SAFETY DATA SHEET

TECENTRIQ® Vials (840 mg/14 ml)

SECTION 1. IDENTIFICATION

Product name : TECENTRIQ® Vials (840 mg/14 ml)
Product code : RO554-1267/F05

Manufacturer or supplier’s details
Company name of supplier : Genentech, Inc.
Address : 1 DNA Way
South San Francisco, CA 94080
USA
Telephone : 001-(650) 225-1000
E-mail address : info.sds@roche.com
Emergency telephone number : US Chemtrec phone (800)-424-9300

Recommended use of the chemical and restrictions on use
Recommended use : Formulated pharmaceutical active substance
Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)
Not a hazardous substance or mixture.

GHS label elements
Not a hazardous substance or mixture.

Other hazards
None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atezolizumab</td>
<td>1380723-44-3</td>
<td>6.0</td>
</tr>
<tr>
<td>.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl</td>
<td>57-50-1</td>
<td>4.11</td>
</tr>
<tr>
<td>L-Histidine</td>
<td>71-00-1</td>
<td>0.31</td>
</tr>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>0.08</td>
</tr>
<tr>
<td>Sorbitan, monododecanoate, poly(oxy-1,2-ethanediyl) derivs.</td>
<td>9005-64-5</td>
<td>0.04</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>&gt; 89.0</td>
</tr>
</tbody>
</table>
SECTION 4. FIRST AID MEASURES

General advice: Do not leave the victim unattended.

If inhaled:
- Move to fresh air.
- If unconscious, place in recovery position and seek medical advice.
- If symptoms persist, call a physician.

In case of skin contact:
- If on skin, rinse well with water.

In case of eye contact:
- Immediately flush eye(s) with plenty of water.
- Remove contact lenses.
- Protect unharmed eye.
- If eye irritation persists, consult a specialist.

If swallowed:
- Keep respiratory tract clear.
- Do not give milk or alcoholic beverages.
- Never give anything by mouth to an unconscious person.
- If symptoms persist, call a physician.
- Rinse mouth with water.

Most important symptoms and effects, both acute and delayed:
- None known.

Notes to physician:
- The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media:
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Specific hazards during firefighting:
- No information available.

Hazardous combustion products:
- In case of fire hazardous decomposition products may be produced such as:
  - Carbon monoxide
  - Nitrogen oxides (NOx)

Further information:
- Standard procedure for chemical fires.
- Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special protective equipment for fire-fighters:
- Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment:
- Refer to protective measures listed in sections 7 and 8.
Environmental precautions: Local authorities should be advised if significant spillages cannot be contained.

Methods and materials for containment and cleaning up: Wipe up with absorbent material (e.g. cloth, fleece). Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion: Normal measures for preventive fire protection.

Advice on safe handling: For personal protection see section 8. Smoking, eating and drinking should be prohibited in the application area.

Conditions for safe storage: Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions: See label, package insert or internal guidelines

Materials to avoid: No materials to be especially mentioned.

Storage temperature: Protected from heat and light.

Further information on storage stability: No decomposition if stored and applied as directed.

Packaging material: Suitable material: Stainless steel, glass, Vials

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Ingredients with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Atezolizumab</td>
<td>1380723-44-3</td>
<td>IOEL</td>
<td>0.220 mg/m³</td>
<td>Roche Industrial Hygiene Committee (RIHC)</td>
</tr>
<tr>
<td>.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl</td>
<td>57-50-1</td>
<td>TWA</td>
<td>10 mg/m³</td>
<td>ACGIH</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (Respirable)</td>
<td>5 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total)</td>
<td>10 mg/m³</td>
<td>NIOSH REL</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (total dust)</td>
<td>15 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>TWA (respirable)</td>
<td>5 mg/m³</td>
<td>OSHA Z-1</td>
</tr>
</tbody>
</table>
SAFETY DATA SHEET

TECENTRIQ® Vials (840 mg/14 ml)

<table>
<thead>
<tr>
<th>Engineering measures</th>
<th>No data available</th>
</tr>
</thead>
</table>

**Personal protective equipment**

**Respiratory protection**: No personal respiratory protective equipment normally required.

**Hand protection**: In case of contact through splashing:
- **Material**: Nitrile rubber
- **Break through time**: > 30 min
- **Glove thickness**: > 0.11 mm

In case of full contact:
- **Material**: butyl-rubber
- **Break through time**: > 480 min
- **Glove thickness**: > 0.4 mm

**Remarks**: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.

**Eye protection**: Safety glasses

**Skin and body protection**: Protective suit

**Hygiene measures**: Handle in accordance with good industrial hygiene and safety practice.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

**Appearance**: Aqueous solution, Clear liquid, Sterile liquid

**Color**: colorless, light yellow

**Odor**: No data available

**Odor Threshold**: No data available

**pH**: 5.8

**Melting point/range**: No data available

**Boiling point/boiling range**: No data available

**Evaporation rate**: No data available
Self-ignition: Not applicable

Upper explosion limit / Upper flammability limit: No data available

Lower explosion limit / Lower flammability limit: No data available

Vapor pressure: No data available

Relative vapor density: No data available

Relative density: No data available

Density: 1.1 g/cm³ (68 °F / 20 °C)

Solubility(ies)
  Water solubility: completely miscible
  Solubility in other solvents: No data available

Partition coefficient: n-octanol/water: No data available

Autoignition temperature: No data available

Decomposition temperature: No data available

Viscosity
  Viscosity, dynamic: No data available
  Viscosity, kinematic: No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity: No dangerous reaction known under conditions of normal use.

Chemical stability: Stable under normal conditions.

Proteins are temperature-sensitive; the thermal denaturation has an impact on quality but does not affect Plant and Process Safety; during decomposition no flammable gas, no organic peroxide and no oxidising substances are created. Does not contain any antimicrobial preservative; therefore, care must be taken to ensure the sterility of the prepared solution.

Possibility of hazardous reactions: Stable under recommended storage conditions. No hazards to be specially mentioned.

Conditions to avoid: No data available

Incompatible materials: No data available
SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity
Not classified based on available information.

Components:
Atezolizumab:
Acute oral toxicity : Remarks: Not bioavailable by oral administration

-alpha.-D-Glucopyranoside, -beta.-D-fructofuranosyl:
Acute oral toxicity : LD50 Oral (Rat): 29,700 mg/kg

Skin corrosion/irritation
Not classified based on available information.

Serious eye damage/eye irritation
Not classified based on available information.

Respiratory or skin sensitization

Skin sensitization
Not classified based on available information.

Respiratory sensitization
Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Components:
-alpha.-D-Glucopyranoside, -beta.-D-fructofuranosyl:
Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
                      : Result: negative

Carcinogenicity
Not classified based on available information.

Components:
-alpha.-D-Glucopyranoside, -beta.-D-fructofuranosyl:
Remarks : No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

IARC
No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA
No component of this product present at levels greater than or equal to 0.1% is on OSHA’s list of regulated carcinogens.
NTP No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

Reproductive toxicity
Not classified based on available information.

Components:
Atezolizumab:
Effects on fetal development : Species: Humans
Result: Critical exposure in human after parenteral administration only

Species: Humans
Result: Parenteral administration to pregnant women can cause fetal harm

STOT-single exposure
Not classified based on available information.

Components:
.alpha.-D-Glucopyranoside, beta.-D-fructofuranosyl:
Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure
Not classified based on available information.

Components:
.alpha.-D-Glucopyranoside, beta.-D-fructofuranosyl:
Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration toxicity
Not classified based on available information.

Components:
.alpha.-D-Glucopyranoside, beta.-D-fructofuranosyl:
No data available

Further information

Components:
Atezolizumab:
Remarks : Globular proteins are generally well biodegradable

.alpha.-D-Glucopyranoside, beta.-D-fructofuranosyl:
Remarks : Health injuries are not known or expected under normal use.
SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.
Chronic aquatic toxicity : This product has no known ecotoxicological effects.
Toxicity Data on Soil : Not expected to adsorb on soil.
Other organisms relevant to the environment : No data available

Persistence and degradability

Components:

Atezolizumab:
Biodegradability : Result: Globular proteins are generally well biodegradable

Bioaccumulative potential

Components:

Atezolizumab:
Partition coefficient: n-octanol/water : Remarks: No data available

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:
Partition coefficient: n-octanol/water : log Pow: -3.7 (68 °F / 20 °C)

Mobility in soil
No data available

Other adverse effects

Product:
Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:
Atezolizumab:
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Version 1.2
Revision Date: 11-07-2022
Date of last issue: 01-28-2020
Date of first issue: 06-10-2017

Additional ecological information:
Monoclonal antibodies are proteins with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected.

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods
Waste from residues: Can be disposed as waste water, when in compliance with local regulations.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations
UNRTDG
Not regulated as a dangerous good
IATA-DGR
Not regulated as a dangerous good
IMDG-Code
Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

Domestic regulation
49 CFR
Not regulated as a dangerous good

Special precautions for user
Remarks: Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION

CERCLA Reportable Quantity
Listed substances in the product are at low enough levels to not be expected to exceed the RQ

SARA 304 Extremely Hazardous Substances Reportable Quantity
This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity
This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards: No SARA Hazards
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Version: 1.2
Revision Date: 11-07-2022
Date of last issue: 01-28-2020
Date of first issue: 06-10-2017

SARA 313: This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act
This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act
The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS Number</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>&gt;= 0 - &lt; 0.1 %</td>
</tr>
</tbody>
</table>

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS Number</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acetic acid</td>
<td>64-19-7</td>
<td>&gt;= 0 - &lt; 0.1 %</td>
</tr>
</tbody>
</table>

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307
This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations

Massachusetts Right To Know
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

Pennsylvania Right To Know
Water 7732-18-5
Atezolizumab 1380723-44-3
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1
Acetic acid 64-19-7

Maine Chemicals of High Concern
Product does not contain any listed chemicals

Vermont Chemicals of High Concern
Product does not contain any listed chemicals

Washington Chemicals of High Concern
Product does not contain any listed chemicals

California Permissible Exposure Limits for Chemical Contaminants
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

The ingredients of this product are reported in the following inventories:

AIIC: Not in compliance with the inventory

DSL: This product contains the following components that are not on the Canadian DSL nor NDSL.

Atezolizumab

NZIoC: On the inventory, or in compliance with the inventory
ENCS : Not in compliance with the inventory
ISHL : Not in compliance with the inventory
KECI : Not in compliance with the inventory
PICCS : Not in compliance with the inventory
IECSC : Not in compliance with the inventory
TCSI : Not in compliance with the inventory
TSCA : Product contains substance(s) not listed on TSCA inventory.
TECI : Not in compliance with the inventory

**TSCA list**
No substances are subject to a Significant New Use Rule.
No substances are subject to TSCA 12(b) export notification requirements.

**SECTION 16. OTHER INFORMATION**

**NFPA 704:**

**HMIS® IV:**

<table>
<thead>
<tr>
<th>HEALTH</th>
<th>/</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>FLAMMABILITY</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>PHYSICAL HAZARD</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

- **ACGIH** : USA. ACGIH Threshold Limit Values (TLV)
- **NIOSH REL** : USA. NIOSH Recommended Exposure Limits
- **OSHA P0** : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
- **OSHA Z-1** : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- **ACGIH / TWA** : 8-hour, time-weighted average
The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.