

Genentech  
**\*\*MATERIAL SAFETY DATA SHEET\*\***

Date Issued: September 24, 2004  
Supersedes: September 3, 2004

Version: 3.1  
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**Section 1 – Product and Company Identification**

Product Name: Herceptin®  
Product Number: N/A  
Chemical Name: Anti-p185<sup>HER2</sup>  
Chemical Family: Protein

Company Name: Genentech, Inc.  
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

This material derives its biotherapeutic benefit from a monoclonal antibody (trastuzumab). It is not considered to be or to contain hazardous chemicals based on evaluations made by our company under the OSHA Hazard Communication Standard, 29 CFR 1910-1200. Note: Adverse health effects have been observed in patients following IV injection of high doses of this protein for treatment of serious or life-threatening medical conditions. However; injection of clinical doses is not a route of exposure in an occupation setting; therefore, no adverse health effects associated with occupational exposure are expected.

For more additional product information, please visit Genentech's web site at [www.gene.com](http://www.gene.com) and click on the products link.

**Section 3 – Composition/Information on Ingredient**

<u>Component(s)</u>	<u>CAS Number</u>
Trastuzumab	180288-69-1
L-Histidine HCL	5934-29-2
L-Histidine	71-00-1
Polysorbate 20, USP	9005-64-5
Trehalose dihydrate	6138-23-4
Water sterile for injection (Contains 1.1% benzyl alcohol as a preservative)	

Formula: Antibody framework region derived from human immunoglobulin G<sub>1</sub>(IgG<sub>1</sub>)  
Synonyms: Trastuzumab, recombinant humanized monoclonal antibody to HER2 protein, rhuMAb HER2

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**Section 4 – First Aid Measures**

No special first aid measures. Follow standard hygiene practices, such as washing hands after handling.

**Section 5 – Fire Fighting Measures**

Flammability/Explosivity: Not flammable or explosive. No special fire fighting measures.

**Section 6 – Accidental Release Measures**

If material is released or spilled, soak up material with absorbent material 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**

Refrigeration (2-8° C, 36-46° F) is advised to maintain longer pharmacological activity. Protect from sunlight. Avoid agitation.

**Section 8 – Exposure Control and Personal Protective Equipment**

No special protective clothing required. Follow standard hygiene practices, such as washing hands after handling.

**Section 9 – Physical and Chemical Properties**

Molecular Weight	~140 kDa
pH:	~6.0
Boiling Point (degrees C):	No data available
Melting Point	No data available
Vapor Pressure:	~17 mmHg
Solubility in Water:	Soluble
Evaporation Rate:	Negligible
Appearance:	White to pale yellow, odorless, lyophilized powder
Specific Gravity:	~1
Vapor Density:	No data available
Percent Volatile:	Non volatile

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**Section 10 – Stability and Reactivity**

Stability: Stable

Hazardous Polymerization: Will not occur

Hazardous Decomposition Products: No data available

**Section 11 – Toxicological Information**

This material is not considered to be or to contain hazardous chemicals based on evaluations made by our company under the OSHA Hazard Communication Standard, 29 CFR 1910-1200.

**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 per U.S. DOT or IATA

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

**Section 15 – Regulatory Information**

Not listed by NTP, IARC or OSHA as a carcinogen. Not listed under 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. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Material Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.