

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 |
|----------------|------------------------------------|
| 720-700 | Is [®] -anti-dsDNA |
| 720-710 | Is [®] -Rheumatoid Factor |
| 720-790 | Is [®] -ANA ELISA Screen |

1. PRODUCT AND COMPANY IDENTIFICATION

| | | | |
|----------------------------|---|----------------|-----------------|
| Kit Components | Calibrator | Sample Diluent | Substrate TMB |
| | Positive Control | Conjugate | Wash |
| | Negative Control | | Stop O 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% |
| Hydrochloric Acid | 7647-01-0 | 8.3% |
| 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 |
| 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 |
| 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

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1. PRODUCT AND COMPANY IDENTIFICATION

| | |
|----------------------------|---|
| Kit Components | Stop O 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 % |
|-------------------|-----------|----------|
| Hydrochloric Acid | 7647-01-0 | 8.3% |

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

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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

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