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

1.1. Product identifier

Product name: TECENTRIQ® Vials (1,200 mg/20 ml)
Product code: SAP-10154949
Synonyms:
- Atezolizumab Drug Product
- TECENTRIQ(R) (1,200 mg/20 ml)
- MPDL3280A

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

Use:
- pharmaceutical active substance (antineoplastic)

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: Atezolizumab

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

Date: 7.7.17/LS (SEISMO)  Replacing edition of: 14.6.16  Page: 1/7
SECTION 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Ingredients</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atezolizumab</td>
<td>5.43 %</td>
<td></td>
</tr>
<tr>
<td>L-Histidine</td>
<td>0.28 %</td>
<td></td>
</tr>
<tr>
<td>Sucrose</td>
<td>3.72 %</td>
<td></td>
</tr>
<tr>
<td>Polysorbate 20</td>
<td>0.04 %</td>
<td></td>
</tr>
</tbody>
</table>

*1 referring to: Atezolizumab

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 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
- water spray jet, dry powder, foam, carbon dioxide
- adapt extinguishing media to surrounding fire conditions

Flash point (liquid)
> 110 °C

*2
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

*2 referring to: Polysorbate 20

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 liquids by means of sand, earth or another suitable material
- rinse with plenty of water

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - no special measures necessary if stored and handled as prescribed

Suitable materials - glass, enamel, stainless steel

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C
- protected from heat and light
- do not shake solution

Validity - in the unopened original container, after opening the content should be used within a short period, see expiry date on the label

Packaging materials - vials
## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

**Threshold value (Roche) air**

- **IOEL (Internal Occupational Exposure Limit):** 0.220 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 (e.g., made of neoprene, nitrile or butyl rubber)

**Eye protection**

- Safety glasses

*1 referring to: Atezolizumab

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

- **Color:** colorless to slightly yellow
- **Form:** sterile liquid
- **Solubility:**
  - 38.2 g/l, water (20 °C)
  - 100 g/l, water

*2 referring to: Polysorbate 20

*3 referring to: L-Histidine

- **Partition coefficient:** log P<sub>ow</sub> -3.32 (octanol/water)
- **pH value:** 5.8

### 9.2. Other information

**Note**

- No information available

*2 referring to: Polysorbate 20

*3 referring to: L-Histidine

## 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
- \(\text{LD}_{50} > 15'000\) mg/kg (oral, rat) \(^*1\)
- \(\text{LD}_{50} > 32'850\) mg/kg (oral, rat) \(^*2\)
- \(\text{LD}_{50} 29'700\) mg/kg (oral, rat) \(^*3\)

Local effects
- skin: non-irritant (rabbit; OECD No. 404) \(^*2\)

Sensitization
- anaphylactic reactions may occur following the intravenous application of proteins; after inhalative exposure no cases of hypersensitivity have been described \(^*1\)

Mutagenicity
- negative, both with and without metabolic activation (OECD No. 476 (Mammalian Cell Gene Mutation Test)) \(^*2\)

Carcinogenicity
- no information available

Reproductive toxicity
- critical exposure in human after parenteral administration only
- 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
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
- readily biodegradable
  60.3 %, 28 d
  (Manometric Respirometry Test, OECD No. 301 F)

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: Atezolizumab
*2 referring to: Polysorbate 20
*3 referring to: L-Histidine
*4 referring to: Sucrose

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
- none

Edition documentation
- changes from previous version in sections 8

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.