

Classified as hazardous in accordance with the criteria of EPA New Zealand

Section 1 - Identification

Product Identifier

Product Name	<u>Candesartan cilexetil</u>
CAS No	145040-37-5
Molecular Formula	C33 H34 N6 O6
Molecular Weight	610.67
Recommended Use	Laboratory chemicals.
Uses advised against	No Information available

Product Code	466190000; 466190010
Address	Thermo Fisher Scientific New Zealand Ltd 244 Bush Road, Albany, Auckland, New Zealand
Emergency Tel.	CHEMTREC® 09 980 6780 or +64 9 980 6780
Telephone / Fax Numbers	Tel: 09 980 6700 Fax: 09 980 6788
E-mail address	ANZinfo@thermofisher.com

Section 2 - Hazard(s) Identification

Classification under Work Safe New Zealand

Classified as hazardous in accordance with the criteria of EPA New Zealand

GHS Classification

Physical hazards

Based on available data, the classification criteria are not met

Health hazards

Reproductive Toxicity	Category 2
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Environmental hazards

Acute aquatic toxicity	Category 1
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Label Elements

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

H361 - Suspected of damaging fertility or the unborn child

H400 - Very toxic to aquatic life

Precautionary Statements**Prevention**

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

P280 - Wear protective gloves/protective clothing/eye protection/face protection

P273 - Avoid release to the environment

Response

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P391 - Collect spillage

Storage

P403 - Store in a well-ventilated place

Disposal

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

Other hazards which do not result in classification

Section 3 - Composition and Information on Ingredients

Component	CAS No	Weight %
Candesartan cilexetil	145040-37-5	<=100

Section 4 - First Aid Measures

Description of first aid measures

General Advice	If symptoms persist, call a physician.
New Zealand Emergency Tel.	CHEMTREC® 09 980 6780 or +64 9 980 6780
Inhalation	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
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.
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 None reasonably foreseeable.

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.

Extinguishing media which must not be used for safety reasons

No information available.

Specific Hazards Arising from the Chemical

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

Hazardous Combustion Products

Carbon oxides, Nitrogen oxides (NO_x).

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

Personal Precautions, Protective Equipment and Emergency Procedures

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

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

Precautions to prevent secondary hazards

Clean contaminated objects and areas thoroughly observing environmental regulations

Reference to Other Sections

Refer to protective measures listed in Sections 8 and 13.

Section 7 - Handling and Storage

Precautions for Safe Handling

Advice on 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.

Hygiene Measures

Handle in accordance with good industrial hygiene and safety practice. Keep away from food, drink and animal feeding stuffs. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing and gloves, including the inside, before re-use. Wash hands before breaks and after work.

Conditions for Safe Storage, Including any Incompatibilities

Storage Conditions

Keep container tightly closed in a dry and well-ventilated place. To maintain product quality: Keep refrigerated.

Incompatible Materials

Oxidizing agent.

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

Section 8 - Exposure Controls and Personal Protection

Control parameters**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

Appropriate engineering 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

Individual protection measures, such as 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, Neoprene, Natural rubber, PVC.	See manufacturers recommendations	-	AS/NZS 2161	(minimum requirement)

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

Physical State	Solid	
Appearance		
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	No information available	
Flammability (liquid)	Not applicable	Solid
Flammability (solid,gas)	No information available	
Explosion Limits	No data available	
Flash Point	No information available	Method - No information available
Autoignition Temperature	No data available	
Decomposition Temperature	No data available	
Viscosity	Not applicable	Solid
Water Solubility	No information available	
Solubility in other solvents	No information available	
Partition Coefficient (n-octanol/water)		
Component	log Pow	
Candesartan cilexetil	>3	
Vapor Pressure	No data available	
Density / Specific Gravity	No data available	
Bulk Density	No data available	
Vapor Density	Not applicable	Solid
Particle characteristics	No data available	
Other information		
Molecular Formula	C33 H34 N6 O6	
Molecular Weight	610.67	
Evaporation Rate	Not applicable - Solid	

Section 10 - Stability and Reactivity

Reactivity	None known, based on information available
Stability	Stable under normal conditions.
Sensitivity to Mechanical Impact	No information available
Sensitivity to Static Discharge	No information available
Hazardous Polymerization	No information available.
Hazardous Reactions	None under normal processing.
Conditions to Avoid	Heat, flames and sparks.
Incompatible Materials	Oxidizing agent.

Hazardous Decomposition Products Carbon oxides. Nitrogen oxides (NOx).

Section 11 - Toxicological Information

Acute Effects**Information on likely routes of exposure****Product Information**

Inhalation	Not an expected route of exposure.
Eyes	Avoid contact with eyes.
Skin	Avoid contact with skin.
Ingestion	May be harmful if swallowed.

Numerical measures of toxicity**(a) acute toxicity;**

Oral	Based on available data, the classification criteria are not met
Dermal	No data available
Inhalation	No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Candesartan cilexetil	> 2 g/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;
Reproductive Effects**

Category 2
Possible risk of impaired fertility Possible risk of harm to the unborn child

(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**

Aquatic ecotoxicity	Very toxic to aquatic organisms. The product contains following substances which are hazardous for the environment.
Terrestrial ecotoxicity	There is no data for this product
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

Component	log Pow	Bioconcentration factor (BCF)
Candesartan cilexetil	>3	No data available

Mobility No information available.

Other adverse effects

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 treatment methods

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 Disposal agencies or waste contractors must comply with the New Zealand Hazardous Substances (Disposal) Regulations. 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

NZS 5433:2020

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

IATA

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

Hazard Class 9
Packing Group III

IMDG/IMO

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

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable, packaged goods

Special Precautions No special precautions required. Please refer to the applicable dangerous goods regulations for additional information.

Additional information None known

Section 15 - Regulatory Information

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

National Regulations

There are no applicable tolerable exposure limits or environmental exposure limits according to the EPA Controls for Hazardous Substances

Certified handlers, tracking and controlled substance license requirements

Certified handlers are required for some substances. This includes substances requiring a controlled substance license, and most explosives, vertebrates toxic agents, and certain fumigants. Acutely toxic substances which are a Category 1 or 2, such as pesticides also require Certified handlers. Please check the Health and Safety at Work Act 2015 for further information. Tracking is required for some highly hazardous substances. These substances need to be under the control of an appropriately trained person or appropriately secured. Please check the Health and Safety at Work Act 2015 for further information.

Prohibition or notification/licensing requirements

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

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

Authorisation/Restrictions according to EU REACH Not applicable

International Inventories

New Zealand (NZIoC), Australia (AICS), Europe (EINECS/ELINCS/NLP), Korea (KECL), China (IECSC), Taiwan (TCSI), Japan (ENCS), Japan (ISHL), Canada (DSL/NDL), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	NZIoC	AICS	EINECS	ELINCS	NLP	KECL	IECSC	TCSI
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Candesartan cilexetil	145040-37-5	-	-	-	-	-	-	X
Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	PICCS	ISHL	ENCS
Candesartan cilexetil	145040-37-5	-	-	-	-	-	-	-

Legend: X - Listed '-' - Not Listed

KECL - NIER number or KE number (<http://ncis.nier.go.kr/en/main.do>)

Section 16 - Other Information

This safety data sheet complies with the requirements of the EPA Hazardous Substances (Hazard Classification) Notice 2020 and WorkSafe New Zealand Regulations

Legend

NZIoC - New Zealand Inventory of Chemicals

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

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

IECSC - Chinese Inventory of Existing Chemical Substances

PICCS - Philippines Inventory of Chemicals and Chemical Substances

TWA - Time Weighted Average

IARC - International Agency for Research on Cancer

NZS 5433:2020 - Transport of Dangerous Goods on Land

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

MARPOL - International Convention for the Prevention of Pollution from Ships

LD50 - Lethal Dose 50%

EC50 - Effective Concentration 50%

WEL - Workplace Exposure Limit

DNEL - Derived No Effect Level

POW - Partition coefficient Octanol:Water

vPvB - very Persistent, very Bioaccumulative

VOC - (Volatile Organic Compound)

AICS - Australian Inventory of Chemical Substances

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

ENCS - Japanese Existing and New Chemical Substances

KECL - Korean Existing and Evaluated Chemical Substances

CAS - Chemical Abstracts Service

ACGIH - American Conference of Governmental Industrial Hygienists

PNEC - Predicted No Effect Concentration

OECD - Organisation for Economic Co-operation and Development

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

LC50 - Lethal Concentration 50%

ATE - Acute Toxicity Estimate

RPE - Respiratory Protective Equipment

NOEC - No Observed Effect Concentration

BCF - Bioconcentration factor

PBT - Persistent, Bioaccumulative, Toxic

Key literature references and sources for data

HSNO classifications provided in the New Zealand Chemical Classification Information Database (CCID).

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

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

EPA Guide to classifying hazardous substances in New Zealand

EPA - Assigning a product to an existing HSNO approval guide

Training Advice

Chemical incident response training.

Revision Date 10-Mar-2023

Revision Summary Not applicable

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