



MATERIAL SAFETY DATA SHEET

BAYER HEALTHCARE PHARMACEUTICALS INC.

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TRANSPORTATION EMERGENCY
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INTERNATIONAL..... : (703) 527-3887

NON-TRANSPORTATION
BAYER EMERGENCY PHONE : 888-84BAYER
BAYER INFORMATION PHONE: 888-84BAYER

Section 1: Product and Company Identification

Product Name: Campath®
Chemical Family: B-cell chronic lymphocytic leukemia treatment

Section 2: Composition/Information on Ingredients

HAZARDOUS INGREDIENTS

This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200.

<u>Ingredient Name/ CAS Number</u>	<u>Exposure Limits</u>	<u>Concentration</u>	
		<u>Min.</u>	<u>Max.</u>
Alemtuzumab	OSHA (PEL): ACGIH (TLV):		75%
Sodium chloride 7647-14-5	OSHA (PEL): Not Established ACGIH (TLV): Not Established		20%
Disodium phosphate 7558-79-4	OSHA (PEL): Not Established ACGIH (TLV): Not Established		10%
Potassium Chloride 7447-40-7	OSHA (PEL): Not Established ACGIH (TLV): Not Established		2%

Material Name: Campath®

Monopotassium phosphate
7778-77-0

OSHA (PEL):
Not Established
ACGIH (TLV):
Not Established

1%

Polysorbate 80
9005-65-6

OSHA (PEL):
Not Established
ACGIH (TLV):
Not Established

1%

EDTA, disodium dihydrate
6381-92-6

OSHA (PEL):
Not Established
ACGIH (TLV):
Not Established

1%

Section 3: Hazards Identification

EMERGENCY OVERVIEW

CAUTION! Color: Clear **Form:** Liquid **Odor:** Odorless

This compound is a cytostatic agent. This compound is an anti-cancer agent. Can severely depress bone marrow function. Avoid exposure by inhalation or direct contact with skin or mucous membranes.

POTENTIAL HEALTH EFFECTS

Route(s) of Entry: Accidental:, Skin Contact, Eye Contact, Ingestion

HUMAN EFFECTS AND SYMPTOMS OF OVEREXPOSURE

General Effects of Exposure

Acute Effects of Exposure:

The toxicology of this material has not been fully investigated, therefore, all due care must be taken in handling and use. Due to the unknown toxicity of this material, it is best handled as a highly hazardous substance. This compound is an anti-cancer agent.

Chronic Effects of Exposure:

The toxicology of this material has not been fully investigated, therefore, all due care must be taken in handling and use.

Carcinogenic Components:

NTP: None

IARC: None

OSHA: None

Medical Conditions

Aggravated by Exposure:

None known.

Human Health Effects

Postnote:

Use only as directed. This is a pharmaceutical material. Can severely depress bone marrow function.

Section 4: First Aid Measures

First Aid for Eye:	In case of contact, flush with copious amounts of water for at least 15 minutes. Call a physician.
First Aid for Skin:	In case of skin contact, wash affected areas with soap and water.
First Aid for Inhalation:	Not an expected entry route.
First Aid for Ingestion:	If ingested, seek medical attention.

Section 5: Fire Fighting Measures

Flash Point:	Not Applicable
<u>Flammable Limits:</u>	
Upper Explosion Limit (UEL %):	Not Established
Lower Explosion Limit (LEL %):	Not Established
<u>Extinguishing Media:</u>	
Suitable:	Use appropriate extinguishing media for surrounding fire.
Special Fire Fighting Procedures:	Firefighters should be equipped with self-contained breathing apparatus to protect against potentially toxic and irritating fumes.

Section 6: Accidental Release Measures

Spill or Leak Procedures:	Use appropriate personal protective equipment during clean up. Absorb material and place in appropriate containers for disposal. Wash spill area with soap and water. Prevent from entering open drains and waterways.
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Section 7: Handling and Storage

Storage Temperature:	
Minimum:	36 °F (2 °C)
Maximum:	46 °F (8 °C)
Shelf Life:	See expiration date on product container label
Special Sensitivity:	Store in a cool dry place, away from oxidizing agents and flammable liquids.
Handling/Storage Precautions:	Keep this and all drugs out of the reach of children. Containers should be kept tightly closed to prevent contamination. Protect from light. Use normal precautions for storage of a drug. Avoid contact with eyes and skin. Wash thoroughly after handling.

Section 8: Exposure Controls/Personal Protection

Personal Protection Equipment

Eye Protection Requirements:	None for normal use.
Skin Protection Requirements:	No special skin protection requirements during normal handling and use.
Ventilation Requirements:	Under normal conditions of use, special ventilation is not required.
Work Practices:	Use caution. Use good personal hygiene - wash hands and exposed skin thoroughly with soap and water after each use.
Additional Protective Measures:	Employers shall provide handwashing facilities which are readily accessible to employees. Educate and train employees in the safe use and handling of this product.

Section 9: Physical and Chemical Properties

Physical Form:	Liquid
Color:	Clear
Odor:	Odorless
pH:	6.8 - 7.4
Boiling Point:	212 °F (100 °C)
Melting/Freezing Point:	Not Applicable
Solubility in Water:	Soluble
Specific Gravity:	Not Established
Vapor Density:	Not Applicable

Section 10: Stability and Reactivity

Stability:	Stable
Hazardous Polymerization:	Will not occur
Conditions to Avoid:	None known.
Decomposition Products:	None known.

Section 11: Toxicological Information

Toxicity Data for Campath®

Toxicity Note:	Severe, prolonged and in rare instances fatal, myelosuppression has occurred in patients with leukemia and lymphoma receiving Campath. Bone marrow aplasia and hypoplasia were observed in patients with CLL. Campath should be discontinued for severe
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hematologic toxicity or in any patient with evidence of autoimmune hematologic toxicity.

Carcinogenicity: Studies have not been performed.

Mutagenicity: Studies have not been performed.

Toxicity to Reproduction/Fertility: Women of childbearing potential and men of reproductive potential should use effective contraceptive methods during treatment and for a minimum of 6 months following therapy.

Toxicity Data for Disodium phosphate

Toxicity Note: No data available for this component.

Section 12: Ecological Information

Ecological Data for Campath®

Ecological Data for Disodium phosphate

Ecological Note: No data available for this component.

Section 13: Disposal Considerations

Waste Disposal Method: Waste disposal should be in accordance with existing federal, state and local environmental control laws.

Section 14: Transportation Information

Technical shipping name: Pharmaceutical

Domestic Surface Transportation (DOT)

Hazard Class or Division: Non-Regulated

Marine Transportation (IMO / IMDG)

Hazard Class Division Non-Regulated
Number:

Air Transportation (ICAO / IATA)

Hazard Class Division Non-Regulated
Number:

Section 15: Regulatory Information

United States Federal Regulations

**OSHA Hazcom Standard
Rating:**

Not subject to OSHA

TSCA Inventory List:

**This product is exempt from TSCA under Section 3 (2)(B)(vi)
when used for pharmaceutical application.**

CERCLA Hazardous Substance:

Component(s)
Disodium phosphate

Reportable Quantity
5,000 lb

SARA Title III

SARA Section 302 Extremely Hazardous Substances:

Component(s)/
CAS Number
None

Concentration
Min. Max.

SARA Section 311/312 Hazard Categories: Exempt from SARA Section 311/312

SARA Section 313 Toxic Chemicals:

Component(s)/
CAS Number
None

Reporting
Threshold

Concentration
Min. Max.

RCRA Status:

If discarded in its purchased form, this product would not be a hazardous waste either by listing or by characteristic. However, under RCRA, it is the responsibility of the product user to determine at the time of disposal, whether a material containing the product or derived from the product should be classified as a hazardous waste. (40 CFR 261.20-24)

The following chemicals are specifically listed by individual states; other product specific health and safety data in other sections of the MSDS may also be applicable for state requirements. For details on your regulatory requirements you should contact the appropriate agency in your state.

State Right-to-Know Information

Component(s)/
CAS Number

State Code

Concentration
Min. Max.

Sodium chloride
7647-14-5

PA-N, NJ-N

10%

30%

Disodium phosphate
7558-79-4

PA-H, NJ-H, MA-H

5%

10%

Potassium Chloride
7447-40-7

PA-N, NJ-N

1%

5%

State Code Translation Table

PA-N = Pennsylvania Non-hazardous
PA-H = Pennsylvania Hazardous Substance List
NJ-N = New Jersey Other - includes predominant ingredients
NJ-H = New Jersey Hazardous Substance List
MA-H = Massachusetts Hazardous Substance List

Section 16: Other Information

Material Name: Campath®

Contact: Product Safety Department
Phone: 888-BAYER84
MSDS Number: 000000003261
Version Date: 08/06/2008
MSDS Version: 1

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