Safety Data Sheet

HERCEPTIN(R) Vials (150 mg)

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

1.1. Product identifier

Product name	HERCEPTIN(R) Vials (150 mg)	
Product code	SAP-10046108	
Synonyms	- HERCEPTIN(R) Lyophilized Vials (150 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

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	51.3 %	
L-Histidine hydrochloride monohydrate 5934-29-2	1.2 %	
L-Histidine 71-00-1	0.7 %	
Trehalose dihydrate 6138-23-4	46.6 %	
Polysorbate 20 9005-64-5	0.2 %	

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 pale 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: 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 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 1, 3

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.