

Safety Data Sheet

# RITUXAN HYCELA™ Vials (1,400 mg/23,400 Units per 11.7 ml)

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

### 1.1. Product identifier

Product name RITUXAN HYCELATM Vials (1,400 mg/23,400 Units per 11.7 ml)

Product code SAP-10131539

Synonyms - RITUXAN HYCELATM 1,400 mg rituximab and 23,400 Units hyaluronidase human per 11.7 mL (120 mg/2,000 Units per mL)  
- MabThera® SC Vials 1,400mg/11.7ml

### 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	Local representation:
	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

## 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 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

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## 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/m<sup>3</sup> \*1  
- IOEL (Internal Occupational Exposure Limit): 0.04 mg/m<sup>3</sup> \*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

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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

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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
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#### 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	
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#### 12.4. Mobility in soil

Note	- no information available	
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#### 12.5. Results of PBT and vPvB assessment

Note	- no information available	
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#### 12.6. Other adverse effects

Note	- no information available	
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*1 referring to:	Hyaluronidase (rHuPH20)	
*2 referring to:	Rituximab	

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## 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.