Monobind, Inc.

SAFETY DATA SHEET

SECTION 1. IDENTIFICATION

1.1. Product Identifier(s)

Name: Alpha-Fetoprotein/ β-Human Chorionic Gonadotropin / Unconjugated Estriol (AFP/ hCG/ uE3 VAST®) Triple Screen AccuLite® CLIA Test System
Description: AccuLite® CLIA Microwells
Code: 8575-300
Characteristics: Microplate Enzyme Immunoassay, Chemiluminescence

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

Quantitative determination of AFP / CEA / tPSA concentration in human serum or plasma by a microplate enzyme immunoassay, Chemiluminescence.
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
Name or commercial name: Monobind Inc.
Registered office: 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 Established
Registration number: 2020726

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

None

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances and/or Mixtures

All concentrations of potentially hazardous substances or mixtures are below the specific concentration limits and M-factors for hazardous identification. As preparations, the product components are not classified as hazardous.

3.1.1. AFP / hCG / uE3 Combi-Cal® Calibrators
N/A

3.1.2. AFP Tracer Reagent
N/A

3.1.3. hCG Tracer Reagent
N/A

3.1.4. uE3 Tracer Reagent
N/A

3.1.5. uE3 Biotin Reagent
N/A

3.1.6. Sample Diluent
N/A

3.1.7. Light Reaction Wells
N/A

3.1.8. Signal A
N/A

3.1.9. Signal B
N/A

3.1.10. Wash Solution Concentrate
N/A

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
Cover with suitable absorbing material. After removing the substance, rinse the spot of spilling thoroughly with water and soap. Dispose of waste according to all federal, state, and local regulations.

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

7.2.1. Kit and unopened components:
Store at temperatures between + 2 and + 8 °C in a dry and dark place until expiration date. Avoid extended exposure to heat and light.

7.2.1. Opened components:
Stable for sixty (60) days when stored at 2-8 °C.

7.2.2. For prepared reagents (see product insert):
Diluted wash buffer should be stored at room temperature (2-30 °C) for up to 60 days.
Working Signal solution should be stored at 2-8 °C and is stable for thirty-six (36) hours.

7.3. Specific end uses
Product procedure should be performed by a skilled individual or trained professional for in vitro diagnostic use only.

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:	Tracer Reagent, Biotin Reagent, Diluent, Wash Solution Concentrate, Signal Solutions
Solid:	Calibrators (powder), Microtiter strips
Colour	
Straw:	Calibrators, Diluent
Orange:	AFP Tracer Reagent
Red:	uE3 Tracer Reagent
Blue-green:	hCG Tracer Reagent
Blue:	uE3 Biotin Reagent
Clear:	Signals, Wash

9.1.2. Odour: Odourless

9.1.3. Odour threshold: Not applicable

9.1.4. pH value: Stop solution: < 3
Calibrators: 7.4 ± 0.2
Tracer Reagent: 7.3 ± 0.2
Biotin: 7.3 ± 0.2
Microtiter strips: 7.5 ± 0.2
Wash Solution Concentrate: 8.8 ± 0.2
Substrate Reagent A: 9.0 ± 0.2
Substrate Reagent B: 5.0 ± 0.2

9.1.5. Melting point/freezing point: Not determined
9.1.6. Initial boiling point/ boiling range: Not determined
9.1.7. Flash point: Not applicable
9.1.8. Evaporation rate: Not determined
9.1.9. Flammability (solid, gas): Not flammable
9.1.10. Upper/lower flammability or explosive limits: Not applicable
9.1.11. Vapour pressure: Not determined
9.1.12. Vapour density: Not determined
9.1.13. Relative density: Not determined
9.1.14. Solubility: Water soluble
9.1.15. Partition coefficient: n-octanol/water: Not determined
9.1.16. Auto-ignition temperature: Not applicable
9.1.17. Decomposition temperature: Not determined
9.1.18. Viscosity: Not determined
9.1.19. Explosive properties: None
9.1.20. 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

Excessive heat and light

10.5.Incompatible materials

Acids

10.6.Hazardous decomposition products

Not determined

SECTION 11. TOXICOLOGICAL INFORMATION:

11.1.Information on toxicological effects

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 ≥ 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

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.Other adverse affects

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

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 Annex II of MARPOL73/78 and the IBC Code

Not applicable

SECTION 15. REGULATORY INFORMATION

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

SARA Reporting Requirements: None

TSCA All components in product preparations are lifted 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 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 2 (2019-Sep-17): Updated to include component pH value details
Revision 1 (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 0 (2013-MAY-01): Initial creation

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 kits are designed for biomedical research. 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: Records Administration VERIFIED BY: AShatola DEPT: QA

APPROVED BY: _____ DEPT: Administration EFFECTIVE DATE: 2019-SEP-17

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