Material Safety Data Sheet

RITUXAN(R) Vials (100 mg/10 ml)

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

1.1. Product identifier

Product name		RITUXAN(R) Vials (100 mg/10 ml)	
Product code		SAP-10063468	
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:	Local representation:
	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

Emergency Overview

Form		sterile liquid
Color		colorless, clear
Potential Health Effects	-	Exposure: Inhalation, Ingestion, Skin contact, Eye contact
	-	Carcinogenicity: formulation not listed by NTP, IARC or OSHA

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**
Rituximab CAS: 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/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)
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

*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.