

# SAFETY DATA SHEET

## SECTION 1. IDENTIFICATION

### 1.1. Product Identifier(s)

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

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

Quantitative determination of Cancer Antigen 15-3 concentration in human serum 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. CA 15-3 Calibrators (A-F)  
N/A
- 3.1.2. CA 15-3 Tracer 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 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: Calibrators, Tracer Reagent, Biotin Reagent, Dilution Matrix, Wash Solution Concentrate, Signal Solutions

Solid: Microtiter strips

Colour

Straw: Calibrators

Yellow: Tracer Reagent

Green: Biotin Reagent

Clear: Signal, Wash, Dilution Matrix

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  $\geq 0.1\%$  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

## 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

Effective Date: 2019-09-17 Rev. 2

Page 3 of 4

MSDS 5675-300

**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 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 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**

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APPROVED BY: <u><i>Fred Lopez</i></u>	DEPT: Administration	EFFECTIVE DATE: 2019-SEP-17	
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