



# SAFETY DATA SHEET

Revision date: 26-Jan-2018

Version: 2.0

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## 1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND THE COMPANY/UNDERTAKING

### Product Identifier

**Material Name:** Avelumab Injection

**Trade Name:** BAVENCIO  
**Synonyms:** Anti PD-L1; aPD-L1; Avelumab  
**Chemical Family:** Monoclonal antibody

**Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Intended Use:** Pharmaceutical product

### Details of the Supplier of the Safety Data Sheet

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## 2. HAZARDS IDENTIFICATION

### Classification of the Substance or Mixture

**GHS - Classification** Not classified as hazardous

### Label Elements

**Hazard Statements:** Not classified in accordance with international standards for workplace safety.

### Other Hazards

An Occupational Exposure Value has been established for one or more of the ingredients (see Section 8).

### Note:

This document has been prepared in accordance with standards for workplace safety, which requires the inclusion of all known hazards of the product or its ingredients regardless of the potential risk. The precautionary statements and warning included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

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**Additional Information:** This substance is a human monoclonal antibody produced by recombinant DNA and cell culture technology. There are no known hazards associated with this substance and it is not suspected of any microbial contamination, however, no formal testing for the absence of such contaminants has been performed. As with any protein, the possibility of allergic reactions exists.

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### Hazardous

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
ACETIC ACID	64-19-7	200-580-7	Skin Corr. 1A (H314) Flam. Liq. 3 (H226)	<1
Sucrose	57-50-1	200-334-9	Not Listed	*
Avelumab	1537032-82-8	Not Listed	Not Listed	10-20

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Sodium acetate trihydrate	6131-90-4	Not Listed	Not Listed	*
Polysorbate 20	9005-64-5	Not Listed	Not Listed	*
Water	7732-18-5	231-791-2	Not Listed	*

**Additional Information:** \* Proprietary  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

### 4. FIRST AID MEASURES

#### Description of First Aid Measures

- Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.
- Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
- Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately. It is considered unlikely that, if swallowed, significant amounts of this material would be absorbed into the blood circulation.
- Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

#### Most Important Symptoms and Effects, Both Acute and Delayed

- Symptoms and Effects of Exposure:** No data available
- Medical Conditions Aggravated by Exposure:** None known

#### Indication of the Immediate Medical Attention and Special Treatment Needed

- Notes to Physician:** None

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### 5. FIRE FIGHTING MEASURES

**Extinguishing Media:** Extinguish fires with CO2, extinguishing powder, foam, or water.

**Special Hazards Arising from the Substance or Mixture**

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire / Explosion Hazards:** Fine particles (such as mists) may fuel fires/explosions.

**Advice for Fire-Fighters**

During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions, Protective Equipment and Emergency Procedures**

Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Environmental Precautions**

Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Methods and Material for Containment and Cleaning Up**

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Follow Biosafety Level 1 and Good Laboratory Practices.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Cleanup operations should only be undertaken by trained personnel.

### 7. HANDLING AND STORAGE

**Precautions for Safe Handling**

Restrict access to work area. Avoid open handling. Minimize generating airborne mists and vapors. A change area to facilitate 'good laboratory/manufacturing' decontamination practices is recommended. Avoid inhalation and contact with skin, eye, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Conditions for Safe Storage, Including any Incompatibilities**

**Storage Conditions:** Store as directed by product packaging.

**Specific end use(s):** Pharmaceutical drug product

### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Control Parameters**

Refer to available public information for specific member state Occupational Exposure Limits.

**ACETIC ACID**

ACGIH Threshold Limit Value (TWA)	10 ppm
ACGIH Threshold Limit Value (STEL)	15 ppm
Australia STEL	15 ppm
	37 mg/m <sup>3</sup>
Australia TWA	10 ppm
	25 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Austria OEL - MAKs	10 ppm 25 mg/m <sup>3</sup>
Belgium OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Bulgaria OEL - TWA	25.0 mg/m <sup>3</sup>
Cyprus OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Czech Republic OEL - TWA	25 mg/m <sup>3</sup>
Denmark OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Estonia OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Finland OEL - TWA	5 ppm 13 mg/m <sup>3</sup>
Germany - TRGS 900 - TWAs	10 ppm 25 mg/m <sup>3</sup>
Germany (DFG) - MAK	10 ppm 25 mg/m <sup>3</sup>
Greece OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Hungary OEL - TWA	25 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 ppm 25 mg/m <sup>3</sup>
Latvia OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Luxembourg OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Malta OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Netherlands OEL - TWA	25 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	10 ppm 25 mg/m <sup>3</sup>
Poland OEL - TWA	25 mg/m <sup>3</sup>
Portugal OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Romania OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Slovakia OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Slovenia OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Spain OEL - TWA	10 ppm 25 mg/m <sup>3</sup>
Sweden OEL - TWAs	5 ppm 13 mg/m <sup>3</sup>
Switzerland OEL - TWAs	10 ppm 25 mg/m <sup>3</sup>
Vietnam OEL - TWAs	25 mg/m <sup>3</sup>
<b>Sucrose</b>	
ACGIH Threshold Limit Value (TWA)	10 mg/m <sup>3</sup>
Australia TWA	10 mg/m <sup>3</sup>

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### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Belgium OEL - TWA	10 mg/m <sup>3</sup>
Bulgaria OEL - TWA	10.0 mg/m <sup>3</sup>
Estonia OEL - TWA	10 mg/m <sup>3</sup>
France OEL - TWA	10 mg/m <sup>3</sup>
Ireland OEL - TWAs	10 mg/m <sup>3</sup>
Latvia OEL - TWA	5 mg/m <sup>3</sup>
Lithuania OEL - TWA	10 mg/m <sup>3</sup>
OSHA - Final PELs - TWAs:	15 mg/m <sup>3</sup>
Portugal OEL - TWA	10 mg/m <sup>3</sup>
Slovakia OEL - TWA	6 mg/m <sup>3</sup>
Spain OEL - TWA	10 mg/m <sup>3</sup>

The Biotherapeutic Occupational Exposure Band (B-OEB) is an acceptable daily intake (ADI) range, based on available hazard data with appropriate safety factors applied. Engineering control measures should be utilized to bring exposures into the relevant B-OEB; supplementary administrative controls and personal protective equipment are to be used to achieve exposure control to the bottom of the band.

#### Avelumab

**Pfizer Occupational Exposure Band (OEB):** B-OEB Default (control exposure to the range of 10 µg/day to <100 µg/day)

#### Exposure Controls

##### Engineering Controls:

Engineering controls should be used as the primary means to control exposures. It is recommended that all large scale operations should be fully enclosed. Air recirculation is not recommended.

##### Personal Protective Equipment:

Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

##### Hands:

Wear impervious disposable gloves (e.g. Nitrile, etc.) as minimum protection (double recommended). (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

##### Eyes:

Wear safety glasses as minimum protection (goggles recommended). (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

##### Skin:

Wear impervious disposable protective clothing when handling this compound. Full body protection is recommended (scale dependent). (Protective clothing must meet the standards in accordance with EN13982, ANSI 103 or international equivalent.)

##### Respiratory protection:

Under normal conditions of use, if the applicable Biotherapeutic Occupational Exposure Band (B-OEB) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the B-OEB (e.g. particulate respirator with a full mask, P3 filter). (Respirators must meet the standards in accordance with EN136, EN143, ASTM F2704-10 or international equivalent.)

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical State:</b>	Liquid	<b>Color:</b>	Clear to light brown
<b>Odor:</b>	No data available.	<b>Odor Threshold:</b>	No data available.
<b>Molecular Formula:</b>	Mixture	<b>Molecular Weight:</b>	150 kDa
<b>Solvent Solubility:</b>	No data available		
<b>Water Solubility:</b>	No data available		
<b>pH:</b>	No data available.		

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

**Melting/Freezing Point (°C):** No data available  
**Boiling Point (°C):** No data available.  
**Partition Coefficient: (Method, pH, Endpoint, Value)**  
**Polysorbate 20**  
No data available  
**Sodium acetate trihydrate**  
No data available  
**Water**  
No data available  
**ACETIC ACID**  
No data available  
**Avelumab**  
No data available  
**Sucrose**  
No data available  
**Decomposition Temperature (°C):** No data available.  
  
**Evaporation Rate (Gram/s):** No data available  
**Vapor Pressure (kPa):** No data available  
**Vapor Density (g/ml):** No data available  
**Relative Density:** No data available  
**Viscosity:** No data available

#### Flammability:

<b>Autoignition Temperature (Solid) (°C):</b>	No data available
<b>Flammability (Solids):</b>	No data available
<b>Flash Point (Liquid) (°C):</b>	No data available
<b>Upper Explosive Limits (Liquid) (% by Vol.):</b>	No data available
<b>Lower Explosive Limits (Liquid) (% by Vol.):</b>	No data available

### 10. STABILITY AND REACTIVITY

**Reactivity:** No data available  
**Chemical Stability:** Stable under normal conditions of use.  
**Possibility of Hazardous Reactions**  
**Oxidizing Properties:** No data available  
**Conditions to Avoid:** Fine particles (such as mists) may fuel fires/explosions. As a precautionary measure, keep away from heat sources and electrostatic discharge.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers  
**Hazardous Decomposition Products:** No data available

### 11. TOXICOLOGICAL INFORMATION

#### Information on Toxicological Effects

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.  
**Known Clinical Effects:** Common adverse effects include nausea, diarrhea, muscle pain, fatigue, loss of appetite (anorexia), swelling, skin rash.

#### Acute Toxicity: (Species, Route, End Point, Dose)

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### 11. TOXICOLOGICAL INFORMATION

#### ACETIC ACID

Mouse Sub-tenon injection (eye) LC 50 5620 ppm/1H  
Rat Oral LD 50 3310mg/kg  
Rabbit Dermal LD 50 1060uL/kg

#### Sucrose

Rat Oral LD 50 29,700 mg/kg

**Irritation / Sensitization Comments:** **Eye Irritation:** Not determined, however, based on the composition may cause irritation.  
**Skin Irritation:** Not determined, however, based on the composition, may be harmful, may cause irritation and may be a potential allergen.  
**Skin Sensitization:** Not determined, however, based on the characteristics of this substance may have the potential to be a skin sensitizer.

#### Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

##### Avelumab

1 Month(s)	Monkey	Intravenous	140 mg/kg/week	NOAEL	None identified
3 Month(s)	Monkey	Intravenous	140 mg/kg/week	NOAEL	None identified

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.

### 12. ECOLOGICAL INFORMATION

**Environmental Overview:** Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

#### Toxicity:

##### Aquatic Toxicity: (Species, Method, End Point, Duration, Result)

#### ACETIC ACID

Fathead Minnow	NPDES	LC-50	96 Hours	88 mg/L
Bluegill Sunfish	NPDES	LC-50	96 Hours	75 mg/L
Goldfish	NPDES	LC-50	24 Hours	423 mg/L

**Persistence and Degradability:** No data available

**Bio-accumulative Potential:** No data available

**Mobility in Soil:** No data available

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### 13. DISPOSAL CONSIDERATIONS

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### 14. TRANSPORT INFORMATION

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

### 15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

#### ACETIC ACID

CERCLA/SARA 313 Emission reporting	Not Listed
CERCLA/SARA Hazardous Substances and their Reportable Quantities:	5000 lb 2270 kg
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 2 Schedule 5 Schedule 6
EU EINECS/ELINCS List	200-580-7

#### Sodium acetate trihydrate

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed

#### Polysorbate 20

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS/ELINCS List	Not Listed



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### 15. REGULATORY INFORMATION

#### Sucrose

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	200-334-9

#### Water

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
REACH - Annex IV - Exemptions from the obligations of Register:	Present
EU EINECS/ELINCS List	231-791-2

#### Avelumab

CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

### 16. OTHER INFORMATION

#### Text of CLP/GHS Classification abbreviations mentioned in Section 3

Skin corrosion/irritation-Cat.1A; H314 - Causes severe skin burns and eye damage  
Flammable liquids-Cat.3; H226 - Flammable liquid and vapor

**Data Sources:** Pfizer proprietary drug development information. Publicly available toxicity information.

**Reasons for Revision:** Updated Section 1 - Identification of the Substance/Preparation and the Company/Undertaking. Updated Section 2 - Hazard Identification. Updated Section 3 - Composition / Information on Ingredients. Updated Section 8 - Exposure Controls / Personal Protection. Updated Section 11 - Toxicology Information.

**Revision date:** 26-Jan-2018

**Prepared by:** Product Stewardship Hazard Communication  
Pfizer Global Environment, Health, and Safety Operations

Pfizer Inc believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

**End of Safety Data Sheet**