

SAFETY DATA SHEET

SECTION 1. **IDENTIFICATION**

1.1. Product Identifier(s)

Name: Total Thyroxine (Total T4) AccuBind® ELISA Test System

Description: AccuBind® ELISA Microwells

Code: 225-300

Microplate Enzyme Immunoassay, Colorimetric Characteristics:

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

Quantitative determination of total thyroxine concentration in human serum or plasma by a microplate enzyme immunoassay,

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

2020726 Registration number: 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

COMPOSITION/INFORMATION ON INGREDIENTS SECTION 3.

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. The following substance exceeds the generic cut-off value and is listed with its concentration level. At this concentration level, the substance is not hazardous. See section 16 for definitions for all risk and hazards classifications.

Total T4 Calibrators (A-F) 3.1.1.

N/A

3.1.2. Total T4 Enzyme Reagent

T3/T4 Conjugate Buffer 3.1.3.

N/A

3.1.4. T4 Antibody Coated Plate

N/A

3.1.5. Substrate A

N/A

3.1.6. Substrate B

N/A

3.1.7. Wash Solution Concentrate

N/A

3.1.8. Stop Solution

Chemical Name	Identification	Hazard Code Risk Phrase	Hazard Class Category Code	Hazard Statement	Concentration
Hydrochloric Acid	CAS: - EC: 231-595-7	C; R34 Xi: R37	Skin Corr. 1B STOT SE 3	H314 H335	< 5 %

SECTION 4. FIRST-AID MEASURES

4.1. Description of first aid measures

Immediately rinse with soap and plenty of water. Use personal protective working aids. General instructions:

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.

7.2.2. Opened components:

Opened reagents are stable for sixty (60) days when stored at 2-8 °C.

7.2.3. For prepared reagents (see product insert):

Diluted wash buffer should be stored at room temperature (2-30 °C) for up to 60 days.

Working substrate solution should be stored at 2-8 °C and is stable for one (1) year.

Working T4 Enzyme-Conjugate Solution should be stored at 2-8 °C and used within twenty-four (24) 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, Enzyme Reagent, Conjugate Buffer, Wash Solution Concentrate, Substrate Solutions,

Stop Solution

Solid: Microtiter strips

Colour

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Straw: Calibrators
Red: Conjugate Buffer
Yellow: Enzyme Reagent
Clear: Stop, Substrates, Wash

9.1.2. Odour: Odourless
9.1.3. Odour threshold: Not applicable
9.1.4. pH value: Stop solution: < 3

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Calibrators: 7.4 ± 0.2 Enzyme: 7.3 ± 0.2

Microtiter strips: 7.5 ± 0.2

Wash Solution Concentrate: 8.8 ± 0.2 Substrate Reagent A: 3.2 ± 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 applicable9.1.8. 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:
9.1.17. Decomposition temperature:
9.1.18. Viscosity:
9.1.19. Explosive properties:
Not applicable
Not determined
Not determined
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:
If inhaled:
If contact with skin:
If contact with eyes:
No known health effects
No known health effects
No known health effects
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

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Not determined

12.4. Mobility in soil

Not determined

12.5.Results of PBT and vPvB assessment

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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

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None

SECTION 16. OTHER INFORMATION

Revision 3 (2019-Sep-17): Updated to include component pH value details

Revision 2 (2015-MÁY-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 (2005-DEC-22): Initial creation

Hazard Statements		Hazard Class and Category Codes	
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
Hazard Codes		Risk Phrases	
С	Corrosive	R34	Causes burns
Xi	Irritant	R37	Irritating to respiratory system

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: AShahk DEPT: QA

REVISION: 3 DCO: 1361

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