Genentech
MATERIAL SAFETY DATA SHEET

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 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.

Section 3 – Composition/Information on Ingredients

Component(s)	CAS Number
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_1.
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.

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 outergarment,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

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, under Medicines.

Section 12 – Ecological Information

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

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.