# Safety Data Sheet

## LUCENTIS® Prefilled Syringe (0.3 mg/0.05 ml)

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

**Product name**: LUCENTIS® Prefilled Syringe (0.3 mg/0.05 ml)

**Product code**: SAP-10180132

**Synonyms**:
- LUCENTIS® PFS (6 mg/ml)
- LUCENTIS® PFS (0.3 mg/0.05 ml)

### 1.2. Relevant identified uses of the substance or mixture and uses advised against

**Use**
- to treat Diabetic Macular Edema (DME) and Diabetic Retinopathy (DR)

### 1.3. Details of the supplier of the safety data sheet

**Company information**
- Enquiries: Genentech, Inc.
  1 DNA Way
  South San Francisco
  USA-CA 94080
  United States of America

  Phone: 001-(650) 225-1000
  E-Mail: info.sds@roche.com
  US Chemtrec phone: (800)-424-9300

**Local representation**

### 1.4. Emergency telephone number

**Emergency telephone number**
- US Chemtrec phone: (800)-424-9300

*1 referring to: Ranibizumab

## SECTION 2: Hazards identification

### Classification of the substance or mixture / Label elements

**GHS Classification**: no classification and labelling according to GHS

### Other hazards

**Note**: no information available
SECTION 3: Composition/information on ingredients

Characterization  recombinant humanised monoclonal antibody (Ranibizumab) with excipients

Ingredients  Concentration  GHS-Classification (pure ingredient)

Ranibizumab  0.6 %
347396-82-1

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact  - rinse immediately with tap water for at least 20 minutes - open eyelids forcibly

Skin contact  - remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents

Inhalation  - remove the casualty to fresh air and keep him/her calm
            - in the event of symptoms get medical treatment

4.2. Most important symptoms and effects, both acute and delayed

Note  - no information available

4.3. Indication of any immediate medical attention and special treatment needed

Note to physician  - treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media  - water spray jet, dry powder, foam, carbon dioxide
            - adapt extinguishing media to surrounding fire conditions

Flash point (liquid)  not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards  - no particular hazards known

5.3. Advice for firefighters

Protection of fire-fighters  - precipitate gases/vapours/mists with water spray
SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - no special precautions required

6.2. Environmental precautions

Environmental protection - no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect spilled solutions with inert adsorbent and hand over to waste removal

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials - glass

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C
- do not freeze
- protected from heat and light

Validity - 2 to 8 °C, in the unopened original container, see "best use before" date stated on the label

Packaging materials - prefilled syringes
- keep it in the outer carton in order to protect from light

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.2 mg/m³

8.2. Exposure controls

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- respiratory protection not necessary during normal operations
- breathing apparatus in case of aerosol mist formation

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)
LUCENTIS® Prefilled Syringe (0.3 mg/0.05 ml)

Eye protection - safety glasses  
*1 referring to: Ranibizumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Color colorless to slightly yellow  
Form sterile liquid  
pH value 5.5

9.2. Other information
Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity
Note - no information available

10.2. Chemical stability
Stability - as for all other proteins, monoclonal antibodies are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created  
- does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution

10.3. Possibility of hazardous reactions
Note - no information available

10.4. Conditions to avoid
Conditions to avoid - warming

10.5. Incompatible materials
Note - no information available

10.6. Hazardous decomposition products
Note - no information available
### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Effect Type</th>
<th>Effect Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>no information available</td>
</tr>
<tr>
<td>Local effects</td>
<td>no information available</td>
</tr>
<tr>
<td>Sensitization</td>
<td>anaphylactic reactions may occur following the parenteral application of proteins; rare cases of hypersensitivity have been described</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>no information available</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>no information available</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus</td>
</tr>
<tr>
<td></td>
<td>the systemic exposure to ranibizumab is low after ocular administration, but due to its mechanism of action, ranibizumab must be regarded as potentially teratogenic and embryo-/foetotoxic</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>no information available</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>no information available</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>no information available</td>
</tr>
<tr>
<td>Note</td>
<td>elimination half-life (after a single dose): ~ 2.9 d</td>
</tr>
<tr>
<td></td>
<td>due to its human tissue specificity, any standard toxikological program is inadequate for the preclinical safety evaluation of ranibizumab</td>
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<tr>
<td></td>
<td>therapeutic dose (intravitreal): 300 µg</td>
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<tr>
<td></td>
<td>no significant toxicities were observed with treatment</td>
</tr>
<tr>
<td>Potential Health Effects</td>
<td>Exposure: Inhalation, Ingestion, Skin contact, Eye contact</td>
</tr>
<tr>
<td></td>
<td>Carcinogenicity: not listed by NTP, IARC or OSHA</td>
</tr>
</tbody>
</table>

*1 referring to: Ranibizumab

### SECTION 12: Ecological information

#### 12.1. Toxicity

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Effect Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecotoxicity</td>
<td>monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected</td>
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</tbody>
</table>

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#### 12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>Degradability Type</th>
<th>Effect Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ready biodegradability</td>
<td>globular proteins are generally well biodegradable</td>
</tr>
</tbody>
</table>

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12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*1 referring to: Ranibizumab

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal
- drain very small quantities into wastewater treatment plant

SECTION 14: Transport information

Note - not classified as Dangerous Good according to the Dangerous Goods Regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases, which are likely to endanger the public health, harm the environment or cause a complaint, to the NJDEPE Hotline and to local officials.
- State and local regulations vary and may impose additional reporting requirements.
The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.