Safety Data Sheet

PERJETA(R) (420 mg)

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

1.1. Product identifier

Product name		PERJETA(R) (420 mg)
Product code		SAP-10113898
Synonyms	-	Pertuzumab intravenous infusion 30 mg/ml

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

Use	-	pharmaceutical active substance (antineoplastic)	*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: Pertuzumab

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 humanized monoclonal antibody	*1

Ingredients	**Concentration**
Pertuzumab CAS: 380610-27-5	3.00 %

*1 referring to: Pertuzumab

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 - 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	- Does not present a fire hazard

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	- absorb small spills with absorbent material - rinse 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 - do not freeze
Validity	- 2 to 8 °C, see expiry date on the label, after opening the content should be used within a short period
Packaging materials	- vials

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 not necessary during normal operations
Hand protection	- protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection	- safety glasses

*1 referring to: Pertuzumab

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color	colorless to brownish
Form	liquid
Density	1.03 g/ml (20 °C)

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

10.3. Possibility of hazardous reactions

Note	-	no information available

10.4. Conditions to avoid

Note	-	no information available

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	-	not bioavailable by oral administration			*1
Subacute toxicity	-	NOAEL	250	mg/kg/w (s.c., cynomolgus monkey, 4 weeks)	*1

Sensitization	-	anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described with other monoclonal antibodies *1
Subchronic toxicity	-	LD_{lo} 50 mg/kg/w (i.v., cynomolgus monkey; 26 weeks) *1
Potential Health Effects	-	Exposure: Inhalation, Ingestion, Skin contact, Eye contact
	-	Carcinogenicity: not listed by NTP, IARC or OSHA

*1 referring to: Pertuzumab

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

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

PBT/vPvB	-	substance does not meet the criteria for PBT or vPvB

12.6. Other adverse effects

Note	-	no information available

*1 referring to: Pertuzumab

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 9

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.