

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

Product name	TECENTRIQ® Vials (840 mg/14 ml)	
Product code	SAP-10166870	
Synonyms	- Atezolizumab Drug Product - TECENTRIQ(R) (840 mg/14 ml) - MPDL3280A	*1

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

Use	- pharmaceutical active substance (antineoplastic)	*1
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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	Local representation:
	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
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*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
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Other hazards

Note	- no information available
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SECTION 3: Composition/information on ingredients

Ingredients	Concentration	GHS-Classification (pure ingredient)
Atezolizumab 1380723-44-3	5.43 %	
L-Histidine 71-00-1	0.28 %	
Sucrose 57-50-1	3.72 %	
Polysorbate 20 9005-64-5	0.04 %	
*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
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4.3. Indication of any immediate medical attention and special treatment needed

Note to physician	- treat symptomatically
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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

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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 *1

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) *3
100 g/l, water *2

Partition coefficient log P_{ow} -3.32 (octanol/water) *3

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

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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	*1
	- LD ₅₀ > 15'000 mg/kg (oral, rat)	*3
	- LD ₅₀ > 32'850 mg/kg (oral, rat) (OECD No. 401)	*2
	- LD ₅₀ 29'700 mg/kg (oral, rat)	*4
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	

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Note - therapeutic dose (i.v.): 15 mg/kg/3w *1

*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 *1
- readily biodegradable
60.3 %, 28 d
(Manometric Respirometry Test, OECD No. 301 F) *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

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.