

# SAFETY DATA SHEET

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

## Section 1 - Identification

**Product Name Epinastine hydrochloride** 

**CAS No** 108929-04-0

**Product Code** 471580010; 471582500

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 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

E-mail address

No hazards identified

**Health hazards** 

**Acute Oral Toxicity** Category 3

**Environmental hazards** 

No hazards identified

**Label Elements** 



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Signal Word Danger

#### **Hazard Statements**

H301 - Toxic if swallowed

### **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 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor

P330 - Rinse mouth

P405 - Store locked up

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

#### Other information

No information available

This product does not contain any known or suspected endocrine disruptors

Toxic to terrestrial vertebrates

# Section 3 - Composition and Information on Ingredients

Component	CAS No	Weight %	
Epinastine hydrochloride	108929-04-0	<=100	

# Section 4 - First Aid Measures

**Inhalation** Remove to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth

method if victim ingested or inhaled the substance; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Immediate medical attention is required.

**Ingestion** Do NOT induce vomiting. Call a physician or poison control center immediately.

**Skin Contact** Wash off immediately with plenty of water for at least 15 minutes. Immediate medical

attention is required.

Eye Contact In the case of contact with eyes, rinse immediately with plenty of water and seek medical

advice.

General Advice Show this safety data sheet to the doctor in attendance. Immediate medical attention is

required.

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.

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

No information available.

#### **Hazardous Decomposition Products**

Carbon oxides, Nitrogen oxides (NOx), Hydrogen chloride.

### **Specific Hazards Arising from the Chemical**

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

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

# Section 6 - Accidental Release Measures

#### **Emergency procedures**

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation. Keep people away from and upwind of spill/leak. Evacuate personnel to safe areas.

#### **Environmental Precautions**

Should not be released into the environment.

### **Methods for Containment and Clean Up**

#### Clean-up methods - small spillage

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

#### Clean-up methods - large spillage

Typically only supplied is small quantiites 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. Do not get in eyes, on skin, or on clothing. Avoid dust formation. Use only under a chemical fume hood. Do not breathe (dust, vapor, mist, gas). Do not ingest. If swallowed then seek immediate medical assistance.

## Conditions for Safe Storage, Including any Incompatibilities

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

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

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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) (Australian/New Zealand Standard

AS/NZS 1337 - Eye protectors for Industrial applications)

Hand Protection Protective gloves

Glove material	U	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 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.

Skin and body protection Long sleeved clothing

Repiratory 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 repiratory protective devices

**Recommended Filter type:** Particulates filter conforming to EN 143 (or AUS/NZ equivalent)

Recommended half mask:- 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** No information available.

# Section 9 - Physical and Chemical Properties

#### Information on basic physical and chemical properties

**Appearance** 

Physical State Powder Solid

Odor No information available

Odor ThresholdNo data availablepHNo information availableMelting Point/Range273 °C / 523.4 °F

Softening Point

Boiling Point/Range

428 °C / 802.4 °F

Flash Point

No information available

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 DensityNot applicableSolid

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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 No data available **Decomposition Temperature** Not applicable **Viscosity** 

**Explosive Properties** No information available

No information available **Oxidizing Properties** 

Other information

Molecular Formula C16 H15 N3. CI H

**Molecular Weight** 285 78

# Section 10 - Stability and Reactivity

Reactivity None known, based on information available

Stability Stable under normal conditions.

Heat, flames and sparks. **Conditions to Avoid** 

**Incompatible Materials** None known.

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

**Hazardous Polymerization** No information available.

# Section 11 - Toxicological Information

#### Information on Toxicological Effects

### **Product Information**

(a) acute toxicity;

Oral Category 3 Dermal No data available Inhalation No data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation	
Epinastine hydrochloride	LD50 = 192 mg/kg (Rat)			

(b) skin corrosion/irritation; No data available

(c) serious eye damage/irritation; No data available

(d) respiratory or skin sensitization;

No data available Respiratory No data available Skin

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

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(g) reproductive toxicity; No data available

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

None known. **Target Organs** 

Not applicable (j) aspiration hazard;

Solid

Other Adverse Effects The toxicological properties have not been fully investigated.

Symptoms / effects, both acute and No information available

delayed

# Section 12 - Ecological Information

**Ecotoxicity effects** Contains no substances known to be hazardous to the environment or that are not

degradable in waste water treatment plants.

Persistence and Degradability No information available **Bioaccumulative Potential** No information available

No information available. Mobility

**Endocrine Disruptor Information Persistent Organic Pollutant Ozone Depletion Potential** 

This product does not contain any known or suspected endocrine disruptors

This product does not contain any known or suspected substance 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. Waste codes should be assigned by the user based on the application for which

the product was used. Do not empty into drains.

# Section 14 - Transport Information

### IMDG/IMO

**UN-No** UN2811

**Proper Shipping Name** TOXIC SOLID, ORGANIC, N.O.S.

**Technical Shipping Name** Epinastine hydrochloride

**Hazard Class** 6.1 **Packing Group** 

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ADG

**Proper Shipping Name** TOXIC SOLID, ORGANIC, N.O.S.

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Technical Shipping Name Epinastine hydrochloride

Hazard Class 6.1 Packing Group III

<u>IATA</u>

UN-No UN2811

Proper Shipping Name TOXIC SOLID, ORGANIC, N.O.S. Epinastine hydrochloride

Hazard Class 6.1
Packing Group

Environmental hazards No hazards identified

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 licencing requirements when they apply.

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

### **International Inventories**

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

### **International Regulations**

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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 dispoal 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
Epinastine hydrochloride	108929-04-0	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

**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

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

MARPOL - International Convention for the Prevention of Pollution from Ships

NZS 5433:2020 - Transport of Dangerous Goods on Land

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)

NZIoC - New Zealand Inventory of Chemicals

**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

Predicted No Effect Concentration (PNEC)

IMO/IMDG - International Maritime Organization/International Maritime

Dangerous Goods Code

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

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

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

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

#### **Training Advice**

Chemical hazard awareness training, incorporating labelling, Safety Data Sheets (SDS), Personal Protective Equipment (PPE) and hygiene.

Use of personal protective equipment, covering appropriate selection, compatibility, breakthrough thresholds, care, maintenance, fit and standards.

First aid for chemical exposure, including the use of eye wash and safety showers.

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Revision Date 23-Aug-2024

**Revision Summary** SDS sections updated.

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**

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