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

1.1. Product identifier

Product name RITUXAN(R) Vials (500 mg/50 ml)
Product code SAP-10063481
Synonyms - Rituxan

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

Use - pharmaceutical active substance (antineoplastic)
      - pharmaceutical active substance (antirheumatic)

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

*1 referring to: Rituximab

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: chimeric monoclonal antibody (rituximab) with excipients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rituximab</td>
<td>1 %</td>
</tr>
</tbody>
</table>

CAS: 174722-31-7

*1 referring to: Rituximab

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact: rinse immediately with tap water for 10 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: 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 - 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 - rinse with plenty of water

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials - glass, polyethylene, PVC

Note - no incompatibilities between Rituxan and polyvinylchloride or polyethylene bags have been observed
- do not shake the solution

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, see expiry date on the label

Packaging materials - 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): 0.04 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 is recommended for dusty operations.

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)
SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color: colorless, clear
Form: sterile liquid
pH value: 6.5

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: stable under the conditions mentioned in chapter 7

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: do not shake the solution, formation of foam
### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Effect</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute toxicity</strong></td>
<td>MTD &gt; 100 mg/kg (i.v., cynomolgus monkey) *1</td>
</tr>
<tr>
<td></td>
<td>MTD &gt; 100 mg/kg (i.p., mouse) *1</td>
</tr>
<tr>
<td><strong>Sensitization</strong></td>
<td>Anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described</td>
</tr>
<tr>
<td><strong>Note</strong></td>
<td>Side effect(s) during therapy: tumor lysis syndrome, allergic symptoms, respiratory disorders, cardiac arrhythmias, hypotension, changes in blood count, vomiting, urticaria, fever, shivering, nausea, headache, kidney damages</td>
</tr>
<tr>
<td></td>
<td>Chimeric humanized monoclonal antibody that binds to CD20, a protein present on the cell surface of pre-B- and mature B-lymphocytes *1</td>
</tr>
<tr>
<td><strong>Potential Health Effects</strong></td>
<td>Exposure: Inhalation, Ingestion, Skin contact, Eye contact</td>
</tr>
<tr>
<td></td>
<td>Carcinogenicity: formulation not listed by NTP, IARC or OSHA</td>
</tr>
</tbody>
</table>

*1 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 |

*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: Rituximab

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note - not classified by transport 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 (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Edition documentation - changes from previous version in sections 8

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.