Safety Data Sheet

HERCEPTIN HYLECTA™ Vials (600 mg/5 ml) SC

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

1.1. Product identifier

Product name: HERCEPTIN HYLECTA™ Vials (600 mg/5 ml) SC

Product code: SAP-10112127

Synonyms:
- Herceptin Hylecta SC
- Herceptin Hylecta s.c. 120 mg/ml
- MAB<HER2>SC-rH-13-10-IgG

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	solution of Trastuzumab with exciepients for subcutaneous injection

Ingredients	Concentration	GHS-Classification (pure ingredient)
Trastuzumab 180288-69-1	12 %	
Hyaluronidase (rHuPH20) 757971-58-7	0.004 %	
Trehalose dihydrate 6138-23-4	8 %	

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	-	rinse with tap water for 20 minutes - open eyelids forcibly
Skin contact	-	drench affected skin with water
Inhalation	-	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	- mop or flush the contaminated area with 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 - do not freeze
Validity	- 18 months, 2 to 8 °C, after opening the content should be used within a short period, see expiry date on the label, in the unopened original container
Packaging materials	- vials - 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): 0.1 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
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	colorless to slightly yellow clear to opalescent
Form	liquid
pH value	5.5

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	-	does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution
	-	once transferred from the vial to the syringe, the product is physically and chemically stable at 2 to 8°C for 24 hours

10.3. Possibility of hazardous reactions

Note	-	no information available

10.4. Conditions to avoid

Conditions to avoid	-	warming
	-	light

10.5. Incompatible materials

Note	-	no information available

10.6. Hazardous decomposition products

Note	-	no information available

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
Local effects	assessment of local tolerance after a single subcutaneous application of 60 mg/injection site (0.5 mL/injection site) showed no findings that were attributable to treatment with the test item (rabbit)				
Sensitization	anaphylactic reactions may occur following the 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	- 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
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact				
	- Carcinogenicity: not listed by NTP, IARC or OSHA				

1 referring to: 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) *2

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
2 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 into sewer

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	- contains 2000 U/ml hyaluronidase; corresponds to 0.173 mg rHuPH20 (highest theoretical amount) - 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.