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

## 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>RITUXAN(R) Vials (100 mg/10 ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10063468</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Rituxan</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>pharmaceutical active substance (antineoplastic)</td>
</tr>
<tr>
<td>pharmaceutical active substance (antirheumatic)</td>
</tr>
</tbody>
</table>

## 1.3. Details of the supplier of the safety data sheet

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries: Genentech, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 DNA Way</td>
</tr>
<tr>
<td></td>
<td>South San Francisco</td>
</tr>
<tr>
<td></td>
<td>USA-CA 94080</td>
</tr>
<tr>
<td></td>
<td>United States of America</td>
</tr>
<tr>
<td></td>
<td>Phone 001-(650) 225-1000</td>
</tr>
<tr>
<td></td>
<td>E-Mail <a href="mailto:info.sds@roche.com">info.sds@roche.com</a></td>
</tr>
<tr>
<td></td>
<td>US Chemtrec phone: (800)-424-9300</td>
</tr>
</tbody>
</table>

## 1.4. Emergency telephone number

<table>
<thead>
<tr>
<th>Emergency telephone number</th>
<th>US Chemtrec phone: (800)-424-9300</th>
</tr>
</thead>
</table>

*1 referring to: Rituximab

# SECTION 2: Hazards identification

## Classification of the substance or mixture / Label elements

<table>
<thead>
<tr>
<th>GHS Classification</th>
<th>no classification and labelling according to GHS</th>
</tr>
</thead>
</table>

## Other hazards

<table>
<thead>
<tr>
<th>Note</th>
<th>no information available</th>
</tr>
</thead>
</table>
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>

*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

### 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)
Eye protection: safety glasses
*1 referring to: Rituximab

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>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</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>Sensitization</td>
<td>- anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described</td>
</tr>
<tr>
<td>Note</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>Potential Health Effects</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

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**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.