

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

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	0.6 %	
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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

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 *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

*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

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 and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

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SECTION 16: Other information

Note	- none
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.