

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: VYLOY (Zolbetuximab)

Chemical Name: Proprietary

Product Code: IMAB362, iMAB 362, GC182 iMAB 362, Claudiximab

Formula: Proprietary

Synonyms: IMAB362

1.2. Intended Use of the Product

Use of the substance/mixture: Pharmaceutical research, manufacturing and clinical use. For professional use only.

1.3. Name, Address, and Telephone of the Responsible Party

Company

Astellas US LLC

2375 Waterview Drive

Northbrook, IL 60062

Tel.: 800-888-7704

www.us.astellas.com

1.4. Emergency Telephone Number

Emergency Number : 800-727-7003
Medical Communications

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

GHS-US classification

Not classified

2.2. Label Elements

GHS-US Labeling

No labeling applicable

2.3. Other Hazards

The toxicological properties of this substance have not been fully investigated. Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Sucrose	(CAS-No.) 57-50-1	> 40	Comb. Dust
Zolbetuximab	(CAS-No.) 1496553-00-4	< 20	Not classified
L-Arginine	(CAS-No.) 74-79-3	> 20	Comb. Dust
Phosphoric acid	(CAS-No.) 7664-38-2	< 10	Met. Corr. 1, H290 Acute Tox. 4 (Oral), H302 Skin Corr. 1B, H314 Eye Dam. 1, H318 Aquatic Acute 3, H402
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives	(CAS-No.) 9005-65-6	< 5	Not classified
Nitrogen	(CAS-No.) 7727-37-9	< 5	Simple Asphy

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of First Aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

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First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation develops or persists.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most important symptoms and effects, both acute and delayed

Symptoms/Injuries: The health hazards of this pharmaceutical in industrial settings have not been fully investigated.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: The chronic effects of this substance are unknown.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, dry chemical, foam, carbon dioxide.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Avoid prolonged contact with eyes, skin and clothing. Avoid breathing (vapor, mist, spray).

6.1.1. For Non-emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Responders

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Material for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: When processed, the product dust is combustible. Use care during processing to minimize generation of dust.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Avoid prolonged contact with eyes, skin and clothing. Avoid breathing vapors, mist, spray.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

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7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Store zolbetuximab in the original package at 2 - 8 °C (36 - 46 °F). Do not open the cartons until ready for use.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical research, manufacturing and clinical use. For professional use only.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Phosphoric acid (7664-38-2)		
USA ACGIH	ACGIH TWA (mg/m ³)	1 mg/m ³
USA ACGIH	ACGIH STEL (mg/m ³)	3 mg/m ³
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	1 mg/m ³
USA NIOSH	NIOSH REL (STEL) (mg/m ³)	3 mg/m ³
USA IDLH	US IDLH (mg/m ³)	1000 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	1 mg/m ³
Sucrose (57-50-1)		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	10 mg/m ³ (total dust) 5 mg/m ³ (respirable dust)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)
Nitrogen (7727-37-9)		
USA ACGIH	ACGIH chemical category	Simple asphyxiant See Appendix F: Minimal Oxygen Content

8.2. Exposure Controls

Appropriate Engineering Controls

: Emergency eye wash fountains and safety showers should be available in the immediate vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State

: Solid

Appearance

: White to off-white lyophilized powder

Odor

: No data available

Odor Threshold

: No data available

pH

: No data available

Evaporation Rate

: No data available

Melting Point

: No data available

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Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available
Decomposition Temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapor Pressure	: No data available
Relative Vapor Density at 20 °C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. **Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. **Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** The nature of the decomposition products are unknown.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information On Toxicological Effects

Acute Toxicity: Not classified

Zolbetuximab	
Additional information	Single dose study in mice (1, 10, 50, 100 mg/kg, iv bolus): No toxicity up to 100 mg/kg. Single dose study in cynomolgus monkeys (50, 150 mg/kg, iv bolus): No toxicity up to 150 mg/kg.
Phosphoric acid (7664-38-2)	
LD50 Oral Rat	1530 mg/kg
LD50 Dermal Rabbit	2740 mg/kg
LC50 Inhalation Rat	> 850 mg/m ³ (Exposure time: 1 h)
Sucrose (57-50-1)	
LD50 Oral Rat	29700 mg/kg
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)	
LD50 Oral Rat	37.605 g/kg

Skin Corrosion/Irritation: Not classified

Zolbetuximab	
Additional information	No zolbetuximab-related reactions at infusion sites in 13-week mouse study or 4-week cynomolgus monkey study.

Serious Eye Damage/Irritation: Not classified (Studies have shown that phosphoric acid does not elicit skin or eye irritation in concentrations below 10%.)

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Zolbetuximab	
Additional information	No genotoxicity studies of zolbetuximab have been conducted. The genotoxicity studies routinely conducted for pharmaceuticals are not applicable to biotechnology-derived pharmaceuticals.

Carcinogenicity: Not classified

Zolbetuximab	
Additional information	No carcinogenicity studies have been conducted.

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Reproductive Toxicity: Not classified

Zolbetuximab	
Additional information	Effects on embryo-fetal development in mice (0, 100, 300 mg/kg, iv bolus) NOAEL: 300 mg/kg for both dams and embryo-fetal development.

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Zolbetuximab	
Additional information	13-week toxicity study in mice: (0, 100, 200, 300 mg/kg/week, iv bolus) NOAEL: 300 mg/kg/week. 4-week toxicity study in cynomolgus monkeys: (0, 10, 30, 100 mg/kg/week, iv bolus) Emesis was seen in males treated with 10 or 30 mg/kg on day 8 only NOAEL: 100 mg/kg/week. Reproductive effects: No effects on embryo-fetal development in mice (0, 100, 300 mg/kg, iv bolus) NOAEL: 300 mg/kg for both dams and embryo-fetal development.

Aspiration Hazard: Not classified.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: The chronic effects of this substance are unknown.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Phosphoric acid (7664-38-2)	
LC50 Fish 1	75.1 mg/l

12.2. Persistence and Degradability

Zolbetuximab	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Zolbetuximab	
Bioaccumulative Potential	Not established.

12.4. Mobility in Soil: No additional information available.

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Ecology – Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT: Not regulated for transport.

14.2. In Accordance with IMDG: Not regulated for transport.

14.3. In Accordance with IATA: Not regulated for transport.

SECTION 15: REGULATORY INFORMATION

15.1 US Federal Regulations

L-Arginine (74-79-3)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

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Phosphoric acid (7664-38-2)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
CERCLA RQ	5000 lb
Sucrose (57-50-1)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
Sorbitan, mono-(9Z)-9-octadecenoate, poly(oxy-1,2-ethanediyl) derivatives (9005-65-6)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).
Nitrogen (7727-37-9)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2 US State Regulations

Phosphoric acid (7664-38-2)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) - Environmental Hazard List U.S. - Pennsylvania - RTK (Right to Know) List
Sucrose (57-50-1)
U.S. - Massachusetts - Right To Know List U.S. - Pennsylvania - RTK (Right to Know) List
Nitrogen (7727-37-9)
U.S. - Massachusetts - Right To Know List U.S. - New Jersey - Right to Know Hazardous Substance List U.S. - Pennsylvania - RTK (Right to Know) List

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision	: October 25, 2024
Other Information	: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200.

GHS Full Text Phrases:

Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 3	Hazardous to the aquatic environment - Acute Hazard Category 3
Comb. Dust	Combustible Dust
Eye Dam. 1	Serious eye damage/eye irritation Category 1
Met. Corr. 1	Corrosive to metals Category 1
Simple Asphy	Simple Asphyxiant
Skin Corr. 1B	Skin corrosion/irritation Category 1B
H290	May be corrosive to metals
H302	Harmful if swallowed
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage
H402	Harmful to aquatic life

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.