

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

Section 1 - Identification

Product Name Dronedarone hydrochloride, 98%

CAS No 141625-93-6

Product Code **H36124**

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Emergency Tel. **CHEMTREC®**
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Telephone / Fax Numbers Tel: 1300 735 292
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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
Skin Corrosion/Irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 2
Specific target organ toxicity - (single exposure)	Category 3

Environmental hazards
No hazards identified

Label Elements



Exclamation Mark

Signal Word**Warning****Hazard Statements**

H302 - Harmful if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation

Precautionary Statements

P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P271 - Use only outdoors or in a well-ventilated area
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P312 - Call a POISON CENTER or doctor if you feel unwell
P330 - Rinse mouth
P362 + P364 - Take off contaminated clothing and wash it before reuse
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
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 %
Dronedarone hydrochloride	141625-93-6	<=100

Section 4 - First Aid Measures

Inhalation	Remove to fresh air. Get medical attention immediately 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. Get medical attention immediately if symptoms occur.
Eye Contact	Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get medical attention.
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

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.

Hazardous Decomposition Products

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

Section 6 - Accidental Release Measures

Emergency procedures

Ensure adequate ventilation. Use personal protective equipment as required. Avoid dust formation.

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 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 contact with skin, eyes or 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.

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

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:

Particle filter (or AUS/NZ equivalent)

Recommended half mask:-

Particle filtering: EN149:2001 (or AUS/NZ equivalent)

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 Threshold

No data available

pH

Not applicable

Melting Point/Range	140 - 144 °C / 284 - 291.2 °F	
Softening Point	No data available	
Boiling Point/Range	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 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	Not applicable	
Decomposition Temperature	No data available	
Viscosity	Not applicable	Solid
Explosive Properties	No information available	
Oxidizing Properties	No information available	
Other information		
Molecular Formula	C31H44N2O5S•HCl	
Molecular Weight	593.22	

Section 10 - Stability and Reactivity

Reactivity	None known, based on information available
Stability	Stable under normal conditions.
Conditions to Avoid	Heat, flames and sparks.
Incompatible Materials	Oxidizing agent.
Hazardous Decomposition Products	Carbon monoxide (CO). Carbon dioxide (CO ₂). Sulfur oxides. Nitrogen oxides (NO _x). Hydrogen chloride.
Hazardous Polymerization	No information available.

Section 11 - Toxicological Information

Information on Toxicological Effects

Product Information

(a) acute toxicity;	
Oral	Category 4
Dermal	No data available
Inhalation	No data available
(b) skin corrosion/irritation;	
	Category 2
(c) serious eye damage/irritation;	
	Category 2
(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;	Category 3
Results / Target organs	Respiratory system
(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	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
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. 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	Not regulated
ADG	Not regulated

IATA	Not regulated
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 licensing 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

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
Droneadone hydrochloride	141625-93-6	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/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
ICAO/IATA - International Civil Aviation Organization/International Air Transport Association
MARPOL - International Convention for the Prevention of Pollution from Ships
NZS 5433:2012 - 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
PNEC - Predicted No Effect Concentration (PNEC)
IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code
ADG Australian Code for the Transport of Dangerous Goods by Road and Rail
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.

Revision Date

20-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