Safety Data Sheet

LUCENTIS(R) Prefilled Syringe (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) 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

Local representation:

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

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)

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	*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
	- 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

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

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.