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:
Genentech, Inc.
1 DNA Way
South San Francisco
USA-CA 94080
United States of America

Enquiries: info.sds@roche.com
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

*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

Ingredients

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

*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

- **Note**: 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

#### 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.

- **Hand protection**: protective gloves (e.g., 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

Acute toxicity
- MTD > 100 mg/kg (i.v., cynomolgus monkey) *1
- MTD > 100 mg/kg (i.p., mouse) *1

Sensitization
- anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described

Note
- 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
- chimeric humanized monoclonal antibody that binds to CD20, a protein present on the cell surface of pre-B- and mature B-lymphocytes

Potential Health Effects
- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Carcinogenicity: formulation not listed by NTP, IARC or OSHA

*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

12.2. Persistence and degradability

Ready biodegradability
- 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

*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

Note - Please note this Safety Data Sheet for the bulk product does not apply for the finished, packaged medicinal product intended for the final user.

Edition documentation - changes from previous version in sections 2, 3, 16

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.