# Safety Data Sheet  
**TECENTRIQ® Vials (840 mg/14 ml)**

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

### 1.1. Product identifier

<table>
<thead>
<tr>
<th>Product name</th>
<th>TECENTRIQ® Vials (840 mg/14 ml)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product code</td>
<td>SAP-10166870</td>
</tr>
<tr>
<td>Synonyms</td>
<td>- Atezolizumab Drug Product</td>
</tr>
<tr>
<td></td>
<td>- TECENTRIQ(R) (840 mg/14 ml)</td>
</tr>
<tr>
<td></td>
<td>- MPDL3280A *1</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Company information</th>
<th>Enquiries: Genentech, Inc. 1 DNA Way South San Francisco USA-CA 94080 United States of America</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Local representation: Phone 001-(650) 225-1000 E-Mail <a href="mailto:info.sds@roche.com">info.sds@roche.com</a> US Chemtrec phone: (800)-424-9300</td>
</tr>
</tbody>
</table>

### 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 |
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 1380723-44-3</td>
<td>5.43 %</td>
<td></td>
</tr>
<tr>
<td>L-Histidine 71-00-1</td>
<td>0.28 %</td>
<td></td>
</tr>
<tr>
<td>Sucrose 57-50-1</td>
<td>3.72 %</td>
<td></td>
</tr>
<tr>
<td>Polysorbate 20 9005-64-5</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

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 (eg 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

Partition coefficient - log P₀w -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

<table>
<thead>
<tr>
<th>Effect</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>not bioavailable by oral administration *1</td>
</tr>
<tr>
<td></td>
<td>LD₅₀ &gt; 15'000 mg/kg (oral, rat) *3</td>
</tr>
<tr>
<td></td>
<td>LD₅₀ &gt; 32'850 mg/kg (oral, rat) (OECD No. 401) *2</td>
</tr>
<tr>
<td></td>
<td>LD₅₀ 29'700 mg/kg (oral, rat) *4</td>
</tr>
<tr>
<td>Local effects</td>
<td>skin: non-irritant (rabbit; OECD No. 404) *2</td>
</tr>
<tr>
<td>Sensitization</td>
<td>anaphylactic reactions may occur following the intravenous application of proteins; after inhalative exposure no cases of hypersensitivity have been described *1</td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>negative, both with and without metabolic activation (OECD No. 476 (Mammalian Cell Gene Mutation Test)) *2</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>no information available</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>critical exposure in human after parenteral administration only</td>
</tr>
<tr>
<td></td>
<td>parenteral administration to pregnant women can cause fetal harm *1</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>no information available</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>no information available</td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>no information available</td>
</tr>
</tbody>
</table>

Date: 18.7.17/LS (SEISMO)  Replacing edition of: --  Page: 5/7
Note - therapeutic dose (i.v.): 15 mg/kg/3

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

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
- readily biodegradable
  60.3 %, 28 d
  (Manometric Respirometry Test, OECD No. 301 F)

*1 *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: Atezolizumab
*2 referring to: Polysorbate 20

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

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### 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
- 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**
- first edition

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.