MATERIAL SAFETY DATA SHEET

Date Issued: November 14, 2006 Version: 2.1
Supersedes: August 8, 2006

Section 1 – Product and Company Identification

Product Name: Activase®
Chemical Name: Human tissue-type plasminogen activator
Chemical Family: Protein

Company Name: Genentech
Company Address: 1 DNA Way, South San Francisco, CA 94080
Company Phone: (650) 225-1000
Emergency Phone: (800) 821-8590

Section 2 – Hazards Identification

Emergency Overview

Activase® is considered hazardous per the criteria under the OSHA Hazard Communication Standard (29 CFR 1910.1200). Adverse health effects have been observed in patients following intravenous (IV) injection of therapeutic doses for treatment of acute myocardial infarction, acute ischemic stroke, and acute massive pulmonary embolism. It derives its biotherapeutic benefit from a protein that is not well absorbed by inhalation or by contact with eyes, skin, or mucous membranes. Although the health effects of occupational exposure to this product are not fully known or characterized, no adverse effects are anticipated as a result of occupational or incidental exposure. This product is a white to off-white, lyophilized powder.

For more product information see Section 11 or visit www.gene.com.

Routes of Exposure

Direct contact with eyes, skin, or mucous membranes is the possible primary route of occupational exposure. No adverse health effects through these routes are expected to occur in occupational exposure conditions due to the large size of the protein (~65,000 Daltons) and its poor potential for absorption.

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Section 3 – Composition/Information on IngredientS

Component(s)	CAS Number
Alteplase	105857-23-6
L-arginine	74-79-3
Phosphoric acid	7664-38-2
Polysorbate 80	9005-65-6
Sterile water for injection	7732-18-5

Formula (drug substance): Protein composed of 527 amino acids
Synonyms (drug substance): Tissue plasminogen activator, t-PA, Alteplase

Section 4 – First Aid Measures

Eye/Skin Contact
Immediately flush eyes thoroughly with water or wash skin for at least 5 minutes as a prudent chemical hygiene practice. Report exposure to supervisor.

Section 5 – Fire Fighting Measures

Flammability/Explosivity
Not considered flammable. No explosivity data available. Note: High airborne concentrations of finely divided organic particulates can explode spontaneously in air or if ignited.

Section 6 – Accidental Release Measures

If material is released or spilled, cordon off spill area. Take proper precautions to minimize exposure by using appropriate personal protective equipment. Do not breathe dust. Wet down spilled material to minimize airborne dispersion. Soak up material with absorbent, e.g., paper towels, and wash spill area thoroughly with soap and water. Dispose of collected material in accordance with applicable waste disposal regulations.

Section 7 – Handling and Storage

Avoid contact with skin, eyes and clothing. Wash hands thoroughly after handling. Protect from light and store with desiccant. Store in a well ventilated area.

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Section 8 – Exposure Control and Personal Protective Equipment

Skin Protection

As a prudent chemical hygiene practice, wear protective equipment that minimizes the potential for skin contact, such as latex gloves and lab coat. Wash hands and other potentially exposed areas immediately after handling material.

Eye Protection

As a prudent chemical hygiene practice, use safety glasses with side shields.

Other

Clean all protective equipment after use.

Section 9 – Physical and Chemical Properties

Molecular Weight:	~65,000 Daltons
pH:	Not applicable
Boiling Point (°C):	Not applicable
Melting Point:	No data available
Vapor Pressure:	Not applicable
Solubility in Water:	Soluble
Evaporation Rate:	Not applicable
Appearance & Odor:	White to off-white, lyophilized powder
Specific Gravity:	No data available
Vapor Density:	Not applicable
Percent Volatile:	Not applicable

Section 10 – Stability and Reactivity

Stability:	No data available
Hazardous Polymerization:	Will not occur
Hazardous Decomposition Products:	None expected

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Section 11 – Toxicological Information

Eye
No data available

Skin
No data available

Systemic

Acute
No data available

Chronic
No data available

Reproductive and Developmental Toxicity
Activase® has been shown to have an embryocidal effect in rabbits when intravenously administered in doses of approximately two times (3 mg/kg) the human dose. No maternal or fetal toxicity was evident at 0.65 times (1 mg/kg) the human dose in pregnant rats and rabbits dosed during the period of organogenesis. There are no adequate and well controlled-studies in pregnant women.

Carcinogenicity and Mutagenicity
Long-term studies in animals have not been performed. Short-term studies, which evaluated tumorigenicty of Activase® and effect on tumor metastases in rodents, were negative. Studies to determine mutagenicity (Ames test) and chromosomal aberration assays in human lymphocytes were negative at all concentrations tested. Toxicity to cells, as reflected by a decrease in mitotic index, was evidenced only after prolonged exposure and only at the highest concentrations tested.

Medical Conditions Aggravated by Exposure
None known or reported.

Clinical/Human Studies
Adverse health effects have been observed in patients following intravenous (IV) injection of therapeutic doses for treatment of acute myocardial infarction, acute ischemic stroke, and acute massive pulmonary embolism. The most common complication encountered during Activase® therapy is bleeding. For the complete description of warnings, precautions, and adverse reactions please refer to the Genentech web site at www.gene.com.

Occupational Exposure Limit
None currently established by OSHA, NIOSH, ACGIH, or Genentech.

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Section 12 – Ecological Information

Persistence and Degradability
This product is protein based and will rapidly degrade in the environment.

Aquatic Toxicity
No data available

Section 13 – Disposal Considerations

Dispose of waste residues according to prescribed federal, state, and local guidelines.

Section 14 – Transportation Information

Hazard Class
Not regulated as per U.S. DOT or IATA

UN Number
Not assigned as per U.S. DOT or IATA

Section 15 – Regulatory Information

EUROPEAN UNION (EU) RISK AND SAFETY PHRASES
Not established

Not listed by NTP, IARC or OSHA as a carcinogen. Not listed under California Proposition 65.

Section 16 – Other Information

No additional information.

The above information is offered in good faith and with the belief that it is accurate. While efforts are made to provide useful information relating to handling, in the event of an adverse incident associated with this product, this Material Safety Data Sheet (MSDS) is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.