equipment
DNEL - Derived No Effect Level	NOEC - No Observed Effect Concentration
POW - Partition coefficient Octanol:Water	BCF - Bioconcentration factor
vPvB - very Persistent, very Bioaccumulative	PBT - Persistent, Bioaccumulative, Toxic
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

Training Advice

Chemical incident response training.

Revision Date 17-Nov-2022
Revision Summary Not applicable.

This Safety Data Sheet (SDS) is prepared in accordance to and complies with the requirements of Safe Work Australia - Work Health and Safety Regulations (WHS Regulations).

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