

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

Section 1 - Identification

Product Name Methotrexate

CAS No 59-05-2

Synonyms Amet; Glutamic acid, N-(p-(((2,4-diamino-6-pteridinyI)methyl)methylamino)benzol)-, L-

Product Code **J63075**

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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 2
Germ Cell Mutagenicity	Category 1B
Reproductive Toxicity	Category 1B
Specific target organ toxicity - (single exposure)	Category 3

Environmental hazards

No hazards identified

Label Elements



Skull and Crossbones



Health Hazard

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

H301 - Toxic if swallowed
H315 - Causes skin irritation
H319 - Causes serious eye irritation
H340 - May cause genetic defects
H360 - May damage fertility or the unborn child
H335 - May cause respiratory irritation

Precautionary Statements

P201 - Obtain special instructions before use
P202 - Do not handle until all safety precautions have been read and understood
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 eye protection/ face protection
P330 - Rinse mouth
P332 + P313 - If skin irritation occurs: Get medical advice/attention
P301 + P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor
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
P308 + P313 - IF exposed or concerned: Get medical advice/attention
P362 + P364 - Take off contaminated clothing and wash it before reuse
P403 + P233 - Store in a well-ventilated place. Keep container tightly closed
P405 - Store locked up
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 %
Methotrexate	59-05-2	>95

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.
Notes to Physician	Treat symptomatically.

Section 5 - Fire Fighting Measures

Suitable Extinguishing Media

CO₂, dry chemical, dry sand, alcohol-resistant foam.

Extinguishing media which must not be used for safety reasons

No information available.

Hazardous Decomposition Products

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

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

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

Environmental Precautions

Should not be released into the environment. See Section 12 for additional Ecological Information.

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

Avoid dust formation. Do not get in eyes, on skin, or on clothing. Wear personal protective equipment/face protection. 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

Protect from moisture. Protect from light. Store in freezer. Keep container tightly closed in a dry and well-ventilated place. Store under an inert atmosphere.

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

Use only under a chemical fume hood. 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:

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	Yellow	
Physical State	Powder Solid	
Odor	Odorless	
Odor Threshold	No data available	
pH	No information available	
Melting Point/Range	195 °C / 383 °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)	No information available	
Explosion Limits	No data available	
Vapor Pressure	No information available	
Vapor Density	Not applicable	Solid
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)		
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	C20H22N8O5	
Molecular Weight	454.2046	

Section 10 - Stability and Reactivity

Reactivity	None known, based on information available
Stability	Hygroscopic. Light sensitive.
Conditions to Avoid	Incompatible products, Avoid dust formation, Exposure to light, Exposure to moisture, Exposure to moist air or water.
Incompatible Materials	Strong oxidizing agents, Strong acids.
Hazardous Decomposition Products	Carbon monoxide (CO). Carbon dioxide (CO ₂). Nitrogen oxides (NO _x).
Hazardous Polymerization	Hazardous polymerization does not occur.

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
Methotrexate	LD50 = 135 mg/kg (Rat)		

(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; Category 1B

Mutagenic effects have occurred in humans

(f) carcinogenicity; No data available

There are no known carcinogenic chemicals in this product

(g) reproductive toxicity;
Reproductive Effects
Teratogenicity

Category 1B
Adverse reproductive effects have occurred in humans.
Teratogenic effects have occurred in humans.

(h) STOT-single exposure;

Category 3

Results / Target organs

Respiratory system

(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

Do not empty into drains.

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 InformationIMDG/IMO

UN-No	UN1544
Proper Shipping Name	ALKALOIDS, SOLID, N.O.S.
Technical Shipping Name	(Methotrexate)
Hazard Class	6.1
Packing Group	III

ADG

UN-No	UN1544
Proper Shipping Name	ALKALOIDS, SOLID, N.O.S.
Technical Shipping Name	(Methotrexate)
Hazard Class	6.1
Packing Group	III

IATA

UN-No	UN1544
Proper Shipping Name	ALKALOIDS, SOLID, N.O.S.
Technical Shipping Name	(Methotrexate)
Hazard Class	6.1
Packing Group	III

Environmental hazards	No hazards identified
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Special Precautions	No special precautions required
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Additional information	None known
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Section 15 - Regulatory InformationSafety, health and environmental regulations/legislation specific for the substance or mixtureNational 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
Methotrexate - 59-05-2	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
Methotrexate	-	X	200-413-8	-	X	-	X	-	-		-	KE-09753

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
Methotrexate	59-05-2	Not applicable	Not applicable	Not applicable	Not applicable

Authorisation/Restrictions according to EU REACH

Component	REACH (1907/2006) - Annex XIV - Substances Subject to	REACH (1907/2006) - Annex XVII - Restrictions on Certain Dangerous	REACH Regulation (EC 1907/2006) article 59 - Candidate
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	Authorization	Substances	List of Substances of Very High Concern (SVHC)
Methotrexate	-	Use restricted. See item 75. (see link for restriction details)	-

<https://echa.europa.eu/substances-restricted-under-reach>

Section 16 - Other Information

Legend

AICS - Australian Inventory of Chemical Substances	NZIoC - New Zealand Inventory of Chemicals
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory	EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
DSL/NDL - Canadian Domestic Substances List/Non-Domestic Substances List	ENCS - Japanese Existing and New Chemical Substances
IECSC - Chinese Inventory of Existing Chemical Substances	KECL - Korean Existing and Evaluated Chemical Substances
PICCS - Philippines Inventory of Chemicals and Chemical Substances	CAS - Chemical Abstracts Service
TWA - Time Weighted Average	ACGIH - American Conference of Governmental Industrial Hygienists
IARC - International Agency for Research on Cancer	Predicted No Effect Concentration (PNEC)
ICAO/IATA - International Civil Aviation Organization/International Air Transport Association	IMO/IMDG - International Maritime Organization/International Maritime Dangerous Goods Code
MARPOL - International Convention for the Prevention of Pollution from Ships	ADG Australian Code for the Transport of Dangerous Goods by Road and Rail
NZS 5433:2012 - Transport of Dangerous Goods on Land	OECD - Organisation for Economic Co-operation and Development
LD50 - Lethal Dose 50%	LC50 - Lethal Concentration 50%
EC50 - Effective Concentration 50%	ATE - Acute Toxicity Estimate
WEL - Workplace Exposure Limit	RPE - Respiratory Protective Equipment
DNEL - Derived No Effect Level	NOEC - No Observed Effect Concentration
POW - Partition coefficient Octanol:Water	BCF - Bioconcentration factor
vPvB - very Persistent, very Bioaccumulative	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 18-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