Safety Data Sheet

RITUXAN HYCELA™ Vials (1,600 mg/26,800 Units per 13.4 ml)

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

1.1. Product identifier

Product name: RITUXAN HYCELA™ Vials (1,600 mg/26,800 Units per 13.4 ml)

Product code: SAP-10142723

Synonyms:
- MabThera® SC Vials 1,600mg/13.4ml
- RITUXAN HYCELA™ 1,600 mg rituximab and 26,800 Units hyaluronidase human per 13.4 mL (120 mg/2,000 Units per mL)

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

Use: - pharmaceutical active substance (antineoplastic)

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

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	ready to use solution in a vial for subcutaneous administration

Ingredients	Concentration	GHS-Classification (pure ingredient)
Rituximab 174722-31-7	1 %	
Hyaluronidase (rHuPH20) 757971-58-7	0.002 %	

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse with tap water for 20 minutes - open eyelids forcibly
Skin contact	- drench affected skin with water
Inhalation	- remove the casualty to fresh air - 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	- adapt extinguishing media to surrounding fire conditions - water spray jet, dry powder, foam, carbon dioxide
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	- ensure adequate ventilation

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 spills with inert adsorbent and hand over to waste removal - clean contaminated areas with isopropanol/water or ethanol/water (70/30) soaked wipes

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 - protected from light - do not freeze
Validity	- 30 months, 2 to 8 °C
Packaging materials	- glass vials, colourless - 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): 60 ng/m3	*1
	- IOEL (Internal Occupational Exposure Limit): 0.04 mg/m3	*2

1 referring to: Hyaluronidase (rHuPH20)
2 referring to: Rituximab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	colorless to yellowish clear to opalescent

Form	sterile liquid
pH value	5.0 to 6.0

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 - stable under the conditions mentioned in chapter 7

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Note - no information available

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - do not shake the solution, formation of foam

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- MTD	> 100	mg/kg	(i.v., cynomolgus monkey)	*2
	- MTD	> 100	mg/kg	(i.p., mouse)	*2
Subchronic toxicity	- NOAEL 2 mg/kg/w (s.c., cynomolgus monkey; 39 weeks)				*1
Local effects	- no information available				
Sensitization	with enzymes, repeated inhalation of dust or aerosols as well as direct contact may cause sensitization and allergic reactions in predisposed individuals				*1
Mutagenicity	- no information available				

Carcinogenicity	-	no information available
Reproductive toxicity	-	no information available
STOT-single exposure	-	no information available
STOT-repeated exposure	-	no information available
Aspiration hazard	-	no information available
Note	-	chimeric humanized monoclonal antibody that binds to CD20, a protein present on the cell surface of pre-B- and mature B-lymphocytes *2

1 referring to: Hyaluronidase (rHuPH20)
2 referring to: Rituximab

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 *2

12.2. Persistence and degradability

Ready biodegradability	-	globular proteins are generally well biodegradable *1
	-	globular proteins are generally well biodegradable *2

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: Hyaluronidase (rHuPH20)
2 referring to: Rituximab

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	- none
Edition documentation	- changes from previous version in sections 3

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.