SAFETY DATA SHEET

This safety data sheet was created pursuant to the requirements of:
Regulation (EC) No. 1907/2006 and Regulation (EC) No. 1272/2008

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product Name: EMBLAVEO (aztreonam and avibactam) for Injection

Synonyms: EMBLAVEO, aztreonam/avibactam

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

Recommended use: Pharmaceutical
Antibiotic

1.3. Details of the supplier of the safety data sheet

Supplier: AbbVie Inc.
1 North Waukegan Road
North Chicago, IL 60064
USA
+1-847-932-7900

E-mail Address: AbbVie.SDS@abbvie.com

1.4. Emergency telephone number

Emergency Telephone: CHEMTREC: 1(800) 424-9300 (in USA and Canada)
or +1-703-527-3887 (international)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Serious eye damage/eye irritation	Category 2
Respiratory sensitization	Category 1
Skin sensitization	Category 1

2.2. Label elements



Signal Word: Danger

Hazard Statements:
H317 - May cause an allergic skin reaction
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled

Precautionary Statements
P233 - Keep container tightly closed
P261 - Avoid breathing dust/fume/gas/mist/vapors/spray
P271 - Use only outdoors or in a well-ventilated area
P272 - Contaminated work clothing should not be allowed out of the workplace
P273 - Avoid release to the environment
P280 - Wear protective gloves/protective clothing/eye protection/face protection
P284 - Wear respiratory protection
P302 + P352 - IF ON SKIN: Wash with plenty of water and soap
P304 + P340 - IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing
P321 - Specific treatment (see supplemental first aid instructions on this label)
P333 + P317 - If skin irritation or rash occurs: Get medical help.
P342+P316: If experiencing respiratory symptoms: Get emergence medical help immediately.
P362 + P364 - Take off all contaminated clothing and wash it before reuse
P391 - Collect spillage
P403 - Store in a well-ventilated place
P501 - Dispose of contents/ container to an approved waste disposal plant

2.3. Other hazards

Endocrine Disruptor Information None known

SECTION 3: Composition/information on ingredients

Chemical Name	Weight-%	EINECS/ELINCS Number	EU - GHS Substance Classification	REACH Reg. No
Aztreonam 78110-38-0	30-60	Present	Skin Sens Cat 1 (H317) Eye Irr 2 (H319) Resp Sens Cat 1 (H334) Acute Aquatic Tox 1 (H400)	No data available
L-Arginine 74-79-3	30-60	Present	Not Hazardous*	No data available
Avibactam sodium 1192491-61-4	10-20	NA	Skin Sens Cat 1 (H317) Resp Sens Cat 1 (H334)	No data available

Not Hazardous* - Based on available data, not classified as hazardous according to the criteria of the Globally Harmonized System.

For the full text of the R-phrases mentioned in this Section, see Section 16
For the full text of the H-Statements mentioned in this Section, see Section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide

symptomatic/supportive care as necessary.

Skin Contact: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion: Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Protection of First-aiders: Use personal protective equipment

4.2 Most important symptoms and effects, both acute and delayed

Signs and Symptoms None known from occupational exposure.

Medical Conditions May be Aggravated by Exposure None known from occupational exposure.

4.3. Indication of any immediate medical attention and special treatment needed

Notes To Physician: Treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media: Use extinguishing agent suitable for type of surrounding fire

Unsuitable Extinguishing Media: Not Determined

5.2. Special hazards arising from the substance or mixture

Special Exposure Hazards: Not Determined

5.3. Advice for firefighters

Protective Equipment and Precautions for Firefighters: As in any fire, wear self-contained breathing apparatus and full protective gear

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal Precautions: For personal protection see section 8.

6.2. Environmental precautions

Environmental Precautions: Contain material and prevent release to waterways or soil.

6.3. Methods and material for containment and cleaning up

Methods for Cleaning Up: Recover product and place in an appropriate container for disposal.

6.4. Reference to other sections

Refer to Sections 8, 12, and 13 for further information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Handle in accordance with good industrial hygiene and safety practice.

7.2. Conditions for safe storage, including any incompatibilities

Store according to label instructions.

7.3. Specific end use(s)

Recommended use: Pharmaceutical
Antibiotic

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limits:

Chemical Name	AbbVie Employee Exposure Limit (OEL):	AbbVie PBLEC Category (OEB):	Skin Notation
Aztreonam 78110-38-0	Not applicable	2 (OEL range of >10 - 100 mcg/m³)	None
L-Arginine 74-79-3	Not applicable	1 (OEL >100 mcg/m³)	None
Avibactam sodium 1192491-61-4	Not applicable	2 (OEL range of >10 - 100 mcg/m³)	None

Chemical Name	The Netherlands	Spain	Switzerland	UK OEL/MEL	EU- DNELs
L-Arginine 74-79-3					39 mg/kg bw/day 136.2 mg/m³ 391.4 mg/kg bw/day 552 mg/m³ 782.8 mg/kg bw/day

8.2. Exposure controls

Engineering Controls: No special provisions are required under normal product use conditions.

Respiratory Protection: An approved respirator (i.e. NIOSH, EN, etc.) should be worn when exposures are expected to exceed the applicable limits.

Eyes: Wear eye protection appropriate to exposures when handling the product formulation.

Gloves: Impervious gloves.

Other PPE Data: Wear appropriate body coverings if contact may occur.

Environmental Exposure Controls: Not Determined

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State:	Solid
Appearance:	Powder
Color	white to slightly yellow
Odor:	Not Determined
Melting/Freezing Point @ 760 mmHg (°C):	Not Determined
Boiling Pt. @ 760 mm Hg (°C):	Not Determined
Flammability Limit in Air	Not Determined
upper flammability limit	
lower flammability limit	
Flash Point (°C):	Not Determined
Autoignition Temp. (°C):	Not Determined
pH:	Not Determined
Kinematic viscosity	Not Determined
Solubility(ies):	Not Determined
Partition coefficient: n-octanol/water	Not Determined
Vapor Pressure (@ 760 mm Hg):	Not Determined
Density, g / mL:	Not Determined
Vapor Density (Air = 1):	Not Determined
Bulk Density at 20°C:	Not Determined
Particle characteristics	
Particle Size	
Particle Size Distribution	

9.2. Other information

SECTION 10: Stability and reactivity

10.1. Reactivity

Not Determined

10.2. Chemical stability

Stable under normal conditions

10.3. Possibility of hazardous reactions

Hazardous reactions: Not Determined

10.4. Conditions to avoid

Not Determined

10.5. Incompatible materials

Not Determined

10.6. Hazardous decomposition products

Not Determined

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Routes of Exposure:

Oral: Yes
Dermal: Yes
Inhalation: Yes

Acute Toxicity - Oral: Data for component (s) given below:

Chemical Name	Acute Test	Value	Units	Species
Aztreonam 78110-38-0	LD50 >	10000	mg/kg	Mice

Acute Toxicity - Dermal: Not Determined

Acute Toxicity - Inhalation: Not Determined

Other Toxicology Data: Data for component (s) given below:

Chemical Name	Test Type	Value	Units	Species	Comments
Aztreonam 78110-38-0	LD50 (iv) = LD50 (ip) = LD50 (sc) =	2001 2897 3906	mg/kg	Rats	

Corrosivity: Not Determined

Dermal Irritation: Not Determined

Eye irritation: Not Determined

Sensitization: Aztreonam : The active ingredient is a skin sensitizer. and Respiratory sensitizer.

Toxicokinetics/Metabolism: Not Determined

Target Organ Effects Not Determined

Reproductive Effects No effects expected Data for component (s) given below:

Chemical Name	Species	Dosage	Units	Route	Duration
Aztreonam 78110-38-0	Rats	1800	mg/kg/day		During Gestation

Carcinogenicity Active Ingredient : Not likely to be carcinogenic. Not carcinogenic in animal study.

Mutagenicity: Data for component (s) given below:

Chemical Name	Micronucleus Assay	Ames Test:	Mouse Lymphoma Assay	Chromosomal Abbr. Assay
Aztreonam 78110-38-0	Negative	Negative	Negative	Negative

Aspiration hazard: Not Determined

Notes:
1. ALD: Approximate lethal dosage
2. LC50: Concentration in air that produces 50% mortality
3. LD50: Oral or dermal dosage that produces 50% mortality

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Endocrine disrupting properties None known

11.2.2. Other information

SECTION 12: Ecological information

12.1. Toxicity

Not Determined

12.2. Persistence and degradability

Not Determined

12.3. Bioaccumulative potential

Not Determined

12.4. Mobility in soil

Not Determined

12.5. Results of PBT and vPvB assessment

Chemical safety assessment has not been conducted on the substance/product.

12.6. Endocrine disrupting properties

Endocrine disrupting properties None known

12.7. Other adverse effects

Do not allow undiluted material or large quantities to reach groundwater, bodies of water or sewer system.

Notes:

1. **EC50: Concentration in water that produces 50% mortality in Daphnia sp.**
2. **LC50: Concentration in water that produces 50% mortality in fish.**
3. **EbC50/ErC50: Concentration in water that produces 50% inhibition of growth and in algae.**

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste Disposal Methods: Disposal should be made in accordance with country, federal, state and local regulations.

SECTION 14: Transport information

ADN, ADR, DOT, ICAO/IATA, IMDG/IMO, TDG

Status: Not-Regulated for Transportation

14.1. UN number Not applicable
14.2. Proper shipping name: Not applicable
14.3. Hazard class: Not applicable
14.4. Packing group: Not applicable
14.5. Environmental hazard: Not applicable
14.6. Special provisions: Not applicable
14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

International Inventories

Chemical Name	EINECS/ ELINCS	TSCA	DSL	NDSL	PICCS
Aztreonam 78110-38-0	Present	-	-	Not listed	-
L-Arginine 74-79-3	Present	X	X	Not listed	X
Avibactam sodium 1192491-61-4	-	-	-	Not listed	-

Chemical Name	ENCS	ISHL	IECSC	AICS	KECL	New Zealand
Aztreonam	-	Present	-	-	-	

78110-38-0						
L-Arginine 74-79-3	Present	Present	X	X	Present	
Avibactam sodium 1192491-61-4	-	-	-	-	-	

Legend

EINECS/ELINCS - European Inventory of Existing Commercial Chemical Substances/EU List of Notified Chemical Substances
TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
PICCS - Philippines Inventory of Chemicals and Chemical Substances
ENCS - Japan Existing and New Chemical Substances
ISHL - Japan Industrial Safety and Health Law
IECSC - China Inventory of Existing Chemical Substances
AICS - Australian Inventory of Chemical Substances
KECL - Korean Existing and Evaluated Chemical Substances

Carcinogenicity Rating:

Chemical Name	Weight-%	NTP:	IARC:	ACGIH:
Aztreonam	30-60	Not listed	Not listed	Not listed
L-Arginine	30-60	Not listed	Not listed	Not listed
Avibactam sodium	10-20	Not listed	Not listed	Not listed

SARA 313 Information

Chemical Name	Weight-%	SARA 313 Chemical:	CERCLA RQ/SARA EHS RQ (lbs):	SARA EHS TPQ (lbs):
Aztreonam	30-60	No	Not applicable	Not applicable
L-Arginine	30-60	No	Not applicable	Not applicable
Avibactam sodium	10-20	No	Not applicable	Not applicable

RCRA Status: Not Determined

Proposition 65 Status: Does not contain chemicals known to the state of California to cause cancer or reproductive harm.

WHMIS Hazard Class Not Determined

Notes:

1. SARA = Superfund Amendments and the Reauthorization Act.
2. CERCLA = Comprehensive Environmental Response, Compensation and Liability Act.
3. FIFRA = Federal Insecticide, Fungicide and Rodenticide Act.
4. TSCA = Toxic Substances Control Act.
5. EC = European Community.
6. WHMIS = Canadian Workplace Hazardous Materials Information System.
7. UN GHS = United Nations Globally Harmonized System for Hazard Identification.

15.2. Chemical safety assessment

Chemical safety assessment has not been conducted on the substance/product.

SECTION 16: Other information

Document Authored By: Genetic, Environmental and Occupational Toxicology (GEOTox)

Issued: May-21-2025

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