Safety Data Sheet

HERCEPTIN(R) Vials (440 mg)

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

1.1. Product identifier

Product name		HERCEPTIN(R) Vials (440 mg)
Product code		SAP-10086840
Synonyms	-	HERCEPTIN lyophilized Vials 440 mg

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

Use	-	pharmaceutical active substance (antineoplastic)	*1
	-	active substance in Herceptin	*1

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: Trastuzumab

SECTION 2: Hazards identification

Emergency Overview

Form	lyophilized powder
Color	white to slightly yellow

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	recombinant humanised monoclonal antibody (Trastuzumab) with excipients

Ingredients	Concentration	GHS-Classification (pure ingredient)
Trastuzumab 180288-69-1	51.4 %	
Trehalose dihydrate 6138-23-4	46.7 %	
L-Histidine 71-00-1	0.74 %	
L-Histidine hydrochloride monohydrate 5934-29-2	1.15 %	
Polysorbate 20 9005-64-5	0.01 %	

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 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	-	no special precautions required

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	-	collect solids (avoid dust formation) and hand over to waste removal
	-	flush afterwards with plenty of water

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Suitable materials	-	glass

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	-	2 - 8 °C
	-	protected from light
	-	do not freeze following reconstitution or dilution
Validity	-	2 to 8 °C, in the unopened original container, see "best use before" date stated on the label

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air	-	IOEL (Internal Occupational Exposure Limit): 0.1 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	
	-	breathing apparatus in case of aerosol mist formation	
Hand protection	-	protective gloves (eg made of neoprene, nitrile or butyl rubber)	
Eye protection	-	safety glasses	

1 referring to: Trastuzumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	white to slightly yellow	
Form	lyophilized powder	
pH value	5.4 to 6.6	*2

9.2. Other information

Note	-	no information available	

2 referring to: Herceptin Vials (2% Trastuzumab solution with excipients)

SECTION 10: Stability and reactivity

10.1. Reactivity

Note	-	no information available	

10.2. Chemical stability

Stability	-	does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution	*2
	-	do not dilute with glucose since there cause aggregation of the protein	*2
	-	do not freeze the reconstituted solution	*2

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	*2

2 referring to: Herceptin Vials (2% Trastuzumab solution with excipients)

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	-	MTD	> 94	mg/kg	(i.v., mouse)	*1
	-	MTD	> 47	mg/kg	(i.v., Rhesus monkey)	*1
	-	TD_{lo}	16'000	mg/kg	(oral, rat)	*3
	-	LD_{50}	> 15'000	mg/kg	(oral, rat)	*4
Local effects	-	no information available				
Sensitization	anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described *1					
Mutagenicity	-	no information available				
Carcinogenicity	-	no information available				
Reproductive toxicity	-	parenteral administration to pregnant women can cause fetal harm *1				
STOT-single exposure	-	no information available				
STOT-repeated exposure	-	no information available				
Aspiration hazard	-	no information available				
Note	-	infusions should not be administered through IV line containing dextrose solutions				
	-	Trastuzumab is a humanized monoclonal antibody that targets selectively the extracellular domain of the human epidermal growth factor receptor (HER2) *1				
	-	elimination half-life (after multiple dose): 1.7 to 32.8 days ***1**				

	- Herceptin administration (in therapeutic doses) can result in the development of ventricular dysfunction and congestive heart failure.	*5
	- side effect(s) during therapy: dyspnea, hypotension, tachycardia, bronchspasm, wheezing, reduced oxygen saturation	*5
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact	
	- Carcinogenicity: formulation not listed by NTP, IARC or OSHA	

1	referring to:	Trastuzumab
3	referring to:	Trehalose dihydrate
4	referring to:	L-Histidine
5	referring to:	Diluted Herceptin infusion solution (approx. 0.06% Trastuzumab)

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
	- readily biodegradable 65 % BOD/ThOD, 14 d (Manometric Respirometry Test, OECD No. 301 F)	*1
	- readily biodegradable 87 % BOD/ThOD, 14 d (Manometric Respirometry Test, OECD No. 301 F)	*6

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:	Trastuzumab
6	referring to:	Trastuzumab 2.4% solution with excipients

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues	- observe local/national regulations regarding waste disposal - drain very small quantities into wastewater treatment plant

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 (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 12

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.