

COVER SHEET

Product Name Diamedix ELISA Kits

Company Information Erba Diagnostics
14100 NW 57th Court
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. pylori 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 <i>in-vitro</i> diagnostic device		
Company Information	Erba Diagnostics 14100 NW 57 th Court Miami Lakes, FL 33014 Telephone: 305-418-2320		

2. HAZARD(S) IDENTIFICATION

Route of Entry/Exposure	<input checked="" type="checkbox"/> Skin Contact	<input checked="" type="checkbox"/> Eye Contact	<input checked="" type="checkbox"/> Inhalation	<input checked="" type="checkbox"/> Ingestion
Effects of acute exposure	Skin Contact:	Eye Contact:	Inhalation:	Ingestion:
Effects of chronic exposure	None known			

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS#	Weight %
Proclin 300	N/A	<5%
Sodium Azide	26628-22-8	<5%
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 media	Use alcohol-resistant foam, carbon dioxide water or dry chemical spray. Use water spray to cool fire-exposed containers.
Auto-ignition temperature	N/A
Upper/Lower flammable limit	N/A
Hazardous combustion products	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
Storage	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
Respiratory Protection	Under 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	
pH	N/A	
Vapor Pressure	N/A	
Vapor Density	N/A	
Specific Gravity	N/A	
Evaporation Rate	N/A	
Melting Point	N/A	
Boiling Point	N/A	
Solubility in Water	N/A	

10. STABILITY AND REACTIVITY

Stability	Stable at normal temperatures and pressures.
Hazardous Polymerization	None known
Incompatible Materials	None known
Hazardous Decomposition Products	None known

11. TOXICOLOGICAL INFORMATION

Acute Toxicity	
Irritation	No data available
Synergistic 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. TRANSPORT INFORMATION

DOT	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
TDG	
IATA	
IMDG/IMO	

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Prepared By:	Erba Diagnostics' Regulatory Affairs
Revision Date	01/05/15

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of this publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release; it is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

1. PRODUCT AND COMPANY IDENTIFICATION

Kit Components	Substrate TMB
Catalog Number(s)	See page 1
Recommended Use	Components of an <i>in-vitro</i> diagnostic device
Company Information	Erba Diagnostics 14100 NW 57 th Court Miami Lakes, FL 33014 Telephone: 305-418-2320

2. HAZARD(S) IDENTIFICATION

Route of Entry/Exposure	<input checked="" type="checkbox"/> Skin Contact	<input checked="" type="checkbox"/> Eye Contact	<input checked="" type="checkbox"/> Inhalation	<input checked="" type="checkbox"/> Ingestion
Effects of acute exposure	Skin Contact:	May cause irritation		
	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 %
Substrate solution	N/A	100%
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 media	Use alcohol-resistant foam, carbon dioxide water or dry chemical spray. Use water spray to cool fire-exposed containers.
Auto-ignition temperature	N/A
Upper/Lower flammable limit	N/A
Hazardous combustion products	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
Storage	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
Respiratory Protection	Under 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	
pH	N/A	
Vapor Pressure	N/A	
Vapor Density	N/A	
Specific Gravity	N/A	
Evaporation Rate	N/A	
Melting Point	N/A	
Boiling Point	N/A	
Solubility in Water	N/A	

10. STABILITY AND REACTIVITY

Stability	Stable at normal temperatures and pressures.
Hazardous Polymerization	None known
Incompatible Materials	None known
Hazardous Decomposition Products	None known

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Irritation	No data available
Synergistic 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. TRANSPORT INFORMATION

DOT

TDG

IATA

IMDG/IMO

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

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Prepared By: Erba Diagnostics' Regulatory Affairs

Revision Date 01/05/15

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of this publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release; it is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.

1. PRODUCT AND COMPANY IDENTIFICATION

Kit Components	Stop N Solution
Catalog Number(s)	See page 1
Recommended Use	Components of an <i>in-vitro</i> diagnostic device
Company Information	Erba Diagnostics 14100 NW 57 th Court Miami Lakes, FL 33014 Telephone: 305-418-2320

2. HAZARD(S) IDENTIFICATION

Route of Entry/Exposure	<input checked="" type="checkbox"/> Skin Contact	<input checked="" type="checkbox"/> Eye Contact	<input checked="" type="checkbox"/> Inhalation	<input checked="" type="checkbox"/> Ingestion
Effects of acute exposure	Skin Contact:	May cause irritation		
	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 %
Sulfuric Acid	7664-93-9	2.8%

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.

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 media	Use alcohol-resistant foam, carbon dioxide water or dry chemical spray. Use water spray to cool fire-exposed containers.
Auto-ignition temperature	N/A
Upper/Lower flammable limit	N/A
Hazardous combustion products	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
Storage	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
Respiratory Protection	Under 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	
pH	N/A	
Vapor Pressure	N/A	
Vapor Density	N/A	
Specific Gravity	N/A	
Evaporation Rate	N/A	
Melting Point	N/A	
Boiling Point	N/A	
Solubility in Water	N/A	

10. STABILITY AND REACTIVITY

Stability	Stable at normal temperatures and pressures.
Hazardous Polymerization	None known
Incompatible Materials	None known
Hazardous Decomposition Products	None known

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Irritation	No data available
Synergistic 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. TRANSPORT INFORMATION

DOT
TDG
IATA
IMDG/IMO

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

15. REGULATORY INFORMATION

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

16. OTHER INFORMATION

Prepared By: Erba Diagnostics' Regulatory Affairs

Revision Date 01/05/15

Disclaimer:

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of this publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release; it is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text.