1. Product and Company Identification

Product name: PERJETATM (420 mg)
Product code: SAP-10113898
Use: pharmaceutical active substance (antineoplastic)
Company information:
Enquiries:
Hoffmann-La Roche Inc.
340 Kingsland Street
USA-Nutley, N.J. 07110-1199
United States of America
Phone: 001-973/235 50 00
E-Mail: info.sds@roche.com
US Emergency phone: (800)-827-6243
US Chemtrec phone: (800)-424-9300
Synonyms: Pertuzumab intravenous infusion

2. Hazard identification

Emergency Overview
Form: liquid
Color: colorless to slightly yellow
Hazard Overview:
- May cause allergic reactions.
- May cause birth defects based on animal data.
Potential Health Effects:
- Exposure: Inhalation, Ingestion, Skin contact, Eye contact
- Target Organs: Immune System
- Acute Effects: May cause allergic reactions. This material is not likely to be significantly absorbed via occupational routes of entry due to its chemical structure and large molecular weight.
- Chronic Effects: No adverse effects known
- Carcinogenicity: not listed by NTP, IARC or OSHA
GHS Classification: no classification and labelling according to GHS
Additional Health Information:
- Reproductive Toxicity: May cause birth defects based on animal data. Since this material may affect the developing fetus, females planning to have a child and pregnant women should exercise caution regarding exposure.
- It is also advisable for nursing mothers to exercise caution regarding exposure.
3. Composition/Information on ingredients

Characterization: recombinant humanized monoclonal antibody *1

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pertuzumab</td>
<td>3.00 %</td>
</tr>
</tbody>
</table>

*1 Pertuzumab referring to: Pertuzumab

4. 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
- **Note to physician**: treat symptomatically

5. Fire-fighting measures

- **Suitable extinguishing media**: adapt extinguishing media to surrounding fire conditions
- **Flash point (liquid)**: not applicable
- **Protection of fire-fighters**: precipitate gases/vapours/mists with water spray

6. Accidental release measures

- **Methods for cleaning up**: absorb small spills with absorbent material - rinse with plenty of water

7. Handling and storage

**Storage**

- **Storage conditions**: 2 - 8 °C
- **Validity**: 36 months, 2 to 8 °C, see expiry date on the label, after opening the content should be used within a short period

8. Exposure controls/Personal protection

**Engineering Measures**: see 7.
**PERJETATM (420 mg)**

### Monitoring
- **Threshold value (Roche) air**
  - Category 1 (Roche Group Directive K1, Annex 3): IOEL >= 100 µg/m³

### Personal protective equipment
- **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 (e.g., made of neoprene, nitrile or butyl rubber)
- **Eye protection**
  - Safety glasses

*1 referring to: Pertuzumab

### 9. Physical and chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Colorless to slightly yellow</td>
</tr>
<tr>
<td>Form</td>
<td>Liquid</td>
</tr>
</tbody>
</table>

### 10. Stability and reactivity
- **Stability**
  - Does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution

### 11. Toxicological information

<table>
<thead>
<tr>
<th>Toxicity Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Not bioavailable by oral administration</td>
</tr>
<tr>
<td>Subacute toxicity</td>
<td>NOAEL 250 mg/kg/w (s.c., cynomolgus monkey, 4 weeks)</td>
</tr>
<tr>
<td>Sensitization</td>
<td>Anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described with other monoclonal antibodies</td>
</tr>
<tr>
<td>Subchronic toxicity</td>
<td>LD₅₀ 50 mg/kg/w (i.v., cynomolgus monkey; 26 weeks)</td>
</tr>
</tbody>
</table>

*1 referring to: Pertuzumab

### 12. Ecological information
- **Ready biodegradability**
  - Globular proteins are generally well biodegradable

*1 referring to: Pertuzumab
**Ecotoxicity**

- monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected

*1 referring to: Pertuzumab

**13. Disposal considerations**

- Waste from residues: observe local/national regulations regarding waste disposal

**14. Transport information**

- Note: not classified by transport regulations, proper shipping name non-regulated

**15. Regulatory information**

- 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.

**16. Other information**


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.