

COVER SHEET

Product Name Diamedix ELISA Kits

Erba Diagnostics

14100 NW 57th Court **Company Information**

Miami Lakes, FL 33014 Telephone: 305-418-2320

The following safety data sheets are valid for the Diamedix ELISA Kits listed the table below:

Catalog Number	Product
720-130	Is [®] -H. <i>pylori</i> IgG
720-430	Is®-anti-MPO (P-ANCA)
720-440	Is®-anti-PR-3 (C-ANCA)
720-450	Is®-anti-TPO
720-460	Is®-anti-TG
720-540	Is®-Mumps IgG
720-600	Is®-EBV-VCA IgG
720-610	Is®-EBV-VCA IgM
720-620	Is®-EBNA-1 IgG
720-630	Is®-EBNA-1 IgM
720-640	Is®-EBV-EA-D IgG
720-650	Is®-EBV-EA-D IgM
720-850	Is®-Mycoplasma IgG



1. PRODUCT AND COMPANY IDENTIFICATION

Kit Components Calibrator Sample Diluent Substrate TMB

Positive Control Conjugate Wash

Negative Control Stop N solution

Catalog Number(s) See page 1

Recommended Use Components of an *in-vitro* diagnostic device

Erba Diagnostics

Company Information

14100 NW 57th Court
Miami Lakes, FL 33014

Telephone: 305-418-2320

2. HAZARD(S) IDENTIFICATION

Route of Entry/Exposure

✓ Skin Contact
✓ Eye Contact

✓ Inhalation
✓ Ingestion

Skin Contact: May cause irritation

Effects of acute exposure

Eye Contact:

May cause irritation

Inhalation: May cause irritation

Ingestion: May be fatal if swallowed.

Effects of chronic exposure None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

 Component
 CAS#
 Weight %

 Proclin 300
 N/A
 <5%</td>

 Sodium Azide
 26628-22-8
 <5%</td>

 Sulfuric Acid
 7664-93-9
 2.8%

 TMB
 N/A
 *

In compliance with OSHA Hazard Communication Standard (29 CFR 1910.1200), a chemical is considered hazardous if it contains 1.0% or more of a hazardous compound or 0.1 % or more of a carcinogen. The product does NOT contain hazardous material(s) in excess of these amounts.

*Proprietary information

4. FIRST AID MEASURES

Eye Contact Flush eyes thoroughly with water. If irritation occurs, seek medical attention.

Skin Contact Wash affected area with water for at least 15 minutes

Inhalation Move exposed individual to fresh air. If individual is not breathing, begin artificial

respiration immediately.

Ingestion Seek medical attention if swallowed.

5. FIRE-FIGHTING MEASURES

Flammable No Flash point N/A

Extinguishing mediaUse alcohol-resistant foam, carbon dioxide water or dry chemical spray. Use water spray to

cool fire-exposed containers.

Auto-ignition temperature

Upper/Lower flammable

N/A

N/A



Hazardous combustion

None



6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Protect eyes and mucous membranes from contact. Use good

laboratory practice.

Environmental Precautions Contain spill to prevent contamination of surrounding areas. Do not

flush down the drain.

Leak and spill procedure

Dispose through a sanitary sewer, or use absorbent material and

dispose as non-hazardous waste.

7. HANDLING AND STORAGE

Handling No special precautions required. Use good laboratory practice

Keep container tightly closed away from acids. Store at room

temperature

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal Protective Equipment

Storage

Eye/Face Protection Safety goggles, glasses, or face shield recommended.

Skin Protection Latex or equivalent gloves recommended

Respiratory ProtectionUnder normal use conditions, no respiratory protection is

required.

Engineering MeasuresUse in well ventilated areas. **Exposure Guidelines**Avoid long or repeated exposure

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State N/A

Appearance N/A N/A

Odor N/A
Odor Threshold N/A
pH N/A
Vapor Pressure N/A

Vapor Pressure

Vapor Density

N/A

Specific Gravity

Evaporation Rate

N/A

Melting Point

N/A

Boiling Point

N/A

Solubility in Water

10. STABILITY AND REACTIVITY

Stability Stable at normal temperatures and pressures.

Hazardous PolymerizationNone knownIncompatible MaterialsNone knownHazardous Decomposition ProductsNone known

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

IrritationNo data availableSynergistic Products:No data available



LD50: MOPSO: No data available

Chronic Toxicity

Carcinogenicity Contains no ingredients listed as potential carcinogens by

ACGIH, IARC, NTP, OSHA

Sensitization to Product: No data available

Mutagenic Effects No data available

Reproductive/Developmental/Teratogenic

Effects

No data available

Other Adverse Effects None known

12. ECOLOGICAL INFORMATION

Ecotoxicity No data available

13. DISPOSAL INFORMATION

Waste Disposal Methods Dispose according to all local, state and federal regulations.

14. TRANPORT INFORMATION

Transportation of this product not regulated according to the definition of hazardous in 49CFR (US DOT). Transportation of this product is also not regulated by IATA, ICAO, Canadian TDG, or European ADR

N/A

N/A

IMDG/IMO

15. REGULATORY INFORMATION

SARA 313 No SARA 311/312 Hazardous Category **Acute Health Hazard** No **Chronic Health Hazard** No Fire Hazard No **Sudden Release of Pressure** No **Reactive Hazard** No Clean Water Act N/A Clean Air Act N/A **OSHA** N/A

California Proposition 65 N/A

16. OTHER INFORMATION

Prepared By: Erba Diagnostics' Regulatory Affairs

Revision Date 01/05/15

Disclaimer:

CERCLA

TSCA

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1. PRODUCT AND COMPANY IDENTIFICATION

Kit Components Substrate TMB

Catalog Number(s) See page 1

Recommended Use Components of an *in-vitro* diagnostic device

Erba Diagnostics

14100 NW 57th Court

Company Information Miami Lakes, FL 33014

Telephone: 305-418-2320

2. HAZARD(S) IDENTIFICATION

Route of Entry/Exposure

✓ Skin Contact
✓ Eye Contact
✓ Inhalation
✓ Ingestion

Skin Contact: May cause irritation

Eye Contact: May cause irritation

Libelation May cause irritation

Inhalation: May cause irritation

Ingestion: May be fatal if swallowed.

Effects of chronic exposure None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

ComponentCAS#Weight %Substrate solutionN/A100%

In compliance with OSHA Hazard Communication Standard (29 CFR 1910.1200), a chemical is considered hazardous if it contains 1.0% or more of a hazardous compound or 0.1 % or more of a

carcinogen. The product does NOT contain hazardous material(s).

4. FIRST AID MEASURES

Eye Contact Flush eyes thoroughly with water. If irritation occurs, seek medical attention.

Skin Contact Wash affected area with water for at least 15 minutes

Inhalation Move exposed individual to fresh air. If individual is not breathing, begin artificial

respiration immediately.

Ingestion Seek medical attention if swallowed.

5. FIRE-FIGHTING MEASURES

Flammable No Flash point N/A

Extinguishing mediaUse alcohol-resistant foam, carbon dioxide water or dry chemical spray. Use water spray

to cool fire-exposed containers.

Auto-ignition temperature

Upper/Lower flammable

N/A

N/A

Hazardous combustion

None



6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Protect eyes and mucous membranes from contact. Use good laboratory practice.

Environmental Precautions Contain spill to prevent contamination of surrounding areas. Do not flush down the drain.

Dispose through a sanitary sewer, or use absorbent material and dispose as non-hazardous

waste.



Storage

SAFETY DATA SHEET

7. HANDLING AND STORAGE

Handling No special precautions required. Use good laboratory practice

Keep container tightly closed away from acids. Store at room

temperature

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal Protective Equipment

Eye/Face Protection Safety goggles, glasses, or face shield recommended.

Skin Protection Latex or equivalent gloves recommended

Under normal use conditions, no respiratory protection is **Respiratory Protection**

required.

Engineering Measures Use in well ventilated areas. **Exposure Guidelines** Avoid long or repeated exposure

PHYSICAL AND CHEMICAL PROPERTIES

Physical State N/A

N/A N/A **Appearance**

N/A Odor N/A **Odor Threshold**

N/A pН N/A **Vapor Pressure** N/A **Vapor Density** N/A **Specific Gravity** N/A **Evaporation Rate** N/A **Melting Point Boiling Point** N/A N/A Solubility in Water

STABILITY AND REACTIVITY 10.

Stability Stable at normal temperatures and pressures.

Hazardous Polymerization None known None known **Incompatible Materials Hazardous Decomposition Products** None known

TOXICOLOGICAL INFORMATION 11.

Acute Toxicity

Irritation No data available **Synergistic Products:** No data available LD50: MOPSO: No data available

Chronic Toxicity

Contains no ingredients listed as potential carcinogens by Carcinogenicity

ACGIH, IARC, NTP, OSHA

Sensitization to Product: No data available **Mutagenic Effects** No data available Reproductive/Developmental/Teratogenic

Effects

No data available



Other Adverse Effects

12. ECOLOGICAL INFORMATION

Ecotoxicity No data available

13. DISPOSAL INFORMATION

Waste Disposal Methods Dispose according to all local, state and federal regulations.

None known

14. TRANPORT INFORMATION

Transportation of this product not regulated according to the TDG definition of hazardous in 49CFR (US DOT). Transportation of IATA this product is also not regulated by IATA, ICAO, Canadian IMDG/IMO TDG, or European ADR

REGULATORY INFORMATION 15. **TSCA** N/A **SARA 313** SARA 311/312 Hazardous Category No **Acute Health Hazard** No **Chronic Health Hazard** No Fire Hazard No **Sudden Release of Pressure** No Reactive Hazard No Clean Water Act N/A Clean Air Act N/A **OSHA** N/A **CERCLA** N/A California Proposition 65 N/A

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1. PRODUCT AND COMPANY IDENTIFICATION

Kit Components Stop N Solution **Catalog Number(s)** See page 1

Recommended Use Components of an *in-vitro* diagnostic device

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Eye Contact: May cause irritation
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ComponentCAS#Weight %Sulfuric Acid7664-93-92.8%

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Skin Contact Wash affected area with water for at least 15 minutes

Inhalation Move exposed individual to fresh air. If individual is not breathing, begin artificial

respiration immediately.

Ingestion Seek medical attention if swallowed.

5. FIRE-FIGHTING MEASURES

 $\begin{tabular}{ll} Flammable & No \\ Flash \ point & N/A \end{tabular}$

Extinguishing mediaUse alcohol-resistant foam, carbon dioxide water or dry chemical spray. Use water spray

to cool fire-exposed containers.

Auto-ignition temperature

Upper/Lower flammable

N/A

N/A

Hazardous combustion

None



6. ACCIDENTAL RELEASE MEASURES

Personal Precautions Protect eyes and mucous membranes from contact. Use good laboratory practice.

Environmental Precautions Contain spill to prevent contamination of surrounding areas. Do not flush down the drain.

Leak and spill procedure Use liquid binding material, use neutralizing agent. Dispose as contaminated waste.



7. HANDLING AND STORAGE

Handling No special precautions required. Use good laboratory practice

Keep container tightly closed away from acids. Store at room

Storage temperature

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Personal Protective Equipment

Eye/Face Protection Safety goggles, glasses, or face shield recommended.

Skin Protection Latex or equivalent gloves recommended

Respiratory ProtectionUnder normal use conditions, no respiratory protection is

required.

Engineering Measures
Use in well ventilated areas.

Exposure Guidelines
Avoid long or repeated exposure

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State N/A

Appearance N/A N/A

Odor N/A
Odor Threshold N/A

N/A pН N/A **Vapor Pressure** N/A **Vapor Density** N/A **Specific Gravity** N/A **Evaporation Rate** N/A **Melting Point Boiling Point** N/A N/A Solubility in Water

10. STABILITY AND REACTIVITY

Stability Stable at normal temperatures and pressures.

Hazardous PolymerizationNone knownIncompatible MaterialsNone knownHazardous Decomposition ProductsNone known

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Mutagenic Effects

No data available

No data available

Reproductive/Developmental/Teratogenic

Effects

No data available



Other Adverse Effects

None known

12. ECOLOGICAL INFORMATION

Ecotoxicity No data available

13. DISPOSAL INFORMATION

Waste Disposal Methods Dispose according to all local, state and federal regulations.

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TDG, or European ADR

15. REGULATORY INFORMATION	
TSCA	N/A
SARA 313	
SARA 311/312 Hazardous	ategory No
Acute Health Hazar	l No
Chronic Health Haz	ard No
Fire Hazard	No
Sudden Release of I	ressure No
Reactive Hazard	No
Clean Water Act	N/A
Clean Air Act	N/A
OSHA	N/A
CERCLA	N/A
California Proposition 65	N/A

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