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	- Rituxan	*1

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

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	**Concentration**	**GHS-Classification (pure ingredient)**
Rituximab 174722-31-7	1 %	

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/m^3	*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)

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

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				*1
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	*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

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.