SAFETY DATA SHEET

LUCENTIS(R) Prefilled Syringes (0.5 mg/0.05 ml)

SECTION 1. IDENTIFICATION

Product name : LUCENTIS(R) Prefilled Syringes (0.5 mg/0.05 ml)
Product code : RO489-3594/F01

Manufacturer or supplier’s details
Company name of supplier : Genentech, Inc.
Address : DNA Way 1
94080 South San Francisco
CA
USA
Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com
Emergency telephone : US Chemtrec phone (800)-424-9300
Emergency telephone number : US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use : Formulated pharmaceutical active substance
Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranibizumab</td>
<td>347396-82-1</td>
<td>1.0</td>
</tr>
<tr>
<td>Trehalose (D+)-, 2H2O</td>
<td>6138-23-4</td>
<td>10.0</td>
</tr>
<tr>
<td>L-Histidine monohydrochloride mono-</td>
<td>5934-29-2</td>
<td>0.17</td>
</tr>
<tr>
<td>nohydrate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L-Histidine</td>
<td>71-00-1</td>
<td>0.03</td>
</tr>
<tr>
<td>Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.</td>
<td>9005-64-5</td>
<td>0.01</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>&gt; 88.0</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice: Do not leave the victim unattended.

If inhaled: Move to fresh air.
If unconscious, place in recovery position and seek medical advice.
If symptoms persist, call a physician.

In case of skin contact: If on skin, rinse well with water.

In case of eye contact: Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
If eye irritation persists, consult a specialist.

If swallowed: Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Rinse mouth with water.

Most important symptoms and effects, both acute and delayed: None known.

Notes to physician: The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during firefighting: No information available.

Hazardous combustion products: No hazardous combustion products are known

Further information: Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for fire-fighters: Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Refer to protective measures listed in sections 7 and 8.

Environmental precautions: Local authorities should be advised if significant spillages
Methods and materials for containment and cleaning up:
- Wipe up with absorbent material (e.g. cloth, fleece).
- Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion:
- Normal measures for preventive fire protection.

Advice on safe handling:
- For personal protection see section 8.
  Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage:
- Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions:
- See label, package insert or internal guidelines

Materials to avoid:
- No materials to be especially mentioned.

Storage temperature:
- Protected from heat and light

Further information on storage stability:
- No decomposition if stored and applied as directed.

Packaging material:
- Suitable material: Stainless steel, glass, Vials, Prefilled syringes

SECTION 8. EXPOSURE CONTROLS/PERSOAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ranibizumab</td>
<td>347396-82-1</td>
<td>IOEL</td>
<td>0.2 mg/m3</td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
</tbody>
</table>

Engineering measures:
- No data available

Personal protective equipment

Respiratory protection:
- No personal respiratory protective equipment normally required.

Hand protection
Material:
- Protective gloves
SAFETY DATA SHEET

LUCENTIS(R) Prefilled Syringes (0.5 mg/0.05 ml)

<table>
<thead>
<tr>
<th>Remarks</th>
<th>Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye protection</td>
<td>Safety glasses</td>
</tr>
<tr>
<td>Skin and body protection</td>
<td>Protective suit</td>
</tr>
<tr>
<td>Hygiene measures</td>
<td>Handle in accordance with good industrial hygiene and safety practice.</td>
</tr>
</tbody>
</table>

### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Appearance</th>
<th>Aqueous solution, Sterile liquid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>colorless, light yellow</td>
</tr>
<tr>
<td>Odor</td>
<td>No data available</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>5.5</td>
</tr>
<tr>
<td>Melting point/range</td>
<td>No data available</td>
</tr>
<tr>
<td>Boiling point/boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>does not flash</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>No data available</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Does not sustain combustion.</td>
</tr>
<tr>
<td>Flammability (liquids)</td>
<td>Does not sustain combustion.</td>
</tr>
<tr>
<td>Self-ignition</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Upper explosion limit / Upper flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Lower explosion limit / Lower flammability limit</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility(ies)</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>No data available</td>
</tr>
<tr>
<td>Solubility in other solvents</td>
<td>No data available</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water</td>
<td>No data available</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

LUCENTIS(R) Prefilled Syringes (0.5 mg/0.05 ml)

<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.4</td>
<td>02-13-2020</td>
<td>08-12-2019</td>
<td>06-10-2017</td>
</tr>
</tbody>
</table>

Autoignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, dynamic : No data available
  Viscosity, kinematic : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reactions
  Stable under recommended storage conditions.
  No hazards to be specially mentioned.
Incompatible materials : No data available
Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Components:

Ranibizumab:
Acute oral toxicity : Remarks: Not bioavailable by oral administration

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
OSHA No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.

NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:
Ranibizumab:
Effects on fetal development : Result: Based on its mechanism of action, effects on embryo-fetal development can be assumed

STOT-single exposure
Not classified based on available information.

STOT-repeated exposure
Not classified based on available information.

Aspiration toxicity
Not classified based on available information.

Further information
Components:
Ranibizumab:
Remarks : anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described with other monoclonal antibodies

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity
No data available

Persistence and degradability
Components:
Ranibizumab:
Biodegradability : Result: Globular proteins are generally well biodegradable

Bioaccumulative potential
Components:
Ranibizumab:
Partition coefficient: n-octanol/water : Remarks: No data available
SAFETY DATA SHEET

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Mobility in soil
No data available

Other adverse effects

Product:
Ozone-Depletion Potential: Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:
Ranibizumab:
Additional ecological information: Monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG
Not regulated as a dangerous good

IATA-DGR
Not regulated as a dangerous good

IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

Domestic regulation

49 CFR
Not regulated as a dangerous good
SAFETY DATA SHEET

LUCENTIS(R) Prefilled Syringes (0.5 mg/0.05 ml)

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know

CERCLA Reportable Quantity
This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Component TPQ (lbs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARA 311/312 Hazards</td>
<td>No SARA Hazards</td>
<td></td>
</tr>
</tbody>
</table>

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
This product does not contain any Hazardous Substances listed under the U.S. Clean Water Act, Section 311, Table 116.4A.
This product does not contain any Hazardous Chemicals listed under the U.S. Clean Water Act, Section 311, Table 117.3.
This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307.

US State Regulations

Massachusetts Right To Know

Pennsylvania Right To Know

<table>
<thead>
<tr>
<th>Water</th>
<th>7732-18-5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trehalose (D+)-, 2H2O</td>
<td>6138-23-4</td>
</tr>
</tbody>
</table>

Maine Chemicals of High Concern

Vermont Chemicals of High Concern

Washington Chemicals of High Concern

The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Ranibizumab
L-Histidine monohydrochloride monohydrate

AICS : Not in compliance with the inventory
NFPA:  
- Flammability
- Health
- Instability
- Special hazard

HMIS® IV:  
- HEALTH / 0
- FLAMMABILITY 0
- PHYSICAL HAZARD 0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC -
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