

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

Section 1 - Identification

Product Name Dasatinib monohydrate

CAS No 863127-77-9

Product Code 462320000; 462320010

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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 3
Skin Corrosion/Irritation	Category 2
Serious Eye Damage/Eye Irritation	Category 1
Carcinogenicity	Category 2
Reproductive Toxicity	Category 2
Specific target organ toxicity - (repeated exposure)	Category 1

Environmental hazards

Chronic aquatic toxicity	Category 1
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Label Elements



Skull and Crossbones



Health Hazard



Corrosion



Environment

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

H301 - Toxic if swallowed
 H315 - Causes skin irritation
 H318 - Causes serious eye damage
 H351 - Suspected of causing cancer
 H361 - Suspected of damaging fertility or the unborn child
 H372 - Causes damage to organs through prolonged or repeated exposure
 H410 - Very toxic to aquatic life with long lasting effects

Precautionary Statements

P201 - Obtain special instructions before use
 P202 - Do not handle until all safety precautions have been read and understood
 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
 P302 + P352 - IF ON SKIN: Wash with plenty of soap and water
 P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
 P310 - Immediately call a POISON CENTER or doctor
 P330 - Rinse mouth
 P362 + P364 - Take off contaminated clothing and wash it before reuse
 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 %
Dasatinib monohydrate	863127-77-9	>95
Dasatinib	302962-49-8	-

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	None reasonably foreseeable. Causes severe eye damage.
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 dioxide (CO₂), Carbon monoxide (CO), Hydrogen chloride, Nitrogen oxides (NO_x), Sulfur oxides.

Specific Hazards Arising from the Chemical

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

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

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

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 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. 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. Store in freezer.

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

Ensure that eyewash stations and safety showers are close to the workstation location.

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

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: 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

Appearance	White Pale yellow	
Physical State	Solid	
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	
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	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	C22 H26 Cl N7 O2 S . H2 O	
Molecular Weight	506.02	

Section 10 - Stability and Reactivity

Reactivity	None known, based on information available
Stability	No information available.
Conditions to Avoid	Incompatible products.
Incompatible Materials	Strong oxidizing agents.
Hazardous Decomposition Products	Carbon dioxide (CO ₂). Carbon monoxide (CO). Hydrogen chloride. Nitrogen oxides (NO _x). Sulfur oxides.
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
Dasatinib monohydrate	100 mg/kg (rat)		

(b) skin corrosion/irritation; Category 2

(c) serious eye damage/irritation; Category 1

(d) respiratory or skin sensitization;

Respiratory	No data available
Skin	No data available

(e) germ cell mutagenicity; No data available

(f) carcinogenicity; Category 2

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity;
Reproductive Effects

Category 2
SUSPECT REPRODUCTIVE HAZARD - CONTAINS MATERIAL WHICH MAY INJURE UNBORN CHILD (CAUSE BIRTH DEFECTS) (BASED ON ANIMAL DATA)

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure;

Category 1

Target Organs

No information available.

(j) aspiration hazard;

Not applicable
Solid

Symptoms / effects, both acute and delayed No information available

Section 12 - Ecological Information

Ecotoxicity effects

Very 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.

Persistence and Degradability
Degradation in sewage treatment plant

No information available

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.

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	UN2811
Proper Shipping Name	TOXIC SOLID, ORGANIC, N.O.S.
Technical Shipping Name	Dasatinib monohydrate
Hazard Class	6.1
Packing Group	III

ADG

UN-No	UN2811
Proper Shipping Name	TOXIC SOLID, ORGANIC, N.O.S.
Technical Shipping Name	Dasatinib monohydrate
Hazard Class	6.1
Packing Group	III

IATA

UN-No	UN2811
Proper Shipping Name	TOXIC SOLID, ORGANIC, N.O.S.
Technical Shipping Name	Dasatinib monohydrate
Hazard Class	6.1
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

Classified as a scheduled poison according to the Standard for Uniform Scheduling of Medicines and Poisons.

Component	Standard for the Uniform Scheduling of Medicines and Poisons
Dasatinib - 302962-49-8	Schedule 4 listed - present

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

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
Dasatinib monohydrate	863127-77-9	Not applicable	Not applicable	Not applicable	Not applicable
Dasatinib	302962-49-8	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 5433:2020 - 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.
Chemical incident response training.

Revision Date 18-Apr-2023
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