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

**Product code**  
SAP-10131539

**Synonyms**  
- RITUXAN HYCELA™ 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

**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
SECTION 3: Composition/information on ingredients

Characterization  
ready to use solution in a vial for subcutaneous administration

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rituximab</td>
<td>1 %</td>
<td></td>
</tr>
<tr>
<td>Hyaluronidase (rHuPH20)</td>
<td>0.002 %</td>
<td></td>
</tr>
</tbody>
</table>

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
### 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

Note
- no information available

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

12.2. Persistence and degradability
Ready biodegradability  - globular proteins are generally well biodegradable
- globular proteins are generally well biodegradable

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

Note
- no information available

Note referring to: Hyaluronidase (rHuPH20)
Note 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.