



SAFETY DATA SHEET

1. Identification

Product identifier	Pyrimethamine	
Other means of identification		
Catalog number	1589007	
CAS number	58-14-0	
Chemical name	2,4-Pyrimidinediamine, 5-(4-chlorophenyl)-6-ethyl-	
Recommended use	Specified quality tests and assay use only.	
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.	
Manufacturer/Importer/Supplier/Distributor information		
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

2. Hazard(s) identification

Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 3
	Serious eye damage/eye irritation	Category 2B
	Germ cell mutagenicity	Category 1
	Reproductive toxicity	Category 1
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		
Signal word	Danger	
Hazard statement	Toxic if swallowed. Causes eye irritation. May cause genetic defects. May damage fertility or the unborn child.	
Precautionary statement		
Prevention	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection.	
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical advice/attention.	
Storage	Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	

Hazard(s) not otherwise classified (HNOC)

This product is supplied in a small quantity which does not constitute a combustible dust hazard. The physical properties of this material indicate that in large quantities accumulated dust may be hazardous.

Supplemental information

Pharmacologically active material.

3. Composition/information on ingredients**Substance**

Chemical name	Common name and synonyms	CAS number	%
Pyrimethamine		58-14-0	100

4. First-aid measures**Inhalation**

Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact

Wash off with soap and water. Get medical attention if irritation develops and persists.

Eye contact

Immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.

Ingestion

Call a physician or poison control center immediately. Rinse mouth. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Do not use mouth-to-mouth method if substance is ingested. Induce artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device.

Most important symptoms/effects, acute and delayed

Pharmacologically active material. Occupational exposure may cause physiological effects.

Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically. Administer activated charcoal as a slurry. Perform gastric lavage. Folinic acid should be administered within two hours of ingestion to be most effective in counteracting the effects on the hematopoietic system. For seizures, administer intravenous diazepam or lorazepam. If seizures recur, administer phenobarbital or propofol. Due to the long half-life of this material, daily monitoring of peripheral blood counts is recommended for up to several weeks until normal hematological values are restored.

General information

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures**Suitable extinguishing media**

Water. Foam. Dry chemical or CO₂. Use fire-extinguishing media appropriate for surrounding materials.

Unsuitable extinguishing media

None known.

Specific hazards arising from the chemical

Explosion hazard: Avoid generating dust; fine dust dispersed in air in sufficient concentrations and in the presence of an ignition source is a potential dust explosion hazard.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods

Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards

No unusual fire or explosion hazards noted.

6. Accidental release measures**Personal precautions, protective equipment and emergency procedures**

Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up

Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

Environmental precautions

Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Avoid significant deposits of material, especially on horizontal surfaces, which may become airborne and form combustible dust clouds and may contribute to secondary explosions. Combustible dust clouds may be created where operations produce fine material (dust). Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use Material	Type	Value
-------------------------	------	-------

Pyrimethamine (CAS 58-14-0)	TWA	7 micrograms/m3
-----------------------------	-----	-----------------

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.

Skin protection

Hand protection

Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.

Other

Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection

Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Choose respiratory protection appropriate to the task and the level of existing engineering controls.

Thermal hazards

Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance

Appearance descriptions are general information and not specific to any USP lot.

Physical state

Solid.

Form

Powder.

Color

White.

Odor

Odorless.

Odor threshold

Not available.

pH

Not available.

Melting point/freezing point

451.4 - 453.2 °F (233 - 234 °C)

460.4 - 467.6 °F (238 - 242 °C)

Initial boiling point and boiling range

Not available.

Flash point

Not available.

Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa (77 °F (25 °C))
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Practically insoluble.
Solubility (other)	Acetone: Slightly soluble. Chloroform: Slightly soluble. Ether: Very slightly soluble. Propylene glycol: Very sparingly soluble.
Partition coefficient (n-octanol/water)	-2.7
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Pyrimidine derivative.
Dust explosion properties	
Kst	203 bar.m/s
Minimum ignition energy (MIE) - dust cloud	31 - 41 mJ
Molecular formula	C ₁₂ H ₁₃ CIN ₄
Molecular weight	248.71

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	NO _x . Cl ₂ . Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Causes eye irritation.
Ingestion	Toxic if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics	Coughing. Gastrointestinal disturbances. Central nervous system effects. Bleeding or bruising. Sore mouth or tongue. Pinpoint red spots on skin. Blood in urine. Black or bloody stools. Fever. Chills. Fast heartbeat. Slow breathing.
---	---

Information on toxicological effects

Acute toxicity	Toxic if swallowed.
-----------------------	---------------------

Product	Species	Test Results
Pyrimethamine (CAS 58-14-0)		
Oral		
LD50	Mouse	92 mg/kg
	Rat	440 mg/kg
		128 mg/kg
Skin corrosion/irritation	Based on available data, the classification criteria are not met.	
Serious eye damage/eye irritation	Causes eye irritation.	
Local effects		
Eye irritation		
Result: Irritant.		
Species: Rabbit		
Severity: Mild.		
Skin irritation		
Result: Irritant.		
Species: Rabbit		
Severity: Mild.		
Respiratory or skin sensitization		
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about health hazard is incomplete. Dermal hypersensitivity reactions with therapeutic use have been reported.	
Germ cell mutagenicity	May cause genetic defects.	
Mutagenicity		
Dominant lethal assay		
Result: Positive.		
E. coli assay		
Result: Negative.		
In vitro chromosomal aberrations (human lymphocytes)		
Result: Positive.		
In vivo chromosomal aberrations (bone marrow and spermatogonial cells)		
Result: Positive.		
Species: Mouse		
In vivo chromosomal aberrations (mouse bone marrow cells)		
Result: Positive (chromatid breaks and acentric fragments).		
Rec assay		
Result: Negative.		
Carcinogenicity	Based on available data, the classification criteria are not met.	
200 - 400 ppm Dietary Study		
Result: Negative.		
Species: Rat		
Test Duration: 104 weeks		
500 - 1000 ppm Dietary Study		
Result: Negative.		
Species: Mouse		
Test Duration: 104 weeks		
IARC Monographs. Overall Evaluation of Carcinogenicity		
Pyrimethamine (CAS 58-14-0)	3 Not classifiable as to carcinogenicity to humans.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)		
Not listed.		
US. National Toxicology Program (NTP) Report on Carcinogens		
Not listed.		
Reproductive toxicity	May damage fertility or the unborn child. This material is a folic acid antagonist and interferes with embryo development in experimental animals.	
Reproductivity		
0.6 mg Gestational study (oral)		
Result: Defects in 36% of offspring.		
Species: Rat		

Reproductivity

3 - 10 mg Developmental study
Result: High incidence of cleft palate, mandibular hypoplasia,
neural tube closure defects, and limb defects.
Species: Rat
5 mg/kg Pre-ovulation study
Result: Chromosomal aberrations in 14% of embryos.
Species: Rat

Specific target organ toxicity - single exposure Knowledge about health hazard is incomplete.

Specific target organ toxicity - repeated exposure Knowledge about health hazard is incomplete.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Product	Species		Test Results
Pyrimethamine (CAS 58-14-0)			
Aquatic			
Crustacea	EC50	Water flea (Daphnia magna)	4.1 - 5.6 mg/l, 48 hours
Persistence and degradability	No data is available on the degradability of this substance.		
Bioaccumulative potential			
Octanol/water partition coefficient log Kow			
-2.7			
Mobility in soil	No data available.		
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.		

13. Disposal considerations

Disposal instructions Dispose of contents/container in accordance with local/regional/national/international regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.

Local disposal regulations Dispose in accordance with all applicable regulations.

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Pyrimethamine)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Packing group III

IATA

UN number UN2811
UN proper shipping name Toxic solid, organic, n.o.s. (Pyrimethamine)
Transport hazard class(es)
Class 6.1
Subsidiary risk -
Packing group III

Other information

Passenger and cargo aircraft

Allowed with restrictions.

Cargo aircraft only

Allowed with restrictions.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

DOT; IATA



General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

US federal regulations

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical

Yes

Classified hazard categories

Acute toxicity (any route of exposure)
Serious eye damage or eye irritation
Germ cell mutagenicity
Reproductive toxicity

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)

Not regulated.

US state regulations

California Proposition 65



WARNING: WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm. This product can expose you to Pyrimethamine, which is known to the State of California to cause birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

California Proposition 65 - CRT: Listed date/Developmental toxin

Pyrimethamine (CAS 58-14-0)

Listed: January 29, 1999

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	Yes
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 02-12-2008

Revision date 06-30-2020

Version # 06

Further information Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Disclaimer USP Reference Standards are sold for chemical test and assay purposes only, and NOT for human consumption. The information contained herein is applicable solely to the chemical substance when used as a USP Reference Standard and does not necessarily relate to any other use of the substance described, (i.e. at different concentrations, in drug dosage forms, or in bulk quantities). USP Reference Standards are intended for use by persons having technical skill and at their own discretion and risk. This information has been developed by USP staff from sources considered reliable but has not been independently verified by the USP. Therefore, the USP Convention cannot guarantee the accuracy of the information in these sources nor should the statements contained herein be considered an official expression. NO REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE is made with respect to the information contained herein.