

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

Section 1 - Identification

Product Name Amorolfine hydrochloride

CAS No 78613-38-4

Product Code TOKA2161

Address ThermoFisher Scientific Australia Pty Ltd
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 VICTORIA 3179, Australia

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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
 Skin Corrosion/Irritation

Category 4
 Category 2

Environmental hazards

Chronic aquatic toxicity

Category 2

Label Elements



Exclamation Mark



Environment

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

H302 - Harmful if swallowed

H315 - Causes skin irritation

H411 - Toxic to aquatic life with long lasting effects

Precautionary Statements

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

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

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

P362 + P364 - Take off contaminated clothing and wash it before reuse

Other information

This product does not contain any known or suspected endocrine disruptors

Section 3 - Composition and Information on Ingredients

| Component | CAS No | Weight % |
|--------------------------|------------|----------|
| Amorolfine hydrochloride | 78613-38-4 | >95 |

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 | No special precautions required. |
| 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**Water spray, carbon dioxide (CO₂), dry chemical, alcohol-resistant foam.**Extinguishing media which must not be used for safety reasons**

No information available.

Hazardous Decomposition Products

Carbon monoxide (CO), Sulfur oxides, Nitrogen oxides (NOx), Carbon dioxide (CO₂).

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.

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.

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. Avoid ingestion and inhalation. Avoid dust formation. Do not get in eyes, on skin, or on clothing.

Conditions for Safe Storage, Including any Incompatibilities

Keep containers tightly closed in a dry, cool and well-ventilated place. Protect from moisture.

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**

None under normal use conditions.

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 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

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:

Particle filter Particulates filter conforming to EN 143 (or AUS/NZ equivalent)

Recommended half mask:-

Valve filtering: EN405 or Half mask: EN140 plus filter, EN 141 Particle filtering: EN149:2001 (or AUS/NZ equivalent)

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.

Section 9 - Physical and Chemical Properties

Information on basic physical and chemical properties**Appearance****Physical State**

Solid

Odor

No information available

Odor Threshold

No data available

pH

Not applicable

Melting Point/Range

221 - 223 °C / 429.8 - 433.4 °F

Softening Point

No data available

Boiling Point/Range

No information available

Flash Point

Not applicable

Method - No information available

Evaporation Rate

Not applicable

Solid

Flammability (solid,gas)

Not applicable

Liquid

Explosion Limits

No data available

Vapor Pressure

No data available

Vapor Density

Not applicable

Solid

Specific Gravity / Density**Bulk Density**

Not applicable

Liquid

Water Solubility

9 g/l

Solubility in other solvents

No information available

Partition Coefficient (n-octanol/water)

| | | |
|----------------------------------|--------------------------|-------|
| Component | log Pow | |
| Amorolfine hydrochloride | 5.772 | |
| 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 | C21 H35 N O . H Cl |
| Molecular Weight | 353.97 |

Section 10 - Stability and Reactivity

| | |
|---|--|
| Reactivity | None known, based on information available |
| Stability | Moisture sensitive. |
| Conditions to Avoid | Incompatible products, Excess heat, Avoid dust formation, Exposure to moisture. |
| Incompatible Materials | Strong oxidizing agents. |
| Hazardous Decomposition Products | Carbon monoxide (CO). Sulfur oxides. Nitrogen oxides (NOx). Carbon dioxide (CO ₂). |
| Hazardous Polymerization | Hazardous polymerization does not occur. |

Section 11 - Toxicological Information

Information on Toxicological Effects**Product Information****(a) acute toxicity;**

| | |
|-------------------|-------------------|
| Oral | Category 4 |
| Dermal | No data available |
| Inhalation | No data available |

| Component | LD50 Oral | LD50 Dermal | LC50 Inhalation |
|--------------------------|------------------|-------------|-----------------|
| Amorolfine hydrochloride | 1800 mg/kg (Rat) | | |

(b) skin corrosion/irritation; Category 2

(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 | No information available. |
| (j) aspiration hazard; | Not applicable Solid |
| Other Adverse Effects | The toxicological properties have not been fully investigated. |
| Symptoms / effects, both acute and delayed | No information available |

Section 12 - Ecological Information

| | | | | | |
|---------------------------------------|---|---|------------|-------------------------------|----------|
| Ecotoxicity effects | Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. The product contains following substances which are hazardous for the environment. | | | | |
| | Component | Freshwater Fish | Water Flea | Freshwater Algae | Microtox |
| | Amorolfine hydrochloride | 2,6 mg/l, 96 h (Oncorhynchus mykiss) | | | |
| Persistence and Degradability | Not readily biodegradable | | | | |
| Persistence | May persist. | | | | |
| Degradation in sewage treatment plant | Contains substances known to be hazardous to the environment or not degradable in waste water treatment plants. | | | | |
| Bioaccumulative Potential | Product has a high potential to bioconcentrate | | | | |
| | Component | log Pow | | Bioconcentration factor (BCF) | |
| | Amorolfine hydrochloride | 5.772 | | No data available | |
| Mobility | The product is water soluble, and may spread in water systems. Will likely be mobile in the environment due to its water solubility Is not likely mobile in the environment due its low water solubility and propensity to bind to soil particles | | | | |
| 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 substances, solid, n.o.s. |

| | |
|-------------------------|--------------------------|
| Technical Shipping Name | Amorolfine hydrochloride |
| Hazard Class | 9 |
| Packing Group | III |

ADG

| | |
|-------------------------|---|
| UN-No | UN3077 |
| Proper Shipping Name | Environmentally hazardous substances, solid, n.o.s. |
| Technical Shipping Name | Amorolfine hydrochloride |
| Hazard Class | 9 |
| Packing Group | III |

IATA

| | |
|-------------------------|---|
| UN-No | UN3077 |
| Proper Shipping Name | Environmentally hazardous substances, solid, n.o.s. |
| Technical Shipping Name | Amorolfine hydrochloride |
| 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 licencing 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 |
|--------------------------|------|-------|--------|--------|------|-----|------|-------|------|------|-------|------|
| Amorolfine hydrochloride | - | - | - | - | - | - | - | - | - | 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 |
|--------------------------|------------|----------------|--|---|--|
| Amorolfine hydrochloride | 78613-38-4 | 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

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
PNEC - Predicted No Effect Concentration
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

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 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.

Revision Date

12-Mar-2025

Revision Summary

Update to GHS format.

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