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

1.1. Product identifier

Product name: LUCENTIS(R) Vials (0.3 mg/0.05 ml)
Product code: SAP-10138290
Synonyms:
- LUCENTIS(R) Vials (6 mg/ml)

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

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

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

<table>
<thead>
<tr>
<th>Characterization</th>
<th>recombinant humanised monoclonal antibody (Ranibizumab) with excipients</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranibizumab 347396-82-1</td>
<td>0.6 %</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, after opening the content should be used within a short period

**Packaging materials**  
- vials
- 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)
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
LUCENTIS(R) Vials (0.3 mg/0.05 ml)

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - no information available

Local effects - no information available

Sensitization anaphylactic reactions may occur following the parenteral application of proteins; rare cases of hypersensitivity have been described *1

Mutagenicity - no information available

Carcinogenicity - no information available

Reproductive toxicity should be administered during pregnancy only if the potential benefit justifies the potential risk to the fetus *1

- 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

STOT-single exposure - no information available

STOT-repeated exposure - no information available

Aspiration hazard - no information available

Note elimination half-life (after a single dose): ~ 2.9 d *1
due to its human tissue specificity, any standard toxikological program is inadequate for the preclinical safety evaluation of ranibizumab. *1

the therapeutic dose (intravitreal): 300 µg *1

no significant toxicities were observed with treatment *1

Potential Health Effects Exposure: Inhalation, Ingestion, Skin contact, Eye contact

- Carcinogenicity: not listed by NTP, IARC or OSHA

*1 referring to: Ranibizumab

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected *1

12.2. Persistence and degradability

Ready biodegradability globular proteins are generally well biodegradable *1

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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 (1-609-292-5560) 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>
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</thead>
<tbody>
<tr>
<td>Edition documentation</td>
<td>- first edition</td>
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</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.