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

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 174722-31-7</td>
<td>1 %</td>
<td></td>
</tr>
<tr>
<td>Hyaluronidase (rHuPH20) 757971-58-7</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
- IOEL (Internal Occupational Exposure Limit): 0.04 mg/m³

*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

<table>
<thead>
<tr>
<th>Category</th>
<th>MTD</th>
<th>mg/kg</th>
<th>Route</th>
<th>Animal Species</th>
<th>Duration</th>
<th>*1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MTD</td>
<td>&gt; 100</td>
<td>i.v.</td>
<td>cynomolgus monkey</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>MTD</td>
<td>&gt; 100</td>
<td>i.p.</td>
<td>mouse</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subchronic toxicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>NOAEL</td>
<td>2</td>
<td>s.c.</td>
<td>cynomolgus monkey</td>
<td>39 weeks</td>
<td></td>
</tr>
<tr>
<td>Local effects</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sensitization</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>with enzymes, repeated inhalation of dust or aerosols as well as direct contact may cause sensitization and allergic reactions in predisposed individuals</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutagenicity</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

Note: 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.