

# SAFETY DATA SHEET

according to the OSHA Hazard Communication Standard



## BAVENCIO® (avelumab) 200 mg (20 mg/mL)

Version	Revision Date:	SDS Number:	Date of last issue: 11/13/2023
2.1	04/11/2024	90MDGM353351	Date of first issue: 01/30/2023

### SECTION 1. IDENTIFICATION

Product name : BAVENCIO® (avelumab) 200 mg (20 mg/mL)

#### Manufacturer or supplier's details

Company : EMD Serono, Inc.  
One Technology Place  
MA-02370 Rockland  
United States of America

Responsible Department : e-mail: HealthcareSDS@emdgroup.com

Emergency telephone number : 800-424-9300 CHEMTREC (USA)  
+1-703-527-3887 CHEMTREC (International)  
613-996-6666 CANUTEC (Canada)  
24 Hours/day; 7 Days/week

#### Recommended use of the chemical and restrictions on use

Recommended use : finished pharmaceutical

### 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

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required

#### Other hazards

None known.

### SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Chemical nature : Aqueous solution

#### Components

No hazardous ingredients

### SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical advice.  
If symptoms persist, call a physician.

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- In case of skin contact : Rinse with water.  
If symptoms persist, call a physician.  
Take off all contaminated clothing immediately.
- In case of eye contact : 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.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : Treat symptomatically.
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### SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Specific hazards during fire-fighting : Not combustible.  
  
Ambient fire may liberate hazardous vapours.
- Hazardous combustion products : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.  
Use personal protective equipment.
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### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Advice for non-emergency personnel:  
Do not breathe vapours, aerosols.  
Evacuate the danger area, observe emergency procedures, consult an expert.  
Advice for emergency responders:  
Use personal protective equipment.  
Dispose of promptly.  
Inform the responsible authorities in case of gas leakage, or of entry into waterways, soil or drains.  
Indications about waste treatment see section 13.
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Environmental precautions : If the product contaminates rivers and lakes or drains inform respective authorities.

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

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### SECTION 7. HANDLING AND STORAGE

Technical measures : Install appropriate equipment and wear appropriate personal protective equipment (see "8. Exposure control/personal protection").

Local/Total ventilation : Ensure adequate ventilation.

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.  
  
Observe label precautions.

Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.  
  
Keep container tightly closed in a dry and well-ventilated place.

Materials to avoid : No materials to be especially mentioned.

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

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### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Components with workplace control parameters

Contains no substances with occupational exposure limit values.

**Engineering measures** : Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

#### Personal protective equipment

Respiratory protection : required when vapours/aerosols are generated.

Filter type : filter ABEK

Hand protection

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Material	:	Protective equipment only chosen according to specific regulatory requirements after a risk assessment.
Eye protection	:	Safety glasses
Skin and body protection	:	Protective suit
Protective measures	:	The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
Hygiene measures	:	General industrial hygiene practice.

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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	liquid
Colour	:	colourless
Odour	:	not significant
Odour Threshold	:	Not applicable
pH	:	weakly acid
Melting point/range	:	ca. 32 °F / 0 °C
Boiling point/boiling range	:	ca. 212 °F / 100 °C
		ca. 212 °F / 100 °C (1,013 hPa)
Flash point	:	Not applicable
Flammability (liquids)	:	The product is not flammable.
Upper explosion limit / Upper flammability limit	:	Not applicable
Lower explosion limit / Lower flammability limit	:	Not applicable
Vapour pressure	:	No data available
Density	:	ca. 1 g/cm <sup>3</sup> (68 °F / 20 °C)
		1.02 g/cm <sup>3</sup> (68 °F / 20 °C)

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Solubility(ies)  
Water solubility : soluble

Partition coefficient: n-octanol/water : Not applicable

Not applicable

Viscosity  
Viscosity, kinematic : No data available

Explosive properties : Not classified as explosive.

Oxidizing properties : none

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### SECTION 10. STABILITY AND REACTIVITY

Reactivity : No decomposition if stored and applied as directed.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : Violent reactions possible with:  
The generally known reaction partners of water.

Conditions to avoid : No data available

Incompatible materials : Not applicable

Hazardous decomposition products : No decomposition if stored and applied as directed.

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### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Not classified due to lack of data.

#### Product:

Acute oral toxicity : Remarks: No data available

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

#### Skin corrosion/irritation

Not classified due to lack of data.

#### Product:

Remarks : No data available

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### Serious eye damage/eye irritation

Not classified due to lack of data.

#### Product:

Remarks : No data available

### Respiratory or skin sensitisation

#### Skin sensitisation

Not classified due to lack of data.

#### Respiratory sensitisation

Not classified due to lack of data.

#### Product:

Remarks : No data available

### Germ cell mutagenicity

Not classified due to lack of data.

#### Product:

Genotoxicity in vitro : Remarks: No data available

Genotoxicity in vivo : Remarks: No data available

### Carcinogenicity

Not classified due to lack of data.

**IARC** No component 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 component 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 due to lack of data.

#### STOT - single exposure

Not classified due to lack of data.

#### STOT - repeated exposure

Not classified due to lack of data.

### Repeated dose toxicity

#### Product:

Remarks : No data available

### Aspiration toxicity

Not classified due to lack of data.

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### Further information

#### **Product:**

Remarks : Physiologically active substance.  
Symptoms may be delayed.

Remarks : Handle in accordance with good industrial hygiene and safety practice.

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### **Product:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae/aquatic plants : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No toxicity at the limit of solubility

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : Remarks: No data available

Toxicity to microorganisms : Remarks: No data available

### Persistence and degradability

No data available

### Bioaccumulative potential

No data available

### 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).

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### SECTION 13. DISPOSAL CONSIDERATIONS

#### Disposal methods

Waste from residues : Waste material must be disposed of in accordance with the national and local regulations. Leave chemicals in original containers. No mixing with other waste. Handle uncleaned containers like the product itself.

Contaminated packaging : The hazard and precautionary statements displayed on the label also apply to any residues left in the container.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Packaging that is not properly emptied must be disposed of as the unused product.

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### 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 for product as supplied.

#### National Regulations

#### Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

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### 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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**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 SOCM 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:

acetic acid	64-19-7	>= 0 - < 0.1 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

acetic acid	64-19-7	>= 0 - < 0.1 %
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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

Anti-PD-L1	42640
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#### Pennsylvania Right To Know

water	7732-18-5
D-mannitol	69-65-8
acetic acid	64-19-7

#### Maine Chemicals of High Concern

Anti-PD-L1	42640
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#### Vermont Chemicals of High Concern

Anti-PD-L1	42640
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#### Washington Chemicals of High Concern

Anti-PD-L1	42640
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### The components of this product are reported in the following inventories:

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

AIIC : Not in compliance with the inventory

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

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Anti-PD-L1

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
NZIoC	:	On the inventory, or in compliance with the 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.

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## SECTION 16. OTHER INFORMATION

### Company internal Occupational Exposure Limit (MOEL)

: 24 µg/m<sup>3</sup>

Short Term Exposure (15 min) : 8  
Factor

Pregnancy risk groups : D

Either there are no data for an assessment of damage to the embryo, or foetus or the currently available data are not sufficient for classification in one of the other groups.

### Further information

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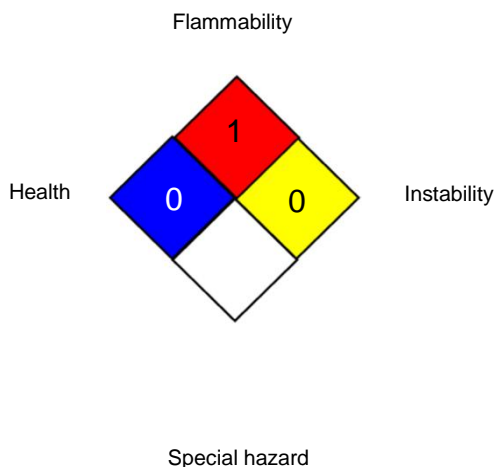
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### NFPA 704:



### HMIS® IV:

HEALTH	/	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

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

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Con-

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trol Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 04/11/2024

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.

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