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

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.
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

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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<tbody>
<tr>
<td>ACETIC ACID</td>
<td>64-19-7</td>
<td>200-580-7</td>
<td>Skin Corr. 1A (H314) Flam. Liq. 3 (H226)</td>
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<td>Sucrose</td>
<td>57-50-1</td>
<td>200-334-9</td>
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<td>Avelumab</td>
<td>1537032-82-8</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>10-20</td>
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<tr>
<th>Ingredient</th>
<th>CAS Number</th>
<th>EU EINECS/ELINCS List</th>
<th>GHS Classification</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Sodium acetate trihydrate</td>
<td>6131-90-4</td>
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<td>Not Listed</td>
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<tr>
<td>Polysorbate 20</td>
<td>9005-64-5</td>
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<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>231-791-2</td>
<td>Not Listed</td>
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</tr>
</tbody>
</table>

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
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/m³
Australia TWA 10 ppm
            25 mg/m³

PZ02981
### 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Country</th>
<th>OEL/TWA</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria OEL - MAKs</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Belgium OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Bulgaria OEL - TWA</td>
<td>25.0 mg/m³</td>
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</tr>
<tr>
<td>Cyprus OEL - TWA</td>
<td>10 ppm</td>
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</tr>
<tr>
<td>Czech Republic OEL - TWA</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Denmark OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Estonia OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Finland OEL - TWA</td>
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<td>13 mg/m³</td>
</tr>
<tr>
<td>Germany - TRGS 900 - TWAs</td>
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</tr>
<tr>
<td>Germany (DFG) - MAK</td>
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</tr>
<tr>
<td>Greece OEL - TWA</td>
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<td>25 mg/m³</td>
</tr>
<tr>
<td>Hungary OEL - TWA</td>
<td>25 mg/m³</td>
<td></td>
</tr>
<tr>
<td>Ireland OEL - TWAs</td>
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<td>25 mg/m³</td>
</tr>
<tr>
<td>Latvia OEL - TWA</td>
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<td>25 mg/m³</td>
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<td>Netherlands OEL - TWA</td>
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<td>Poland OEL - TWA</td>
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</tr>
<tr>
<td>Portugal OEL - TWA</td>
<td>10 ppm</td>
<td>25 mg/m³</td>
</tr>
<tr>
<td>Romania OEL - TWA</td>
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<td>Slovakia OEL - TWA</td>
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<td>Spain OEL - TWA</td>
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<td>Switzerland OEL - TWAs</td>
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<td>25 mg/m³</td>
</tr>
<tr>
<td>Vietnam OEL - TWAs</td>
<td>25 mg/m³</td>
<td></td>
</tr>
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</table>

### Sucrose

<table>
<thead>
<tr>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACGIH Threshold Limit Value (TWA)</td>
</tr>
<tr>
<td>Australia TWA</td>
</tr>
</tbody>
</table>
8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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 EN110, EN143, ASTM F2704-10 or international equivalent.)

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State: Liquid
Odor: No data available.
Molecular Formula: Mixture
Solvent Solubility: No data available
Water Solubility: No data available
pH: No data available
Color: Clear to light brown
Odor Threshold: No data available
Molecular Weight: 150 kDa
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:
  Autoignition Temperature (Solid) (°C): No data available
  Flammability (Solids): No data available
  Flash Point (Liquid) (°C): No data available
  Upper Explosive Limits (Liquid) (% by Vol.): No data available
  Lower Explosive Limits (Liquid) (% by Vol.): 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)
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
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

Not Listed

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

Sodium acetate trihydrate

Not Listed

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

Polysorbate 20

Not Listed

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

Sucrose

<table>
<thead>
<tr>
<th>Compliance</th>
<th>Status</th>
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<tbody>
<tr>
<td>CERCLA/SARA 313 Emission reporting</td>
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<td>California Proposition 65</td>
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Water

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</table>

Avelumab

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</tr>
</tbody>
</table>

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 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