Berlex Biosciences
Division of Berlex Laboratories, Inc.
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MATERIAL SAFETY DATA SHEET

Section 1: Chemical Name and Company Identification

Name: **Campath® (Alemtuzumab)**

Manufactured by: Millennium and ILEX Partners, LP, Cambridge, MA 02142

Distributed by: Berlex Laboratories, Richmond, CA 94804

Distributor's Mailing Address: 2600 Hilltop Drive
P.O. Box 4099
Richmond, California, 94804-0099

Product Information and Emergency Phone: 1-888-Berlex4 (1-888-237-5394)

Section 2: Composition, Information on Ingredients

Component	CAS#	Exposure Limits[1]	Amount Per Ampoule	Concentration
Alemtuzumab	Not applicable	None established	30 mg	1%
Sodium Chloride	7647-14-5	None established	24 mg	0.8%
Dibasic Sodium Phosphate	7558-79-4	None established	3.5 mg	0.1%
Potassium Chloride	7447-40-7	None established	0.6 mg	0.02%
Monobasic Potassium Phosphate	7778-77-0	None established	0.6 mg	0.02%
Polysorbate 80	9005-65-6	None established	0.3 mg	0.01%
Disodium Edetate	6381-92-6	None established	0.056 mg	<0.01%

Campath® (Alemtuzumab) is a genetically engineered monoclonal antibody (Campath-1H) generated by the insertion of sections of a rat monoclonal antibody into a human antibody molecule. Campath is produced in mammalian cell (Chinese hamster ovary) suspension culture in a medium containing neomycin. Neomycin is not detectable in the final product. Campath is directed against a glycoprotein on the surface of certain cells in the blood and other tissues: lymphocytes, monocytes, macrophages and tissues of the male reproductive system. This product is a prescription pharmaceutical. It is intended for intravenous infusion following dilution.

Molecular weight: The Campath-1H antibody has an approximate molecular weight of 150,000 daltons.

[1] The components in Campath are not listed in the American Conference of Governmental Industrial Hygienists (ACGIH) 2000 Threshold Limit Values for Chemical Substances and Physical Agents and Biological Exposure Indices, in 29CFR 1910.1000 (Occupational Safety and Health Administration Table Z-1-A – Limits for Air Contaminants), or in Title 8 Section 5155 of the California Code of Regulations (General Industry Safety Orders, Table AC-1, Permissible Exposure Limits for Chemical Contaminants).

Section 3: Hazards Identification (also see Section 11, Toxicological Information)

Health Hazards:

Toxic.
Biohazard.
May cause serious or fatal depression of the immune system.*
May promote serious or fatal infections.*
May cause serious or fatal anemia or bleeding.*
May cause low blood pressure, coldness, fever, shortness of breath, coughing, chills, rash, nausea, vomiting, fatigue, headache and/or diarrhea.*
May cause mild to severe allergic reaction, which could be local or systemic*
In pregnancy, may cross the placental barrier and be toxic to the fetus.
May be excreted in breast milk and cause harm to the breast-fed infant.
May cause skin irritation.

** The hazards listed are based primarily on adverse events reported after the intravenous infusion of diluted Campath.*

More detailed information is available in the complete prescribing information, which may be obtained by calling the Product Information phone (1-888-237-5394).

Target Organs:

Blood; lymphatic system; reproductive system (male)

Potential Routes of Exposure:

Inhalation, eye, skin or mucous membrane contact, accidental ingestion or injection.

Physical Hazards:

No physical hazards known.

Section 4: First Aid Measures

Toxic effects from absorption through the skin, eyes or by inhalation are unknown.

Inhalation - If dusts or mists are inhaled, remove exposed individual to fresh air. Get immediate medical attention.

Eye Contact - For product contact with the eyes, immediately flush with large quantities of water for at least 15 minutes, and get immediate medical attention.

Skin Contact - In case of product contact with the skin, rinse freely with soap and water. Remove contaminated clothing. Get prompt medical attention.

Ingestion - Although Campath-1H is a protein, and oral ingestion should result in the digestion and inactivation of this material, contact a physician or poison control center promptly.

Accidental Injection - Contact a physician or poison control center immediately. It is recommended that all materials involved in the injection be carefully placed in a clean puncture-proof, leak-proof container in case they are needed to establish how much material was actually injected.

Contact Berlex Laboratories promptly if adverse effects result from exposure to Campath (1-888-237-5394).

Section 5: Fire Fighting Measures

Extinguishing Media:

Campath is nonflammable and noncombustible. Use extinguishing medium that is appropriate for the class of the surrounding fire.

Unusual Fire and Explosion Hazards:

None expected

Products of combustion may include carbon monoxide, carbon dioxide, nitrogen oxides and sulfur dioxide.

Section 6: Accidental Release Measures

Workers should comply with federal, state and local regulations, as well as their employer's procedures, for cleaning up spills of chemical and biological materials.

Small Spills:

Liquids. Wear appropriate personal protective equipment (see Section 8). Isolate spill area; absorb spilled solution with paper towels or other suitable disposable absorbents. Using additional disposables and a suitable collection pan (dust pan), collect spilled material and place all contaminated clean-up materials into a sturdy plastic disposable bag (use care with any broken glass to avoid personal injury or puncture of the disposable bag.) When all contaminated material has been collected, rinse the area with clean water using additional disposable towels.

Upon completion of the clean-up, place all contaminated materials in a suitable and properly labeled receptacle, and discard as BIOHAZARD waste, according to Section 13. Wash hands thoroughly with mild soap and clean water.

Section 7: Handling and Storage

Workers should comply with OSHA and other applicable federal, state and local regulations, as well as their employer's procedures, for handling and storing chemical and biological materials in the workplace.

Avoid generation of dusts and/or mists. If dusts or mists are present, wear appropriate respiratory protection to avoid inhalation.

Do not inhale, ingest, or allow eye, skin, or mucous membrane contact.

Store under refrigeration, between 2°-8° C (36°- 46° F). Do not freeze. Discard if ampoule has been frozen. Protect from direct sunlight.

Note expiration dates.

After dilution, the product may be stored at room temperature (15-30° C or 59-86° F) or refrigerated. Protect from light.

Product should be discarded eight hours after dilution.

Section 8: Exposure Controls, Personal Protection

Workers should comply with OSHA and other applicable federal, state and local regulations, as well as their employer's procedures, for controlling exposure to chemical and biological materials in the workplace.

Eye Protection

Wear chemical protective eyewear (ANSI-approved goggles or safety glasses).

Respiratory Protection

If use of a respirator is indicated (e.g., cleaning up spills while mists are present), use NIOSH/MSHA approved dusts/fumes/mists respirator with high efficiency filter (HEPA) according to your employer's Respiratory Protection Program. The use of a self-contained breathing apparatus is indicated in areas where the oxygen level is less than 19.5%.

Skin Protection

Use latex gloves and appropriate protective clothing (e.g., a lab coat or protective gown) when handling or using. Do not handle Campath if you have an open cut, wound or sore.

Engineering Controls

Handle the material in enclosed or contained processes or with effective local exhaust ventilation (e.g., fume hood or biosafety hood).

Section 9: Physical and Chemical Properties (of unreconstituted product)

Appearance and physical state: Clear, colorless, odorless solution.
Solubility: The product is aqueous and completely miscible with water.
pH: pH 6.8-7.4
Vapor pressure: Not applicable.
Boiling point: Approximately 100°C (212°F)
Freezing point: Approximately 0°C (32°F)
Specific gravity: 1.008
Melting point: Not applicable.
Flash point: Not applicable.

Section 10: Stability and Reactivity

No known hazard to workers due to stability or reactivity.

The product is stable until expiry when stored under refrigeration between 2°-8° C (36°- 46° F).

No known hazardous incompatibilities or hazardous decomposition products. Hazardous polymerization will not occur.

Section 11: Toxicological Information

Acute and Chronic Health Effects:

Campath is toxic. Campath induces a profound reduction in lymphocytic white blood cells. A variety of opportunistic infections have been reported in patients receiving Campath therapy, some of them serious or fatal. Patients who have recently received Campath should not be immunized with live viral vaccines, due to immunosuppression. Campath can cause a reduction in white blood cell, red blood cell and platelet counts. Serious and, in rare instances, fatal, pancytopenia/marrow hypoplasia, autoimmune idiopathic thrombocytopenia and autoimmune hemolytic anemia have occurred in patients receiving Campath therapy.

In one patient, death was reported following the intravenous infusion of 80 milligrams of Campath. In clinical studies, initial doses of diluted Campath of greater than 3 milligrams were not well tolerated. The potential for the toxicity of Campath by intravenous administration is greater in its undiluted form.

There is no known specific antidote for Campath toxicity. Treatment consists of drug supportive therapy.

The most commonly reported infusion-related adverse events in patients receiving Campath treatment were as follows: low blood pressure, coldness, fever, shortness of breath, coughing, chills, rash, nausea, vomiting, fatigue, headache and/or diarrhea.

Carcinogenicity, Mutagenicity, Impairment of Fertility

Carcinogencity

Campath and its components are not listed in the National Toxicology Program (NTP) *Sixth Annual Report on Carcinogens*. They have not been found to be potential carcinogens in the International Agency for Research on Cancer (IARC) *Monographs*, Vols 1-53 and Supplements 1-8, or by OSHA.

No long-term studies in animals have been performed to establish the carcinogenic potential of Campath.

Mutagenicity

No long-term studies in animals have been performed to establish the mutagenic potential of Campath.

Impairment of Fertility

May cause adverse reproductive effects. The Campath-1H antibody is directed against tissues of the male reproductive system.

It is not known whether Campath can affect reproductive capacity or cause fetal harm when administered to a pregnant woman. However, Campath-1H is an IgG antibody. Human IgG is

known to cross the placental barrier and therefore Campath may cross the placental barrier and cause fetal B and T lymphocyte depletion.

Animal reproduction studies have not been conducted with Campath.

Additional Information

For additional information consult the complete prescribing information, which may be obtained by calling the Product Information phone (1-888-237-5394).

Section 12: Ecological Information

No information about environmental fate or effects is known.

Section 13: Disposal Considerations

Wastes containing this material should be properly contained, labeled, stored and disposed of as BIOHAZARD waste. Comply with local, state and federal regulations for the disposal of biohazardous wastes. Establishments authorized to autoclave their biohazard waste should autoclave this material according to validated cycles. Incineration is an appropriate method of destruction when performed in accordance with all applicable local, state and federal laws and regulations.

Section 14: Transport Information

Not regulated by DOT (U.S. Department of Transportation).

Section 15: Regulatory Information

No information applicable.

Section 16: Other Information

References: Campath® (Alemtuzumab) Package Insert
The information provided above is believed to be correct. However, Berlex Laboratories makes no representation as to the accuracy or completeness of this information. It is expected that the user will determine the suitability of the information for the intended applications and use appropriate safety procedures.

Date Revised: June 4, 2002
Prepared By: Laurel Anne Hill

Replaces previous version dated August 6, 2001.