

SAFETY DATA SHEET

DATE PREPARED 2025-08-06

SECTION 1. IDENTIFICATION

1.1. Product Identifier(s)

Description: Anti-H. Pylori IgM AccuBind® ELISA Test System
 Product Code: 1525-300
 Characteristics: Enzyme Immunoassay, Colorimetric

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

For in vitro diagnostic use only. Not for internal or external use in humans or animals.

1.3. Details of the supplier of the safety data sheet

Manufacturer/Importer: Manufacturer
 Company name: Monobind Inc.
 Address: 100 North Pointe Drive, Lake Forest, California
 92630, USA
 Telephone number: +1.949.951.2665
 Fax number: +1.949.951.3539
 Email: info@monobind.com
 FDA Est. Reg number: 2020726
 SRN number: US-MF-000021611

1.4. Emergency telephone number

+1.949.951.2665 (Hours: 8 am-5 pm PST, Monday-Friday)

SECTION 2. HAZARD(S) IDENTIFICATION

2.1. Classification of the substance or mixture

None

2.2. Label elements

None

2.3. Other hazards

Should always be used with caution as if capable of transmitting infectious diseases.
 Should be handled at Biosafety Level 2.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

All concentrations of potentially hazardous substances or mixtures are below the specific concentration limits and M-factors for hazardous identification.

- 3.1.1. Anti-H. Pylori IgM Calibrators (A-E)
N/A
- 3.1.2. Anti-H. Pylori IgM Enzyme Reagent
N/A
- 3.1.3. Anti-H. Pylori IgM Biotin Reagent
N/A
- 3.1.4. Serum Diluent Concentrate
N/A
- 3.1.5. Streptavidin Coated Plate
N/A
- 3.1.6. Substrate A
N/A
- 3.1.7. Substrate B
N/A
- 3.1.8. Wash Solution Concentrate
N/A
- 3.1.9. Stop Solution

Chemical Name	Identification	Hazard Class Category Code	Hazard Statement/ CLP Classification	Concentration
Hydrochloric Acid	CAS: 7647-01-0 EC: 231-595-7	Met. Corr. 1 Acute Tox. 5 oral Skin Corr. 1B STOT SE 3	H290 H303 H314 H335	< 5 %

3.2 Mixtures

All concentrations of potentially hazardous substances or mixtures are below the specific concentration limits and M-factors for hazardous identification.

SECTION 4. FIRST-AID MEASURES

4.1. Description of first aid measures

General instructions:	Immediately rinse with soap and plenty of water. Use personal protective working aids.
If inhaled:	Transport the affected person into the open air. If there are respiratory complaints, oxygen must be administered. If irritation persists, seek medical advice.
In case of skin contact:	Wash contacted area with soap and water. Remove contaminated clothing. If irritation occurs, seek medical advice.
In case of contact with eyes:	Rinse with a stream of water for at least 15 minutes. Thorough rinsing must be ensured by opening the eyelids. If irritation occurs, seek medical advice.
If ingested:	Do NOT induce vomiting. If conscious, rinse the mouth and administer a large amount of water to dilute the substance. In the case of unconsciousness, never administer anything orally. If irritation occurs, seek medical advice.

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

No data available

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

No data available

SECTION 5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Carbon dioxide, dry powder, foam, water

5.2. Special hazards arising from the substance or mixture

None

5.3. Advice for firefighters

Wear appropriate personal protective equipment and clothing. Wear self-contained breathing apparatus, if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes. Wear suitable personal protective clothing.

6.2. Environmental precautions

Avoid penetration into sewerage systems, surface and ground water. Avoid soil pollution.

6.3. Methods and material for containment and cleaning up

Soak up liquid with absorbent disposable paper. Wash affected area with water and detergent. In addition, use precautions for blood products at biosafety level 2 as described in health safety code for laboratory.

6.4. Reference to other sections

See Section 8 for personal protective equipment. See Section 13 for appropriate disposal methods.

SECTION 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid spills. Avoid contact with skin, eyes and clothing. Use suitable protective means to work with the substance. Use in a well-ventilated area. Follow good manufacturing practices when using product. Do not drink, smoke, or eat in work areas.

7.2. Conditions for safe storage, including any incompatibilities

Store material at 2-8 °C for a short period of time. For longer stability, store at -20 °C. Use stabilizers suitable for your application.

7.3 Specific end use(s)

For in vitro diagnostic use only. Not for internal or external use in humans or animals.

SECTION 8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1. Control parameters

No substances with occupational exposure limits.

8.2. Exposure controls

- 8.2.1. Eye/face protection: Safety glasses or goggles with side shields recommended
- 8.2.2. Skin protection: Compatible protective gloves recommended. Wash hands after properly removing and disposing of gloves.
Other skin protection: Laboratory coats are recommended.
- 8.2.3. Respiratory protection: No respiratory protection is required. Use product in rooms enabling good ventilation. If local exhaustion is necessary, general (forced) exhaustion is recommended.
- 8.2.4. Thermal hazards: None

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

- 9.1.1. Appearance:
 - Physical state (at 20 °C):
 - Liquid: Calibrators, Enzyme Reagent, Biotin Reagent, Wash Solution Concentrate, Substrate A, Substrate B, Serum Diluent Concentrate, Stop Solution
 - Solid: Microtiter strips
 - Colour:
 - Orange: Calibrators, Serum Diluent Concentrate
 - Blue/Violet: Enzyme Reagent
 - Green: Biotin Reagent
 - Colorless: Stop, Substrate, Wash
 - Odour: Odorless
- 9.1.2. Odour threshold: Not applicable
- 9.1.3. pH value:
 - Stop solution: < 3
 - Calibrators: 7.4 ± 0.2
 - Enzyme: 5.4 ± 0.2
 - Biotin: 5.3 ± 0.2
 - Microtiter strips: N/A
 - Wash Solution Concentrate: 8.8 ± 0.2
 - Substrate Reagent A: 3.2 ± 0.2
 - Substrate Reagent B: 4.5 ± 0.2
 - Serum Diluent Concentrate : 7.4 ± 0.2
- 9.1.4. Melting point/freezing point: Not determined
- 9.1.5. Initial boiling point/ boiling range: 100-110 °C
- 9.1.6. Flash point: Not applicable
- 9.1.7. Evaporation rate: Not determined
- 9.1.8. Flammability (solid, gas): Not flammable
- 9.1.9. Upper/lower flammability or explosive limits: Not determined

9.1.10. Vapour pressure:	Not determined
9.1.11. Vapour density:	Not determined
9.1.12. Relative density:	Not determined
9.1.13. Solubility:	Water soluble
9.1.14. Partition coefficient: n-octanol/water:	Not determined
9.1.15. Auto-ignition temperature:	Not applicable
9.1.16. Decomposition temperature:	Not determined
9.1.17. Viscosity:	Not determined
9.1.18. Explosive properties:	Not determined
9.1.19. Oxidising properties:	Not determined

9.2. Other information

None

SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity

No known reactivity hazards associated with product

10.2. Chemical stability

Stable under recommended storage conditions

10.3. Possibility of hazardous reactions

No hazardous polymerization

10.4. Conditions to avoid

Exposure to heat

10.5. Incompatible materials

Strong acid or strong alkaline substances

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

11.1.1. Acute toxicity:	Not determined
11.1.2. Skin corrosion/irritation:	Not determined
11.1.3. Serious eye damage/irritation:	Not determined
11.1.4. Respiratory or skin sensitisation:	Not determined
11.1.5. Germ cell mutagenicity:	Not determined
11.1.6. Carcinogenicity:	No component of this product present at levels $\geq 0.1\%$ is identified as probable, possible or confirmed human carcinogen by NTP (National Toxicology Program), IARC (International Agency for Research on Cancer), or OSHA (Occupational Safety & Health Administration)
11.1.7.	Reproductive toxicity: Not determined
11.1.8.	STOT-single exposure: Not determined
11.1.9.	STOT-repeated exposure: Not determined
11.1.10.	Aspiration hazard: Not determined
11.1.11.	Information on likely routes of exposure:
If ingested:	No known health effects
If inhaled:	No known health effects
If contact with skin:	No known health effects
If contact with eyes:	No known health effects
11.1.12	Symptoms related to the physical, chemical, and toxicological characteristics: None after short or long-term exposure

11.2. Information on other hazards

Not applicable

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**
Not determined
- 12.6. Endocrine disrupting properties**
Not determined
- 12.7. Other adverse effects**
Not determined

SECTION 13. DISPOSAL CONSIDERATIONS

- 13.1. Waste treatment methods**
All waste disposals must be carried out in accordance with federal, state, and local legislation and administrative regulations. A licensed professional waste disposal service should be utilized to dispose of material and packaging.

SECTION 14. TRANSPORT INFORMATION

- 14.1. UN number or ID number**
Not available
- 14.2. UN proper shipping name**
Not available
- 14.3. Transport hazard class(es)**
Not available
- 14.4. Packing group**
Not available
- 14.5. Environmental hazards**
Overland transport (ADR/RID): None
Water transport (ADN/IMDG): None
Air transport (ICAO/IATA): None
- 14.6. Special precautions for user**
None
- 14.7. Transport in bulk according to IMO instruments**
Not applicable

SECTION 15. REGULATORY INFORMATION

- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**
SARA Reporting Requirements: None
TSCA: All components in product preparations are listed on the US Toxic Substances Control Act inventory of chemicals or are exempt from listing.
This safety data sheet has been prepared to comply with the requirements of Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II, European Community Regulation No. 1907/2006 REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) and OSHA (Occupational Safety & Health Administration) 1910.1200, Appendix D.
- 15.2. Chemical safety assessment**
None



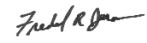
SECTION 16. OTHER INFORMATION

Revision 4 (2025-AUG-06): updated to comply with requirements of Commission Regulation (EU) 2020/878
Revision 3 (2019-SEP-17): updated to include component pH value details

Revision 2 (2015-MAY-05): updated to comply with requirements of Annex II, European Community Regulation No. 1907/2006 (REACH) and OSHA 1910.1200, Appendix D
 Revision 1 (2010-DEC-01): updated to 16 point format
 Revision 0 (2003-JUN-23): Initial creation

Hazard Statements		Hazard Class and Category Codes	
H290	May be corrosive to metals	Met. Corr. 1	Corrosive to Metals
H303	Toxic if swallowed	Acute Tox. (O) 5	Acute toxicity, oral
H314	Causes severe skin burns and eye damage	Skin Corr.	Skin Corrosion/Irritation
H335	May cause respiratory irritation	STOT SE 3	Specific Target Organ toxicity - Single Exposure

The material safety data sheet contains data necessary to ensure safety and health and environmental protection in working with chemical substances. This product is a chemical substance and can be solely used by persons with chemical education at their own risk. Monobind products are formulated for IVD Use, biomedical research, and further manufacturing processes. The manufacturer has no responsibility for damage caused by unsuitable use and by disrespecting the enclosed working instructions. The above-stated information cannot be considered as complete and must be understood to be only a methodical instruction

DOCUMENT HISTORY					
PREPARED BY:		DEPT: R&D	VERIFIED BY:		DEPT: QA
APPROVED BY:		DEPT: Administration			
REVISION:	4	DCO:	1736	EFFECTIVE DATE:	2025-08-06