

Safety Data Sheet

Amivantamab Biosimilar Antibody, Research Grade (EGFR/c-Met)

Cat#: orb2977888

1. PRODUCT INFORMATION

Product Name: Amivantamab Biosimilar Antibody, Research Grade (EGFR/c-Met)

Catalog Number: orb2977888

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

This mixture is a protein formulation for professional laboratory research use only, formulated with a neutral PBS buffer system. Based on available composition information and toxicological data, the product does not meet the hazard classification criteria under the following currently effective global and regional regulations:

European Union: Regulation (EC) No. 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures (CLP Regulation, as amended by Regulation (EU) 2020/878, the latest fully applicable version in 2026), and Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH Regulation).

United Nations: Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 7th Revised Edition. United States: Occupational Safety and Health Administration (OSHA) Hazard Communication Standard 29 CFR 1910.1200 (HazCom 2012).

The product does not contain hazardous chemicals at a concentration of 1% by weight, nor does it contain carcinogens, mutagens or reproductive toxicants (CMR substances), skin sensitizers, persistent bioaccumulative and toxic (PBT) substances, or very persistent and very bioaccumulative (vPvB) substances at or above the classification threshold specified in the above regulations.

Under abnormal operation, improper contact or excessive exposure scenarios, the product may cause mild irritation to the respiratory tract, skin or eyes. Relevant first-aid measures for such scenarios are detailed in Section 4 of this SDS.

2.2 Label Elements

In accordance with the CLP Regulation (EU 2020/878), GHS 7th Revised Edition and OSHA HazCom 2012, the product does not meet the mandatory hazard classification criteria, so statutory hazard labelling is not required for professional laboratory research use scenarios.

2.3 Other Hazards

No other hazards meeting the classification criteria of the above-mentioned effective regulations have been identified. Under improper operation, excessive exposure or non-recommended use scenarios, the product may cause mild transient irritation to the respiratory tract, skin or eyes, which does not reach the mandatory classification threshold of regulatory hazard categories.

3. COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

This product is a mixture formulated with a protein active component and neutral PBS buffer system; the single pure substance section is not applicable.

3.2 Mixtures

The product is a protein mixture for professional laboratory research use only. The buffer composition may vary slightly between batches but does not affect the hazard classification of the product. Relevant component information is shown in the table below

Component Name	CAS	Concentration Range	Regulatory Compliance
Protein	-	0.1–1.0 mg/mL	No hazard classification threshold
Sodium chloride	7647-14-5	0.8–0.9% (w/v)	Below 1% hazard classification threshold
Disodium hydrogen phosphate	7558-79-4	0.1–0.2% (w/v)	Below 1% hazard classification threshold
Potassium dihydrogen phosphate	7447-40-5	0.01–0.03% (w/v)	Below 1% hazard classification threshold
Water	7732-18-5	-	No hazard classification threshold

4. FIRST AID MEASURES

4.1 Description of first aid measures General Advice

Consult a doctor and show this safety data sheet.

If Inhaled

Remove to fresh air and monitor breathing. If breathing becomes difficult, give oxygen. If breathing stops, give artificial respiration. Consult a doctor.

In Case of Skin Contact

Immediately wash skin with copious amounts of soap and water for at least 15 minutes. Remove contaminated clothing and shoes and wash before reusing. Consult a doctor.

In Case of Eye Contact

Flush with copious amounts of water for at least 15 minutes. Consult a doctor.

If Swallowed

Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person. Consult a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Not applicable.

4.3 Indication of immediate medical attention and special treatment needed

Show this safety data sheet to the doctor in attendance. Immediate medical attention is required.

5. FIREFIGHTING MEASURES

5.1 Extinguishing Media Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

In combustion, may emit toxic fumes.

5.1 Precautions for fire-fighters

Wear suitable protective clothing to prevent contact with skin and eyes and self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Do not take action without suitable protective clothing — see Section 8 of this SDS. Evacuate personnel to safe areas. Ensure adequate ventilation. Avoid breathing vapors, mist, dust or gas.

6.2 Environmental precautions

Do not let products enter drains.

6.3 Methods and materials for containment and cleaning up

Cover spillage with suitable absorbent material. Hold all material for appropriate disposal as described under Section 13 of this SDS.

6.4 Reference to other sections

For required personal protection equipment see Section 8. For disposal see Section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid inhalation, contact with eyes, skin and clothing. Avoid the formation of dust and aerosols. Use in a well-ventilated area. Keep away from sources of ignition. Avoid prolonged or repeated exposure. Replace the contaminated clothing immediately and wash hands and face after using of the substances.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool, well-ventilated area. Keep away from direct sunlight. Keep container tightly sealed until ready to use.

7.3 Specific end use(s)

In addition to use mentioned in Section 1.2, unforeseen other specific end uses.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters.

Contains no substances with occupational exposure limit values and biological limit values.

8.2 Exposure controls Appropriate Engineering Controls

Use in a fume hood where applicable. Ensure all engineering measures described under Section 7 of this SDS are in place. Ensure laboratory is equipped with a safety shower and eye wash station.

Personal Protection Equipment Eye / Face Protection

Use appropriate safety glasses.

Skin Protection

Use appropriate chemical resistant gloves (minimum requirement use standard BS EN 374:2003). Gloves should be inspected before use. Wash and dry hands thoroughly after handling.

Body Protection

Wear appropriate protective clothing.

Respiratory Protection

If risk assessment indicates necessary, use a suitable respirator.

Environment exposure controls

No data available.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	Lyophilized white powder or clear liquid.	Vapor Pressure	No data available.
Odor	Little to none.	Vapor Density	No data available.
Odor Threshold	No data available.	Relative Density	No data available.
pH	7.0–7.4	Solubility(ies)	No data available.
Melting/Freezing Point	No data available.	Partition Coefficient	No data available.
Boiling Point/Range	No data available.	Autoignition Temperature	No data available.
Flash Point	No data available.	Decomposition Temperature	No data available.
Evaporation Rate	No data available.	Viscosity	No data available.
Flammability (Solid, Gas)	No data available.	Explosive Properties	No data available.
Upper / Lower Flammability Limits	No data available.	Oxidizing Properties	No data available.

9.1 Other safety information

No data available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

Stable under recommended transport or storage conditions.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions will not occur under normal transport or storage conditions. Decomposition may occur on exposure to conditions or materials listed below.

10.4 Conditions to avoid

Heat, moisture.

10.5 Incompatible materials

Strong acids / alkalis, strong oxidizing/reducing agents.

10.6 Hazardous decomposition products

Under recommended conditions of storage and use, hazardous decomposition products should not be produced.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

This section is compiled based on toxicological data of the product's core components, in full compliance with the data requirements of the CLP Regulation (EU 2020/878), GHS 7th Revised Edition and OSHA HazCom 2012.

Acute Toxicity

No data available.

Skin Corrosion / Irritation

No data available. Under prolonged or repeated improper contact, transient mild local irritation may occur, which does not reach the classification threshold of Skin Irritant Category 2 under CLP/GHS, and the classification criteria are not met.

Serious Eye Damage / Irritation

No standardized in vivo eye irritation test data available for the target protein; the buffer system is neutral with no eye damage or serious irritant properties. Under direct contact and insufficient flushing, transient mild redness and irritation may occur, which does not reach the classification threshold of Eye Irritant Category 2 under CLP/GHS, and the classification criteria are not met.

Respiratory or Skin Sensitization

No data indicating that the target protein or buffer components have respiratory or skin sensitization properties; the product does not contain known skin sensitizers at or above the regulatory classification threshold, and the classification criteria are not met.

Germ Cell Mutagenicity

No data indicating mutagenic properties; the product does not contain known germ cell mutagens at or above the regulatory classification threshold, and the classification criteria are not met.

Carcinogenicity

No data indicating carcinogenic properties; the product does not contain known carcinogens at or above the 0.1% (w/w) regulatory classification threshold, and the classification criteria are not met.

Reproductive Toxicity

No data indicating reproductive or developmental toxic properties; the product does not contain known reproductive toxicants at or above the regulatory classification threshold, and the classification criteria are not met.

Specific Target Organ Toxicity (Single/Repeated Exposure)

No data indicating specific target organ toxicity; the classification criteria are not met.

Aspiration Hazard

The product is a lyophilized powder or aqueous solution with low volatility; no aspiration hazard data available, and the classification criteria are not met.

Symptoms / Routes of Exposure

Inhalation: If aerosols or dust are generated and inhaled, transient irritation of the throat and upper respiratory tract, or mild chest tightness may occur.

Skin Contact: Prolonged or repeated contact may cause transient mild local redness or irritation at the contact site.

Eye Contact: Direct splashing contact may cause transient mild redness, tearing and irritation of the conjunctiva. **Ingestion:** Accidental ingestion may cause transient irritation of the oral cavity and gastrointestinal tract.

Delayed / Immediate Effects: No known delayed toxic effects under normal recommended use conditions.

11.2 Information on other hazards Endocrine disrupting properties

No data available.

Other information

No other unlisted toxic hazards have been identified under normal recommended use and storage conditions.

12. ECOLOGICAL INFORMATION

- Toxicity: No data available.
- Persistence and degradability: No data available.
- Bioaccumulative potential: No data available.
- Mobility in soil: No data available.
- Results of PBT and vPvB assessment: No data available.
- Endocrine disrupting properties: No data available.
- Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods Product

Transfer to a suitable container and arrange for collection by specialized disposal company in accordance with national, regional, or local legislation.

Contaminated Packaging

Dispose of in a regulated landfill site or other method for hazardous or toxic wastes in accordance with national, regional, or local legislation.

14. TRANSPORT INFORMATION

- 14.1 UN-Number: Not applicable.
- 14.2 UN proper shipping name: Not applicable.
- 14.3 Transport hazard class(es): Not applicable.
- 14.4 Packaging group: Not applicable.
- 14.5 Environmental hazards: No information available.

14.6 Special precautions for users: No information available.

14.7 IMDG / ADR / RID / DOT-US / IATA: Does not meet the criteria for classification as hazardous for transport.

15. REGULATORY INFORMATION

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

TSCA (Toxic Substances Control Act)	Not applicable.
SARA 313	Not applicable.
SARA 311 / 312	Not applicable.
CERCLA Reportable Quantity	Not applicable.
Prop 65	Not applicable.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been made for this product.

16. OTHER INFORMATION

The above information was acquired by diligent search and/or investigation, and the recommendations are based on prudent application of professional judgment. The information shall not be taken as being all inclusive and is to be used only as a guide. All materials and mixtures may present unknown hazards and should be used with caution. Since Biorbyt Ltd. cannot control the actual methods, volumes, or conditions of use, the Company shall not be held liable for any damage or losses resulting from the handling or from contact with the product as described herein.