



# SAFETY DATA SHEET

## 1. Identification

<b>Product identifier</b>	<b>Chlorambucil</b>	
<b>Other means of identification</b>		
<b>Catalog number</b>	1106001	
<b>CAS number</b>	305-03-3	
<b>Chemical name</b>	4-[p-[Bis(2-chloroethyl)amino]phenyl]butyric acid	
<b>Recommended use</b>	For analytical laboratory use only.	
<b>Recommended restrictions</b>	Not for use as a drug. Not for administration to humans or animals.	
<b>Manufacturer/Importer/Supplier/Distributor information</b>		
<b>Manufacturer</b>		
<b>Company name</b>	U. S. Pharmacopeia	
<b>Address</b>	12601 Twinbrook Parkway Rockville MD 20852-1790 United States	
<b>Telephone</b>	Technical Services	301-816-8129
<b>Website</b>	www.usp.org	
<b>E-mail</b>	RSTECH@usp.org	
<b>Emergency phone number</b>	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US & Canada	+1 703-527-3887

## 2. Hazard(s) identification

<b>Physical hazards</b>	Not classified.	
<b>Health hazards</b>	Acute toxicity, oral	Category 3
	Skin corrosion/irritation	Category 2
	Serious eye damage/eye irritation	Category 2A
	Sensitization, skin	Category 1
	Germ cell mutagenicity	Category 1B
	Carcinogenicity	Category 1
	Reproductive toxicity	Category 1A
	Specific target organ toxicity, repeated exposure	Category 1 (bone marrow)
<b>Environmental hazards</b>	Not classified.	
<b>OSHA defined hazards</b>	Not classified.	
<b>Label elements</b>		



**Signal word** Danger

**Hazard statement** Toxic if swallowed. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation. May cause genetic defects. May cause cancer. May damage fertility or the unborn child. Causes damage to organs (bone marrow) through prolonged or repeated exposure.

## Precautionary statement

### Prevention

Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing must not be allowed out of the workplace.

### Response

If swallowed: Immediately call a poison center/doctor. Rinse mouth. If on skin: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse. 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

Potent pharmacologically active material.

## 3. Composition/information on ingredients

### Substance

Chemical name	Common name and synonyms	CAS number	%
Chlorambucil		305-03-3	100

Information provided in the SDS is not specific to the lot provided. Refer to the label and USP Certificate/Product Information Sheet for the assigned value of a particular lot.

## 4. First-aid measures

### Inhalation

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

### Skin contact

Remove contaminated clothing immediately and wash skin with soap and water. If skin irritation occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

### 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. Do not use mouth-to-mouth method if substance is ingested. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. 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

Bone marrow suppression. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

### Indication of immediate medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

### 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.

## 6. Accidental release measures

### Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. 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. 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 materials, 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. 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

Chlorambucil (CAS  
305-03-3)

TWA

0.5 micrograms/m3

### Biological limit values

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

### Appropriate engineering controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). 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

Consider double gloves. 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 disposable lab coat, disposable sleeve covers and two pair of gloves as appropriate for the task. 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

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head cover 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

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of USP materials.

## 9. Physical and chemical properties

### Appearance

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

#### Physical state

Solid.

<b>Form</b>	Granular. Crystalline. Powder. Needles.
<b>Color</b>	White. Off-white.
<b>Odor</b>	Slight.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not available.
<b>Melting point/freezing point</b>	147.2 - 156.2 °F (64 - 69 °C)
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not available.
<b>Evaporation rate</b>	Not available.
<b>Flammability (solid, gas)</b>	Not available.
<b>Upper/lower flammability or explosive limits</b>	
<b>Flammability limit - lower (%)</b>	Not available.
<b>Flammability limit - upper (%)</b>	Not available.
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not available.
<b>Vapor density</b>	Not available.
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	
<b>Solubility (water)</b>	Very slightly soluble.
<b>Solubility (other)</b>	Acetone: Freely soluble. Acids: Soluble. Benzene: Soluble. Dilute alkali: Soluble. Ether: Soluble.
<b>Partition coefficient (n-octanol/water)</b>	1.47 at pH 7.4
<b>Auto-ignition temperature</b>	Not available.
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not available.
<b>Other information</b>	
<b>Chemical family</b>	Tertiary amine (nitrogen mustard alkylating agent).
<b>Dust explosion properties</b>	
<b>Kst</b>	143 bar.m/s
<b>St class</b>	1
<b>Minimum ignition energy (MIE) - dust cloud</b>	30 - 40 mJ
<b>Molecular formula</b>	C14H19Cl2NO2
<b>Molecular weight</b>	304.21

## 10. Stability and reactivity

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

## 11. Toxicological information

### Information on likely routes of exposure

<b>Inhalation</b>	Knowledge about health hazard is incomplete.
<b>Skin contact</b>	Causes skin irritation. May cause an allergic skin reaction.
<b>Eye contact</b>	Causes serious eye irritation.
<b>Ingestion</b>	Toxic if swallowed.

<b>Symptoms related to the physical, chemical and toxicological characteristics</b>	Gastrointestinal disturbances. Joint pain. Skin rash. Itching. Fever. Chills. Cough. Hoarseness. Lower back or side pain. Swelling of feet or lower legs. Sore mouth or tongue. Change in menstrual cycle. Bleeding or bruising. Painful or difficult urination. Black or bloody stools. Blood in urine. Pinpoint red spots on skin. Clumsiness. Agitation. Seizures.
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### Information on toxicological effects

<b>Acute toxicity</b>	Toxic if swallowed.
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Product	Species	Test Results
Chlorambucil (CAS 305-03-3)		
<b>Oral</b>		
LD50	Mouse	80 mg/kg
	Rat	76 mg/kg

<b>Skin corrosion/irritation</b>	Causes skin irritation.
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<b>Serious eye damage/eye irritation</b>	Causes serious eye irritation.
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### Respiratory or skin sensitization

<b>Respiratory sensitization</b>	Knowledge about health hazard is incomplete.
<b>Skin sensitization</b>	May cause an allergic skin reaction. Allergic skin reactions have been reported in literature.

<b>Germ cell mutagenicity</b>	May cause genetic defects. This material causes chromatid or chromosomal damage in humans. This material has shown to be mutagenic in both in vitro and in vivo tests.
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<b>Carcinogenicity</b>	May cause cancer. Secondary malignancies are potential delayed effects of many antineoplastic agents, although it is not clear whether the effect is related to their mutagenic or immunosuppressive action. The effect of dose and duration of therapy is also unknown, although risk seems to increase with long-term use. Although information is limited, available data seem to indicate that the carcinogenic risk is greatest with the alkylating agents. There have been reports of acute leukemia occurring in patients treated with this material for malignant and nonmalignant diseases. The risk appears to be related to cumulative dose or duration of therapy, but a threshold cumulative dose has not been defined. Animal studies have shown this material to be carcinogenic in rodents.
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### IARC Monographs. Overall Evaluation of Carcinogenicity

Chlorambucil (CAS 305-03-3)	1 Carcinogenic to humans.
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### OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

### US. National Toxicology Program (NTP) Report on Carcinogens

Chlorambucil (CAS 305-03-3)	Known To Be Human Carcinogen.
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<b>Reproductive toxicity</b>	May damage fertility or the unborn child. Therapeutic use of this material during pregnancy has been associated with birth defects in the newborn. Antineoplastic therapy can adversely affect male and female fertility through gonadal suppression, resulting in the absence of menstruation or sperm. The effects appear to be related to dose and length of therapy and may be irreversible. This material has caused birth defects in animal studies.
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<b>Specific target organ toxicity - single exposure</b>	Knowledge about health hazard is incomplete.
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<b>Specific target organ toxicity - repeated exposure</b>	Causes damage to organs (bone marrow) through prolonged or repeated exposure.
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<b>Aspiration hazard</b>	Based on available data, the classification criteria are not met.
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<b>Further information</b>	Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.
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## 12. Ecological information

### Ecotoxicity

Product	Species	Test Results
Chlorambucil (CAS 305-03-3)		
<b>Aquatic</b>		
Crustacea	EC50	Daphnia
		> 10 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

1.47, at pH 7.4

1.7

**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 in accordance with all applicable 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. U035: Waste Benzenebutanoic acid, 4-[bos(2-chloroethyl)amino]-

#### US RCRA Hazardous Waste U List: Reference

Chlorambucil (CAS 305-03-3)

U035

**Waste from residues / unused products** Not available.

**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. (Chlorambucil RQ = 10 LBS)
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. (Chlorambucil)
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.

**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)**

Chlorambucil (CAS 305-03-3)

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)  
Skin corrosion or irritation  
Serious eye damage or eye irritation  
Respiratory or skin sensitization  
Germ cell mutagenicity  
Carcinogenicity  
Reproductive toxicity  
Specific target organ toxicity (single or repeated exposure)

**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:** This product can expose you to Chlorambucil, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information go to [www.P65Warnings.ca.gov](http://www.P65Warnings.ca.gov).

**California Proposition 65 - CRT: Listed date/Carcinogenic substance**

Chlorambucil (CAS 305-03-3)

Listed: February 27, 1987

**California Proposition 65 - CRT: Listed date/Developmental toxin**

Chlorambucil (CAS 305-03-3)

Listed: January 1, 1989

## 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)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
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	10-20-2005
Revision date	02-14-2023
Version #	07
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.
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