SAFETY DATA SHEET

DATE PREPARED 2025-08-06

SECTION 1. IDENTIFICATION

1.1. Product Identifier(s)

Description: Cancer Antigen 15-3 (CA 15-3) AccuLite® CLIA Test System
Product Code: 5675-300
Characteristics: Enzyme Immunoassay, Chemiluminescence

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. CA 15-3 Calibrators (A-F)
N/A
3.1.2. CA 15-3 Enzyme Reagent
N/A
3.1.3. CA 15-3 Biotin Reagent
N/A
3.1.4. CA 15-3 Dilution Matrix
N/A
3.1.5. Light Reaction Wells
N/A
3.1.6. Signal Reagent A
N/A
3.1.7. Signal Reagent B
N/A
3.1.8. Wash Buffer Concentrate
N/A

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

Information on basic physical and chemical properties

9.1.1.	Appearance:	
	Physical state (at 20 °C):	
	Liquid:	Calibrators, Tracer Reagent, Biotin Reagent, Wash Buffer Concentrate, Dilution Matrix, Signal Reagent A, Signal Reagent B
	Solid:	Microtiter strips
	Colour:	
	Green:	Biotin
	Yellow:	Tracer
	White:	Streptavidin Coated Plate
	Colorless:	Calibrators, Signal A, Signal B, Wash, Matrix
	Odour:	Odorless
9.1.2.	Odour threshold:	Not applicable
9.1.3.	pH value:	Calibrators: 7.4 ± 0.2 Tracer: 5.3 ± 0.2 Biotin: 6.3 ± 0.2 Dilution Matrix: 7.4 ± 0.2 Microtiter strips: N/A Wash Buffer Concentrate: 8.8 ± 0.2 Signal Reagent A: 9.3 ± 0.2 Signal Reagent B: 5.0 ± 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 ≥ 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 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 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 3 (2025-AUG-06): updated to comply with requirements of Commission Regulation (EU) 2020/878
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. Human Serum Albumin Lyophilized – Low Endotoxin is formulated for 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.

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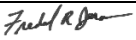
APPROVED BY:		DEPT: Administration			
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