



# Drotrecogin Alfa (Activated) for Injection

Eli Lilly and Company  
Material Safety Data Sheet

Effective Date: 18-Jul-2001

## Section 1 - Chemical Product and Company

**Manufacturer:**  
Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285

**Manufacturer's Emergency Phone:**  
1-317-276-2000  
**CHEMTREC:**  
1-800-424-9300 (North America)  
1-703-527-3887 (International)

**Common Name:** Drotrecogin Alfa (Activated) for Injection

**Chemical Name:** Blood-coagulation factor XIVA

**Synonym(s):** 203638 Formulation; APC Vial; Blood-coagulation Factor XIVA Vial; Recombinant Human Activated Protein C Vial; Recombinant Human Activated Protein C for Injection; rhAPC Vial

**Trademarks(s):** Bicade; Cyvade; Vicade; Xigris; Xigris; Xygris; Xygris; Zovant; Zyvast

**Lilly Item Code(s):** VL7559; VL7560; VL7561

See attached glossary for abbreviations.

## Section 2 - Composition / Information on Ingredients

<b>Ingredient</b>	<b>CAS</b>	<b>Concentration %</b>
Drotrecogin Alfa (Activated)	42617-41-4	6 - 8
Excipients	NA	92 - 94

Contains no hazardous components (one percent or greater) or carcinogens (one-tenth percent or greater) not listed above.

**Exposure Guidelines:** Drotrecogin alfa (activated) - LEG 250 micrograms/m<sup>3</sup> TWA (respirable) for 8 or 12 hours, 800 micrograms/m<sup>3</sup> TWA (respirable) for 15 minutes STEG.

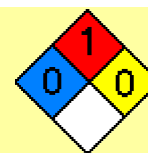
## Section 3 - Hazards Identification

**Appearance:** White to off-white lyophilized powder

**Physical State:** Solid

**Odor:** Odorless

## Emergency Overview



**Emergency Overview Effective Date:** 18-Jul-2001

**Lilly Laboratory Labeling Codes:**

**Health** 0

**Fire** 1

**Reactivity** 0

**Primary Physical and Health Hazards:** Blood Effects.

**Caution Statement:** Effects of exposure to Drotrecogin Alfa (Activated) for Injection may include delayed clotting.

**Routes of Entry:** Inhalation and skin contact.

**Effects of Overexposure:** Effects of exposure may include delayed clotting. Drotrecogin alfa (activated) is not expected to be active orally.

**Medical Conditions Aggravated by Exposure:** Hemophilia and individuals on coumadin, heparin, or other anticoagulant therapy.

**Carcinogenicity:** Drotrecogin alfa (activated) - No carcinogenicity data found. Not listed by IARC, NTP, ACGIH, or OSHA.

## Section 4 - First Aid Measures

**Eyes:** Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or other physician immediately.

**Skin:** Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation develops.

**Inhalation:** Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

**Ingestion:** Call a physician or poison control center. No first aid procedures are normally required.

## Section 5 - Fire Fighting Measures

**Flash Point:** No applicable information found

**UEL:** No applicable information found

**LEL:** No applicable information found

**Extinguishing Media:** Use water, carbon dioxide, dry chemical, foam, or Halon.

**Unusual Fire and Explosion Hazards:** As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.

**Hazardous Combustion Products:** May emit toxic fumes when exposed to heat or fire.

## Section 6 - Accidental Release Measures

**Spills:** Vacuum material with appropriate dust collection filter in place. Be aware of potential for dust explosion when using electrical equipment. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear protective equipment, including eye protection, to avoid exposure (see Section 8 for specific handling precautions).

## Section 7 - Handling and Storage

**Storage Conditions:** Refrigerator: 2 to 8 C (36 to 46 F). Protect unconstituted vials from light.

## Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

**Respiratory Protection:** Use an approved respirator.

**Eye Protection:** Chemical goggles and/or face shield.

**Ventilation:** Laboratory fume hood or local exhaust ventilation.

**Other Protective Equipment:** Chemical-resistant gloves and body covering to minimize skin contact. If handled in a ventilated enclosure, as in a laboratory setting, respirator and goggles or face shield may not be required. Safety glasses are always required.

## Section 9 - Physical and Chemical Properties

**Appearance:** White to off-white lyophilized powder

**Odor:** Odorless

**Boiling Point:** No applicable information found

**Melting Point:** No applicable information found

**Specific Gravity:** No applicable information found

**pH:** No applicable information found

**Evaporation Rate:** No applicable information found

**Water Solubility:** Soluble

**Vapor Density:** No applicable information found

**Vapor Pressure:** No applicable information found

## Section 10 - Stability and Reactivity

**Stability:** Stable at normal temperatures and pressures.

**Incompatibility:** May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.).

**Hazardous Decomposition:** May emit toxic fumes when heated to decomposition.

**Hazardous Polymerization:** Will not occur.

## Section 11 - Toxicological Information

### Acute Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

**Oral:** No applicable information found.

**Skin:** No applicable information found.

**Inhalation:** No applicable information found.

**Intravenous:** Drotrecogin alfa (activated)- Monkey, median lethal dose between 5 mg/kg and 25 mg/kg, hemorrhage, vascular inflammation, thrombus, embolism, decreased activity.

**Skin Contact:** No applicable information found.

**Eye Contact:** Drotrecogin alfa (activated)- Cell culture test, nonirritant

### Chronic Exposure

No data available for mixture or formulation. Data for ingredient(s) or related material(s) are presented.

**Target Organ Effects:** Drotrecogin alfa (activated) - Blood effects (hemorrhage due to delayed clotting time).

**Reproduction:** No studies available for drotrecogin alfa (activated). Fertility and teratology studies conducted with a similar recombinant activated Protein C molecule reported no adverse maternal, reproductive, or developmental changes.

**Sensitization:** Drotrecogin alfa (activated) - Monkey, intravenous, negative hypersensitivity.

**Mutagenicity:** Drotrecogin alfa (activated) - Negative in chromosomal aberration and mouse micronucleus assays.

## Section 12 - Ecological Information

No applicable ecological information found.

## Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

## Section 14 - Transport Information

### Regulatory Organizations:

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

## Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Eli Lilly and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

### U.S. Regulations

Drotrecogin alfa (activated)

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 - Not on this list

OSHA Substance Specific - No

### EU Regulations

#### EC Classification

Not assigned an overall EC classification.

## Section 16 - Other Information

**MSDS Sections Revised:** MSDS Name and sections 1, 2, 3, 7, 11, and 15.

**Emergency Overview Sections Revised:** New caution.

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it

is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Eli Lilly and Company  
Hazard Communication  
317-277-6029

## **GLOSSARY:**

ACGIH = American Conference of Governmental Industrial Hygienists  
AIHA = American Industrial Hygiene Association  
BEI = Biological Exposure Index  
CAS Number = Chemical Abstract Service Registry Number  
CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)  
CHAN = Chemical Hazard Alert Notice  
CHEMTREC = Chemical Transportation Emergency Center  
DOT = Department of Transportation  
EC = European Community  
EINECS = European Inventory of Existing Chemical Substances  
ELINCS = European List of New Chemical Substances  
EPA = Environmental Protection Agency  
HEPA = High Efficiency Particulate Air (Filter)  
IARC = International Agency for Research on Cancer  
ICAO/IATA = International Civil Aviation Organization/International Air Transport Association  
IEG = Lilly Interim Exposure Guideline  
IMO = International Maritime Organization  
Kow = Octanol/Water Partition Coefficient  
LEG = Lilly Exposure Guideline  
LEL = Lower Explosive Limit  
MSDS = Material Safety Data Sheet  
MSHA = Mine Safety and Health Administration  
NA = Not Applicable, except in Section 14 where NA = North America  
NADA = New Animal Drug Application  
NAIF = No Applicable Information Found  
NCI = National Cancer Institute  
NIOSH = National Institute for Occupational Safety and Health  
NOS = Not Otherwise Specified  
NTP = National Toxicology Program  
OSHA = Occupational Safety and Health Administration  
PEL = Permissible Exposure Limit (OSHA)  
RCRA = Resource Conservation and Recovery Act  
RQ = Reportable Quantity  
RTECS = Registry of Toxic Effects of Chemical Substances  
SARA = Superfund Amendments and Reauthorization Act  
STEG = Lilly Short Term Exposure Guideline

STEL = Short Term Exposure Limit

TLV = Threshold Limit Value (ACGIH)

TPQ = Threshold Planning Quantity

TSCA = Toxic Substances Control Act

TWA = Time Weighted Average/8 Hours Unless Otherwise Noted

UEL = Upper Explosive Limit

UN = United Nations

WEEL = Workplace Environmental Exposure Level (AIHA)