

# Abciximab Solution

## Material Safety Data Sheet

Effective Date: 19-Jan-2000

### Section 1 - Chemical Product and Company

**Manufacturer:**

Centocor B.V. (Leiden, The Netherlands),  
a subsidiary of Centocor, Inc.  
200 Great Valley Parkway  
Malvern, PA 19355

**Manufacturer's Emergency Phone:**

(610) 651-6000

**CHEMTREC:**

1-800-424-9300 (North America)

1-703-527-3887 (International)

**MSDS Prepared By:**

Eli Lilly and Company  
Lilly Corporate Center  
Indianapolis, IN 46285  
Phone: 1-317-276-2000

**Common Name:** Abciximab Solution

**Synonym(s):** Abciximab; Abciximab Injection; Monoclonal Antibody; Fab Fragment; 314366 Solution; c7E3 Fab

**Trademarks(s):** ReoPro; ReoPro Injection; Centocor ReoPro

**Lilly Item Code(s):** VL7140; VL7141; VL7149

This vendor supplied document has been supplemented by Eli Lilly and Company using available toxicological, physical, and other information.

See attached glossary for abbreviations.

### Section 2 - Composition / Information on Ingredients

<b>Ingredient</b>	<b>CAS</b>	<b>Concentration %</b>
Abciximab	143653-53-6	NAIF
Water	7732-18-5	NAIF

This pharmaceutical preparation is a monoclonal antibody designed to inhibit platelet aggregation in the blood during and after high-risk coronary angioplasty. It contains a protein of biological origin, a chimeric (mouse and human) Fab fragment of a monoclonal immunoglobulin derived from a well characterized cell-line, devoid of any pathogens, viruses, or host proteins. It is suspended in innocuous buffers and salts.

This product contains no hazardous components as defined in OSHA 29 CFR 1910.1200.

**Exposure Guidelines:** Not established.

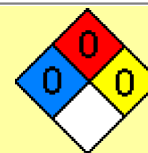
## Section 3 - Hazards Identification

**Appearance:** Clear fluid

**Physical State:** Liquid

**Odor:** Odorless

### Emergency Overview



**Emergency Overview Effective Date:** 11-Feb-1995

**Lilly Laboratory Labeling Codes:**

**Health** 0

**Fire** 0

**Reactivity** 0

**Primary Physical and Health Hazards:** Not Considered a Health Hazard.

**Caution Statement:** Abciximab Solution is not considered to be a health hazard.

**Routes of Entry:** Skin contact.

**Effects of Overexposure:** Eye, no known hazard. Skin, no known hazard on intact skin or on cut or abraded skin. Ingestion, not expected to be active orally. Inhalation, no known hazard.

Acute Effects - Pharmacologic effects of the drug (inhibition of platelet aggregation and increased bleeding time) might be observed with a dose which approaches clinical levels (bolus dose 0.25 mg/kg followed by an infusion at 10 ug/min for 12 hours). This would, in all likelihood, only be seen if the entire amount was received over a short period of time.

Chronic Effects - No chronic occupational effects known.

Because the Fab protein is a chimeric murine-human immunoglobulin, there is a remote possibility that a person with allergy to mouse protein might have an allergic reaction upon contact with this material, such as in a cut, needlestick, eye or mucous membrane, or upon inhalation, with repeated exposures.

**Medical Conditions Aggravated by Exposure:** None known.

**Carcinogenicity:** Not listed by IARC, NTP, ACGIH, or OSHA.

## Section 4 - First Aid Measures

**Eyes:** Immediately flush with water for 15 minutes. If irritation persists, seek medical attention.

**Skin:** Promptly wash with soap and water.

**Inhalation:** Obtain medical follow-up in the event of large exposures.

**Ingestion:** Rinse mouth with water.

**Notes to Physician:** Consult the package insert for health effects details.

## Section 5 - Fire Fighting Measures

**Flash Point:** Not applicable

**UEL:** Not applicable

**LEL:** Not applicable

**Extinguishing Media:** Use extinguishing agent which is suitable for the surrounding fire.

**Unusual Fire and Explosion Hazards:** Product presents no unusual hazard if involved in a fire.

**Hazardous Combustion Products:** None known.

**Special Fire Fighting Procedures:** None normally required.

## Section 6 - Accidental Release Measures

**Spills:** Small Spill - Wear protective gloves. Absorb on suitable material, deposit in appropriate container for disposal. Large Spill - Same as small spill. Avoid creating aerosols.

## Section 7 - Handling and Storage

**Shelf Life:** 2.000000 Years at recommended storage temperature.

**Storage Temp:** 2.000000-8.000000 C Do not freeze.

**Material Handling Precautions:** Protect package from physical damage. Do not shake vials.

## Section 8 - Exposure Controls / Personal Protection

See Section 2 for Exposure Guideline information.

**Engineering Controls:** Manufacturing and packaging operations should be designed to minimize exposure to this material.

**Respiratory Protection:** Recommended for large spills and releases.

**Eye Protection:** Avoid eye contact. Eye protection required for spill clean up.

**Other Protective Equipment:** Avoid skin contact. Impervious protective gloves recommended for use.

**Additional Exposure Precautions:** Avoid direct contact and significant aerosol exposure.

## Section 9 - Physical and Chemical Properties

**Appearance:** Clear fluid

**Odor:** Odorless

**Boiling Point:** No applicable information found

**Melting Point:** No applicable information found

**Specific Gravity:** 1.008

**pH:** 7.100000-7.200000

**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:** Chemically stable indefinitely.

**Incompatibility:** No dangerous chemical reactions known.

**Hazardous Decomposition:** None known.

**Hazardous Polymerization:** Will not occur.

## Section 11 - Toxicological Information

### Acute Exposure

**Oral:** No applicable information found.

**Skin:** No applicable information found.

**Inhalation:** No applicable information found.

**Intravenous:** Rabbit, 2mg/ml, no significant irritation.

**Subcutaneous:** Rabbit, 2mg/ml, no significant irritation.

**Intramuscular:** Rabbit, 2mg/ml, no significant irritation.

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

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

### Chronic Exposure

**Target Organ Effects:** No applicable information found.

**Reproduction:** No applicable information found.

**Sensitization:** No applicable information found.

**Mutagenicity:** Not mutagenic in mammalian cells.

## Section 12 - Ecological Information

No applicable ecological information found.

## Section 13 - Disposal Considerations

**Waste Disposal:** Dispose of as with any other prescription pharmaceutical product. Observe all federal, state, and local regulations.

## Section 14 - Transport Information

**Regulatory Organizations:**

**DOT:** Not Regulated

**ICAO/IATA:** Not Regulated

**IMO:** Not Regulated

**Additional Information:** USDA: Permit required for importation.

## 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

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

**Vendor MSDS Date:** 08-Dec-1999

**Additional Information:** Report to the manufacturer any allegations of adverse effects resulting from handling or accidental contact with this material.

Disclaimer - The information contained herein is based upon data considered true and accurate. To the best of our knowledge, no occupational health hazards have been identified under normal conditions of use, although the occupational health hazards of the product have not been thoroughly investigated. Centocor makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation, and verification.

**MSDS Sections Revised:** Sections 1, 2, 3, 6, 9, 11, 12, and 15.

**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)