

SAFETY DATA SHEET

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

Section 1 - Identification

Product Name Gliclazide

CAS No 21187-98-4

Synonyms 1-(3-Azabicyclo[3.3.0]oct-3-yl)-3-p-tolylsulfonylurea

Product Code TOKG0381

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

Reproductive Toxicity Category 2

Environmental hazards

No hazards identified

Label Elements



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Signal Word Warning

Hazard Statements

H361 - Suspected of damaging fertility or the unborn child

Precautionary Statements

P201 - Obtain special instructions before use

P202 - Do not handle until all safety precautions have been read and understood

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

P308 + P313 - IF exposed or concerned: Get medical advice/attention

P403 - Store in a well-ventilated place

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

Other information

This product does not contain any known or suspected endocrine disruptors

Section 3 - Composition and Information on Ingredients

Component	CAS No	Weight %		
Gliclazide	21187-98-4	>95		

Section 4 - First Aid Measures

Inhalation Remove to fresh air. If not breathing, give artificial respiration. Get medical attention if

symptoms occur.

Ingestion Get medical attention if symptoms occur. Clean mouth with water and drink afterwards

plenty of water.

Skin Contact Wash off immediately with plenty of water for at least 15 minutes. If skin irritation persists,

call a physician.

Eye Contact Get medical attention. Rinse immediately with plenty of water, also under the eyelids, for at

least 15 minutes.

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.

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Hazardous Decomposition Products

Carbon monoxide (CO), Nitrogen oxides (NOx), Sulfur oxides, 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

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

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. Keep in suitable, closed containers for disposal.

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. 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 container tightly closed. 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

Exposure Controls

Engineering Measures

None under normal use conditions.

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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

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

Solid

and maintenance of repiratory protective devices

Particle filter (or AUS/NZ equivalent) Recommended Filter type:

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 Solid

Odor no data available **Odor Threshold** No data available Not applicable Ha

Melting Point/Range 163 - 169 °C / 325.4 - 336.2 °F

Softening Point No data available **Boiling Point/Range** No information available Flash Point No information available

Method - No information available Solid

Not applicable **Evaporation Rate** No information available

Flammability (solid,gas) No data available

Explosion Limits

Vapor Pressure No data available **Vapor Density** Not applicable

Specific Gravity / Density No data available **Bulk Density** No data available Water Solubility Insoluble

Solubility in other solvents No information available

Partition Coefficient (n-octanol/water)

No data available **Autoignition Temperature Decomposition Temperature** No data available

Solid Not applicable **Viscosity**

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Other information

Molecular Formula C15 H21 N3 O3 S

Molecular Weight 323.41

Section 10 - Stability and Reactivity

Reactivity None known, based on information available

Stability Stable under recommended storage conditions.

Conditions to Avoid Incompatible products.

Incompatible Materials Strong oxidizing agents, Acids, Bases.

Hazardous Decomposition Products Carbon monoxide (CO). Nitrogen oxides (NOx). Sulfur oxides. Carbon dioxide (CO2).

Hazardous Polymerization No information available.

Section 11 - Toxicological Information

Information on Toxicological Effects

Product Information

(a) acute toxicity;

Oral Based on available data, the classification criteria are not met

DermalNo data availableInhalationNo data available

Component	LD50 Oral	LD50 Dermal	LC50 Inhalation
Gliclazide	LD50 = 1750 mg/kg (rat)		
	LD50 = 3 g/kg (Mice)		

(b) skin corrosion/irritation; No data available

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

(d) respiratory or skin sensitization;

RespiratorySkin
No data available
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; Category 2

(h) STOT-single exposure; No data available

(i) STOT-repeated exposure; No data available

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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 No information available

delayed

Section 12 - Ecological Information

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

degradable in waste water treatment plants.

Persistence and Degradability

Persistence

Insoluble in water.

Bioaccumulative Potential

Ozone Depletion Potential

May have some potential to bioaccumulate

Mobility Spillage unlikely to penetrate soil. Is not likely mobile in the environment due its low water

Endocrine Disruptor Information Persistent Organic Pollutant

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 Not regulated

ADG Not regulated

IATA Not regulated

No hazards identified **Environmental hazards**

Special Precautions No special precautions required

Additional information None known

Section 15 - Regulatory Information

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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
Gliclazide - 21187-98-4	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

Component	AICS	NZIoC	EINECS	ELINCS	TSCA	DSL	NDSL	PICCS	ENCS	ISHL	IECSC	KECL
Gliclazide	-	-	244-260-5	-	-	-	-	-	-	Х	Х	KE-18563

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 dispoal Not applicable.

	Component	CAS No	OECD HPV	Restriction of	Seveso III Directive	Seveso III Directive
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				Hazardous Substances (RoHS)	(2012/18/EC) - Qualifying Quantities for Major Accident Notification	(2012/18/EC) - Qualifying Quantities for Safety Report Requirements
I	Gliclazide	21187-98-4	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

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

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 12-Mar-2025

Update to GHS format. **Revision Summary**

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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