

Safety Data Sheet

RITUXAN(R) Vials (500 mg/50 ml)

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 - MabThera® Vials 500 mg/50 ml

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 | Local representation: |
|---------------------|--|-----------------------|

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 chimeric monoclonal antibody (rituximab) with excipients

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| Ingredients | Concentration | GHS-Classification (pure ingredient) |
|--|--|---|
| Rituximab 174722-31-7 | 1 % | |
| SECTION 4: First aid measures | | |
| 4.1. Description of first aid measures | | |
| Eye contact | - rinse immediately with tap water for at least 20 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 | |

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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 not necessary during normal operations
- in case of intense formation of aerosols: respirator with independent air supply or particle respectively filter mask (depending on the aerosol composition)

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

Eye protection - safety glasses

*1 referring to: Rituximab

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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 |
| Local effects | - no information available | | | | |

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|--------------------------|--|
| Sensitization | anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described |
| 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 | <ul style="list-style-type: none">- 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 *1 |
| Potential Health Effects | <ul style="list-style-type: none">- 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 | *1 |
|-------------|---|----|

12.2. Persistence and degradability

| | | |
|------------------------|--|----|
| Ready biodegradability | - globular proteins are generally well biodegradable | *1 |
|------------------------|--|----|

12.3. Bioaccumulative potential

| | |
|------|----------------------------|
| Note | - no information available |
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12.4. Mobility in soil

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| Note | - no information available |
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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 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 - 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 8, 15

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.