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

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

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

**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*
PERJETA(R) (420 mg)

**SECTION 9: Physical and chemical properties**

9.1. Information on basic physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>colorless to brownish</td>
</tr>
<tr>
<td>Form</td>
<td>liquid</td>
</tr>
<tr>
<td>Density</td>
<td>1.03 g/ml (20 °C)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>not bioavailable by oral administration *1</td>
</tr>
<tr>
<td>Subacute toxicity</td>
<td>NOAEL 250 mg/kg/w (s.c., cynomolgus monkey, 4 weeks) *1</td>
</tr>
</tbody>
</table>
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<br/>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.