

Safety Data Sheet

LUCENTIS(R) Vials (0.5 mg/0.05 ml)

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

1.1. Product identifier

Product name LUCENTIS(R) Vials (0.5 mg/0.05 ml)
 Product code SAP-10138289
 Synonyms - LUCENTIS(R) Vials (10 mg/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: Local representation:
 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

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SECTION 3: Composition/information on ingredients

Characterization recombinant humanised monoclonal antibody (Ranibizumab) with excipients

Ingredients	Concentration	GHS-Classification (pure ingredient)
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Ranibizumab 347396-82-1	1 %	
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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

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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 *1

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)

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Eye protection - safety glasses

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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

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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 - 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 *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 - due to its human tissue specificity, any standard toxicological program is inadequate for the preclinical safety evaluation of ranibizumab. - therapeutic dose (intravitreal): 300 µg - no significant toxicities were observed with treatment	*1 *1 *1 *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
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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.

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SECTION 16: Other information

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| Note | - Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user. |
| Edition documentation | - first edition |

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.