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

1.1. Product identifier

Product name: LUCENTIS(R) Prefilled Syringe (0.5 mg/0.05 ml)
Product code: SAP-10172975
Synonyms: - LUCENTIS(R) PFS (10 mg/ml)
           - LUCENTIS(R) PFS (0.5 mg/0.05 ml)

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

Use: - pharmaceutical active substance *1
      - to treat the "wet" type of age-related macular degeneration (ARMD) *1

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

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

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranibizumab</td>
<td>1 %</td>
<td></td>
</tr>
<tr>
<td>347396-82-1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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)
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>Category</th>
<th>Description</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 *1</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 *1</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 *1</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. *1</td>
</tr>
<tr>
<td></td>
<td>therapeutic dose (intravitreal): 300 µg</td>
</tr>
<tr>
<td></td>
<td>no significant toxicities were observed with treatment</td>
</tr>
</tbody>
</table>

*Note: *1 referring to: Ranibizumab

### SECTION 12: Ecological information

**12.1. Toxicity**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</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 *1</td>
</tr>
</tbody>
</table>

**12.2. Persistence and degradability**

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ready biodegradability</td>
<td>globular proteins are generally well biodegradable                                              *1</td>
</tr>
</tbody>
</table>
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.
## SECTION 16: Other information

<table>
<thead>
<tr>
<th>Note</th>
<th>- Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edition documentation</td>
<td>- first edition</td>
</tr>
</tbody>
</table>

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.