

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

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Version: 4.0  
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**Section 1 – Product and Company Identification**

Product Name: Lucentis®  
Product Number: Not applicable  
Chemical Name: Recombinant humanized monoclonal antibody Fab (antibody fragment) to vascular endothelial growth factor (VEGF)  
Chemical Family: High molecular weight 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**

Lucentis® derives its therapeutic benefit from a monoclonal antibody Fab (ranibizumab) that is not well absorbed by inhalation or by contact with eyes, skin, or mucous membranes. Adverse health effects have been observed in patients following intravitreal (vitreous humor between the lens and the retina) (ITV) injection of therapeutic doses for the treatment of neovascular wet age-related macular degeneration (AMD). 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 an odorless, colorless to pale yellow liquid.

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

**Routes of Exposure**

Direct contact of drug product with eyes, skin, or mucous membranes, and inhalation of aerosols, are the possible primary routes of occupational exposure. No adverse health effects through these routes are expected to occur in occupational or incidental exposure conditions due to the large size of ranibizumab (molecular weight of ~48,000 daltons) and its poor potential for absorption.

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

<u>Component(s)</u>	<u>CAS Number</u>
Ranibizumab	347396-82-1
L-Histidine hydrochloride monohydrate	5934-29-2
L-Histidine (free base)	71-00-1
Trehalose dihydrate	6138-23-4
Polysorbate 20	9005-64-5

Formula (drug substance): Antibody framework region derived from human IgG<sub>1</sub>.  
Synonyms: Ranibizumab, rhuFab VEGF, anti-VEGF

**Section 4 – First Aid Measures**

No special first aid measures. Follow standard chemical hygiene practices, such as washing hands after handling. If eyes or skin are exposed, flush eyes thoroughly with water or wash skin for at least 5 minutes as a prudent chemical hygiene practice.

**Section 5 – Fire Fighting Measures**

**Flammability and Explosivity**

Not considered flammable or explosive. No special fire fighting measures.

**Section 6 – Accidental Release Measures**

Take proper precautions to minimize exposure by using appropriate personal protective equipment. If material is released or spilled, soak up with absorbent, e.g., spill pillow, and wash spill area thoroughly with soap and water. Dispose of collected material in accordance with applicable waste disposal regulations.

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**Section 7 – Handling and Storage**

Avoid contact with skin, eyes and clothing. Wash hands thoroughly after handling. 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 chemical hygiene practices, such as wearing a protective outer garment, latex gloves, and safety glasses.

**Section 9 – Physical and Chemical Properties**

Molecular Weight	~48,000 daltons
pH:	~5.5
Boiling Point (degrees C):	~100 degrees C
Melting Point	Not applicable
Vapor Pressure:	Nil
Solubility in Water:	Soluble
Evaporation Rate:	Equal to water
Appearance:	Odorless, colorless to pale yellow liquid
Specific Gravity:	~1
Vapor Density:	No data available
Percent Volatile:	Nil

**Section 10 – Stability and Reactivity**

Stability: Stable  
Hazardous Polymerization: Will not occur  
Hazardous Decomposition Products: None

**Section 11 – Toxicological Information**

**Eye**

Ocular inflammation has been observed following ITV treatment of animals. However, there were generally no lasting effects on ophthalmic parameters, including ocular pathology, electrodiagnostics, or fluorescein angiography. Ranibizumab administration

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did not alter any general toxicologic parameters, including body weight, food consumption, physical examination findings, hematology, serum chemistries, individual organ weight, or anatomical pathology.

In studies in humans, ITV administration has resulted in increased intraocular pressure, conjunctival hemorrhage, eye pain, vitreous floaters, and intraocular inflammation.

**Skin**

No data available

**Systemic**

**Single-Dose**

No data available

**Repeat-Dose**

No data available

**Reproductive and Developmental Toxicity**

Animal reproduction studies have not been conducted with ranibizumab. Although ranibizumab is administered ITV, animal studies have shown that it can reach the systemic circulation. Based on its mechanism of action (ranibizumab inhibits VEGF, which is responsible for formation of new blood vessels during embryonic and fetal development), and its similarity to bevacizumab (Avastin®), there is a potential for developmental toxicity from injection of therapeutic doses.

**Carcinogenicity and Genotoxicity**

No long-term animal studies have been performed to establish the carcinogenic potential of omalizumab. No genotoxicity studies have been performed, but ranibizumab is not expected to be genotoxic.

**Clinical Studies**

See "Eye" above. A complete description of warnings, precautions, and adverse reactions is available at [www.gene.com](http://www.gene.com), under Medicines.

<b>Section 12 – Ecological Information</b>
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**Persistence and Degradability**

This product is a protein and will rapidly degrade in the environment.

**Aquatic Toxicity**

No data available, but not expected to elicit aquatic toxicity

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**Section 13 – Disposal Considerations**

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

**Section 14 – Transportation Information**

**Hazard Class**

This biotherapeutic is non-hazardous under U.S. Department of Transportation (DOT) Hazardous Materials Regulations (49 CFR) and International Air Transport Association (IATA).

**Packing Group**

Not applicable

**United Nations (UN) Number**

Not applicable

**Section 15 – Regulatory Information**

**European Union (EU) Risk and Safety Phrases**

Not assigned

**Other Regulatory**

Not listed by IARC, NTP, OSHA or California Proposition 65 as a carcinogen. Not listed by California's Proposition 65 as a reproductive or developmental toxin

**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.