

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

## Section 1 - Identification

### Product Identifier

Product Name	<u>Levocetirizine dihydrochloride</u>
CAS No	130018-87-0
Molecular Formula	C <sub>21</sub> H <sub>25</sub> Cl N <sub>2</sub> O <sub>3</sub> . 2 H Cl
Molecular Weight	461.81
Recommended Use	Laboratory chemicals.
Uses advised against	No Information available

Product Code	<b>467470000, 467470010, 467470050</b>
Address	Thermo Fisher Scientific New Zealand Ltd 244 Bush Road, Albany, Auckland, New Zealand
Emergency Tel.	<b>CHEMTREC®</b> <b>09 980 6780 or +64 9 980 6780</b>
Telephone / Fax Numbers	Tel: 09 980 6700 Fax: 09 980 6788
E-mail address	<u>ANZinfo@thermofisher.com</u>

## 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

Acute Oral Toxicity Category 4

#### Environmental hazards

Acute aquatic toxicity Category 1

### Label Elements

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

H302 - Harmful if swallowed

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

P273 - Avoid release to the environment

**Response**

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

P330 - Rinse mouth

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 %
Levocetirizine dihydrochloride	130018-87-0	<= 100

## Section 4 - First Aid Measures

**Description of first aid measures**

<b>General Advice</b>	If symptoms persist, call a physician.
<b>New Zealand Emergency Tel.</b>	CHEMTREC® 09 980 6780 or +64 9 980 6780
<b>Inhalation</b>	Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if symptoms occur.
<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. If skin irritation persists, call a physician.
<b>Ingestion</b>	Clean mouth with water and drink afterwards plenty of water. Get medical attention if symptoms occur.
<b>Self-Protection of the First Aider</b>	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. 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.

### **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<sub>x</sub>).

### **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.

**Incompatible Materials**

Strong oxidizing agents.

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	White	
Odor	No information available	
Odor Threshold	No data available	
pH	No information available	
Melting Point/Range	214 °C / 417.2 °F	
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)		
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	
<b>Other information</b>		
Molecular Formula	C21 H25 Cl N2 O3 . 2 H Cl	
Molecular Weight	461.81	
Evaporation Rate	Not applicable - Solid	

## Section 10 - Stability and Reactivity

Reactivity	None known, based on information available
Stability	Stable under recommended storage 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	Incompatible products.
Incompatible Materials	Strong oxidizing agents.
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	Category 4
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

**(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
<b>Persistence and Degradability</b>	
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.
<b>Other adverse effects</b>	
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	Levocetirizine dihydrochloride
Hazard Class	9
Packing Group	III

### IATA

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

### IMDG/IMO

UN-No	UN3077
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<b>Proper Shipping Name</b>	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.
<b>Technical Shipping Name</b>	Levocetirizine dihydrochloride
<b>Hazard Class</b>	9
<b>Packing Group</b>	III
<b>Environmental hazards</b>	Dangerous for the environment Product is a marine pollutant according to the criteria set by IMDG/IMO
<b>Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code</b>	Not applicable, packaged goods
<b>Special Precautions</b>	No special precautions required. Please refer to the applicable dangerous goods regulations for additional information.
<b>Additional information</b>	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

<b>Ozone Depletion Potential</b>	This product does not contain any known or suspected substance
<b>Persistent Organic Pollutant</b>	This product does not contain any known or suspected substance
<b>Rotterdam Convention (PIC)</b>	Not applicable
<b>Authorisation/Restrictions according to EU REACH</b>	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/NDSL), Philippines (PICCS). US EPA (TSCA) - Toxic Substances Control Act, (40 CFR Part 710)

Component	CAS No	NZIoC	AICS	EINECS	ELINCS	NLP	KECL	IECSC	TCSI
Levocetirizine dihydrochloride	130018-87-0	-	-	-	-	-	-	-	X

Component	CAS No	TSCA	TSCA Inventory notification - Active-Inactive	DSL	NDSL	PICCS	ISHL	ENCS
Levocetirizine dihydrochloride	130018-87-0	-	-	-	-	-	X	-



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/NDL** - 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