

## 1. Identification

**Product identifier** Leukeran 2mg Tablets (chlorambucil)  
**Other means of identification** Not available.  
**Synonyms** Chlorambucil, Leukeran  
**Recommended use** Medicinal product.  
**Recommended restrictions** None known.

### Manufacturer / Importer / Supplier / Distributor information

**Company name** Aspen Europe GmbH  
**Address** Industriestrasse- 32-36  
 D-23843 Bad Oldesloe  
 Germany  
**Telephone** (+) 44 1748 828 391  
**E-mail** SDSRequest@aspengl.com

**Emergency phone number** (USA, Canada, Mexico) 1.866.519.4752  
 (Americas) (+) 1 760 476 3962  
 Access code 333974

## 2. Hazard(s) identification

**Physical hazards** Not classified.  
**Health hazards** Sensitization, skin Category 1  
 Germ cell mutagenicity Category 1B  
 Carcinogenicity Category 1B  
 Reproductive toxicity Category 1B  
**OSHA defined hazards** Not classified.

### Label elements



**Signal word** Danger

**Hazard statement** May cause genetic defects. May cause cancer. May cause an allergic skin reaction. May damage fertility. May damage the unborn child.

### Precautionary statement

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Contaminated work clothing must not be allowed out of the workplace. Wear protective gloves/protective clothing/eye protection/face protection.

**Response** If exposed or concerned: Get medical advice/attention. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

**Storage** Store locked up.

**Disposal** Dispose of contents/container in accordance with local/regional/national/international regulations.

**Hazard(s) not otherwise classified (HNOC)** Not classified.

### Supplemental information

Not applicable.

## 3. Composition/information on ingredients

### Mixtures

Chemical name	CAS number	%
Chlorambucil	305-03-3	2.1

**Composition comments** All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

## 4. First-aid measures

<b>Inhalation</b>	Not likely, due to the form of the product.
<b>Skin contact</b>	Immediately flush skin with plenty of water. Remove contaminated clothing and shoes. If skin irritation or rash occurs: Get medical advice/attention. For minor skin contact, avoid spreading material on unaffected skin.
<b>Eye contact</b>	Flush thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Get medical attention if irritation develops and persists.
<b>Ingestion</b>	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth thoroughly with water and give large amounts of water to people not unconscious. Do not induce vomiting without advice from medical personnel.
<b>Most important symptoms/effects, acute and delayed</b>	May cause allergic skin reaction.
<b>Indication of immediate medical attention and special treatment needed</b>	Provide general supportive measures and treat symptomatically. In case of shortness of breath, give oxygen. Keep victim warm. Keep victim under observation. Symptoms may be delayed. Medical treatment in cases of overexposure should be treated as an overdose of a cytotoxic agent. For additional guidance, refer to the current prescribing information or to the local poison control information center.
<b>General information</b>	Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves. IF exposed or concerned: Get medical advice/attention.

## 5. Fire-fighting measures

<b>Suitable extinguishing media</b>	Water fog. Foam. Dry powder.
<b>Unsuitable extinguishing media</b>	Carbon dioxide extinguishers may be ineffective. Do not use water jet as an extinguisher, as this will spread the fire.
<b>Specific hazards arising from the chemical</b>	During fire, gases hazardous to health may be formed.
<b>Special protective equipment and precautions for firefighters</b>	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
<b>Fire-fighting equipment/instructions</b>	Move containers from fire area if you can do so without risk.

## 6. Accidental release measures

<b>Personal precautions, protective equipment and emergency procedures</b>	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate personal protective equipment. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
<b>Methods and materials for containment and cleaning up</b>	Sweep up or vacuum up spillage and collect in suitable container for disposal. Containers with collected spillage must be properly labelled with correct contents and hazard symbol.  Never return spills in original containers for re-use.
<b>Environmental precautions</b>	Avoid discharge into drains, water courses or onto the ground.

## 7. Handling and storage

<b>Precautions for safe handling</b>	Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not taste or swallow. Avoid breathing dust. Avoid contact with skin. Pregnant or breastfeeding women must not handle this product. Wear appropriate personal protective equipment. Observe good industrial hygiene practices. When using, do not eat, drink or smoke. Wash thoroughly after handling. Strict control of access to the working area is essential. Only trained personnel should enter the area during operations. Adopt procedures to prevent contamination of working materials and adjacent areas. This product is listed by US NIOSH as a hazardous drug when handled in health care settings. For additional information about the NIOSH hazardous drugs programme and recommendations for preventing exposure see US NIOSH publication "Preventing Occupational Exposure to Antineoplastic and Other Hazardous Drugs in Health Care Settings." Avoid breaking or crushing tablets.
<b>Conditions for safe storage, including any incompatibilities</b>	Store in a closed container away from incompatible materials. Keep out of the reach of children.

## 8. Exposure controls/personal protection

<b>Occupational exposure limits</b>	No exposure limits noted for ingredient(s).
<b>Biological limit values</b>	No biological exposure limits noted for the ingredient(s).
<b>Appropriate engineering controls</b>	It is strongly advised that dedicated areas and containment, such as glove boxes, isolators, and enclosed material transfer systems be used to prevent personnel exposure and spread of contamination. Local exhaust ventilation (LEV) is not appropriate at this level, since total containment should usually be used.

## Individual protection measures, such as personal protective equipment

<b>Eye/face protection</b>	Risk of contact: Wear safety glasses with side shields (or goggles).
<b>Skin protection</b>	
<b>Hand protection</b>	Wear protective gloves. Suitable gloves can be recommended by the glove supplier. Frequent change is advisable.
<b>Other</b>	Wear suitable protective clothing. Suitable gloves can be recommended by the glove supplier. Frequent change of gloves is advisable.
<b>Respiratory protection</b>	When isolation is not possible, respiratory protective equipment (RPE) should be combined with applicable protective equipment.
<b>Thermal hazards</b>	Wear appropriate thermal protective clothing, when necessary.
<b>General hygiene considerations</b>	When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Contaminated work clothing should not be allowed out of the workplace. Observe any medical surveillance requirements.

## 9. Physical and chemical properties

<b>Appearance</b>	Brown, film-coated, round, biconvex tablets containing 2 mg chlorambucil in amber glass bottles with child-resistant closures. One side is engraved with "GX EG3" and the other side is engraved with an "L."
<b>Physical state</b>	Solid.
<b>Form</b>	Tablet.
<b>Color</b>	Brown.
<b>Odor</b>	Not available.
<b>Odor threshold</b>	Not available.
<b>pH</b>	Not applicable
<b>Melting point/freezing point</b>	Not available.
<b>Initial boiling point and boiling range</b>	Not available.
<b>Flash point</b>	Not applicable
<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 applicable
<b>Flammability limit - upper (%)</b>	Not applicable
<b>Explosive limit - lower (%)</b>	Not available.
<b>Explosive limit - upper (%)</b>	Not available.
<b>Vapor pressure</b>	Not applicable
<b>Vapor density</b>	Not applicable
<b>Relative density</b>	Not available.
<b>Solubility(ies)</b>	Not available.
<b>Partition coefficient (n-octanol/water)</b>	Not applicable
<b>Auto-ignition temperature</b>	Not applicable
<b>Decomposition temperature</b>	Not available.
<b>Viscosity</b>	Not applicable
<b>Other information</b>	
<b>Explosive properties</b>	Not applicable.
<b>Oxidizing properties</b>	Not applicable.

## 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>	Strong oxidizers, strong acids, and strong bases.
<b>Hazardous decomposition products</b>	No hazardous decomposition products are known.

## 11. Toxicological information

### Information on likely routes of exposure

<b>Ingestion</b>	Adverse effects may occur after swallowing.
<b>Inhalation</b>	Not relevant, due to the form of the product.
<b>Skin contact</b>	May cause skin irritation. May cause allergic skin reaction.
<b>Eye contact</b>	Product dust or powder may cause mechanical eye irritation.

**Symptoms related to the physical, chemical and toxicological characteristics** Direct contact with skin and eyes may cause irritation. May cause allergic skin reaction.

### Information on toxicological effects

<b>Acute toxicity</b>	May cause discomfort if swallowed.
<b>Skin corrosion/irritation</b>	Not classified.
<b>Serious eye damage/eye irritation</b>	Not classified.
<b>Respiratory sensitization</b>	Not classified.
<b>Skin sensitization</b>	May cause allergic skin reaction.
<b>Germ cell mutagenicity</b>	May cause genetic defects.
<b>Carcinogenicity</b>	May cause cancer.

#### IARC Monographs. Overall Evaluation of Carcinogenicity

Chlorambucil (CAS 305-03-3) 1 Carcinogenic to humans.

#### NTP Report on Carcinogens

Chlorambucil (CAS 305-03-3) Known To Be Human Carcinogen.

<b>Reproductive toxicity</b>	May damage the unborn child.
<b>Specific target organ toxicity - single exposure</b>	Not classified.
<b>Specific target organ toxicity - repeated exposure</b>	Adverse effects might occur in the following organ(s) following overexposure: bone marrow and formation of blood cells; gastro-intestinal tract; liver.
<b>Aspiration hazard</b>	Not classified.
<b>Chronic effects</b>	Prolonged exposure may cause chronic effects. May cause damage to the following organs through prolonged or repeated exposure: Bone marrow. Liver. Blood.

## 12. Ecological information

<b>Ecotoxicity</b>	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.
<b>Persistence and degradability</b>	The product is expected to be biodegradable.
<b>Bioaccumulative potential</b>	The product is not expected to bioaccumulate.
<b>Partition coefficient n-octanol / water (log Kow)</b>	
Chlorambucil (CAS 305-03-3)	1.47, at pH 7.4
<b>Mobility in soil</b>	The product has poor water-solubility.
<b>Other adverse effects</b>	Not available.

## 13. Disposal considerations

<b>Disposal instructions</b>	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.
<b>Hazardous waste code</b>	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

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

Chlorambucil (CAS 305-03-3) U035

**Waste from residues / unused products** Dispose of in accordance with local regulations. 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** Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

## 14. Transport information

### DOT

Not regulated as a hazardous material by DOT.

### IATA

Not regulated as a dangerous good.

### IMDG

Not regulated as a dangerous good.

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code** Not applicable.

## 15. Regulatory information

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

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

Not regulated.

### US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

### CERCLA Hazardous Substance List (40 CFR 302.4)

Chlorambucil (CAS 305-03-3) LISTED

### Superfund Amendments and Reauthorization Act of 1986 (SARA)

**Hazard categories** Immediate Hazard - No  
Delayed Hazard - Yes  
Fire Hazard - No  
Pressure Hazard - No  
Reactivity Hazard - No

**SARA 302 Extremely hazardous substance** No

**SARA 311/312 Hazardous chemical** Yes

### 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.

**Food and Drug Administration (FDA)** Not regulated.

### US state regulations

#### US. Massachusetts RTK - Substance List

Chlorambucil (CAS 305-03-3)

#### US. New Jersey Worker and Community Right-to-Know Act

Not regulated.

#### US. Pennsylvania RTK - Hazardous Substances

Chlorambucil (CAS 305-03-3)

#### US. Rhode Island RTK

Chlorambucil (CAS 305-03-3)

#### US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

#### US - California Proposition 65 - Carcinogens & Reproductive Toxicity (CRT): Listed substance

Chlorambucil (CAS 305-03-3)

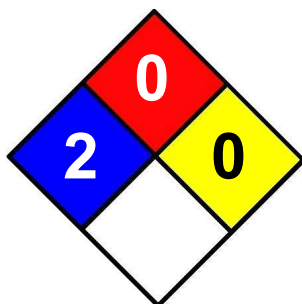
## 16. Other information, including date of preparation or last revision

**Issue date** 10-July-2013

**Revision date** -

**Version #** 01

## NFPA Ratings



## List of abbreviations

IATA: International Air Transport Association.

IMDG: International Maritime Dangerous Goods.

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.

LD50: Lethal Dose, 50%.

## References

GSK Leukeran Tablet SDS Version 14 17 September 2008.

## Disclaimer

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