



MATERIAL SAFETY DATA SHEET

SECTION 1: CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Name(s): Anti-Cardiolipin IgG/IgM Test Kit
Anti-Cardiolipin IgA Test Kit

Product Number(s): 023-001, 023-002, 026-001, 026-006

Corgenix, Inc.
11575 Main Street, Suite 400
Broomfield, CO 80020

Emergency Telephone Number
(800) 729-5661
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SECTION 2: COMPOSITION/INFORMATION ON INGREDIENTS

| <u>Component</u> | <u>CAS Number</u> | <u>Percentage</u> |
|---|------------------------|-------------------|
| Substrate | 54827-17-7 | NA |
| 3,3',5,5'-Tetramethylbenzidine | 54827-17-7 | 100.0 |
| Sample Diluent I | Not Established | NA |
| Bovine Calf Serum | Not Established | 10.0 |
| Water | 7732-18-5 | 88.9 |
| All other ingredients are non-hazardous | NA | NA |
| 33X PBS Wash Concentrate | Not Established | NA |
| Potassium Phosphate Dibasic | 7758-11-4 | 4.7 |
| Sodium Chloride | 7647-14-5 | 28.1 |
| Water | 7732-18-5 | 66.0 |
| All other ingredients are non-hazardous | NA | NA |
| Stopping Solution (0.36 N Sulfuric Acid) | Not Established | NA |
| Sulfuric Acid | 7664-93-9 | 1.0 |
| Water | 7732-18-5 | 99.0 |
| IgA/IgG/IgM Conjugate | Not Established | NA |
| Chemicals in these components are considered proprietary; please contact Corgenix for further information | | |
| IgA/IgG/IgM Normal/Positive Controls | Not Established | NA |
| Human Serum* | Not Established | 99.9 |
| All other ingredients are non-hazardous | NA | NA |
| IgA/IgG/IgM Calibrators | Not Established | NA |
| Human Serum* | Not Established | 99.9 |
| All other ingredients are non-hazardous | NA | NA |

*The human serum or plasma used in these products has been tested and found negative for HIV 1 and 2 antibodies, Hepatitis C Virus (HCV), and Hepatitis B surface antigen.

SECTION 3: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

Substrate

Color: Clear
Physical Form: Liquid
Odor: None identified
Major Health Hazards: Eye/skin irritation
NFPA Rating (Scale 0-4): Health=1; Fire=1; Reactivity=0



Sample Diluent I

Color: Green
Physical Form: Liquid
Odor: None identified
Major Health Hazards: Eye/skin irritation
NFPA Rating (scale 0-4): Health=1; Fire=1; Reactivity=0



33X PBS Wash Concentrate

Color: Clear
Physical Form: Liquid
Odor: None Identified
Major Health Hazards: Eye/skin irritation
NFPA Rating (Scale 0-4): Health=2; Fire=0; Reactivity=0



Stopping Solution (0.36 N Sulfuric Acid)

Color: Clear
Physical Form: Liquid
Odor: None identified
Major Health Hazards: Eye/skin irritation
NFPA Rating (Scale 0-4): Health=1; Fire= 0; Reactivity=0



IgA/IgG/IgM Conjugate

Color: IgA Conjugate = Orange; IgG Conjugate = Blue; IgM Conjugate = Red
Physical Form: Liquid
Odor: None identified
Major Health Hazards: No significant health effects reported.
NFPA Rating (Scale 0-4): Not available

IgA/IgG/IgM Normal/Positive Controls

Color: Yellowish
Physical Form: Liquid
Odor: None identified
Major Health Hazards: Eye/skin irritation
NFPA Rating (Scale 0-4): Health=1; Fire=0; Reactivity=0



IgA/IgG/IgM Calibrators

Color: Yellowish
Physical Form: Liquid
Odor: None Identified
Major Health Hazards: Eye/skin irritation
NFPA Rating (Scale 0-4): Health=1; Fire=0; Reactivity=0





POTENTIAL HEALTH EFFECTS:

Substrate (3,3',5,5'-Tetramethylbenzidine)

Inhalation:

Short Term Exposure: Irritation

Long Term Exposure: No information available

Skin Contact:

Short Term Exposure: Irritation

Long Term Exposure: No information available

Eye Contact:

Short Term Exposure: Irritation

Long Term Exposure: No information available

Ingestion:

Short Term Exposure: No information available

Long Term Exposure: No information available

Carcinogen Status:

OSHA: No

NTP: No

IARC: No

Sample Diluent I (Bovine Calf Serum)

Inhalation:

Short Term Exposure: No information available

Long Term Exposure: No information available

Skin Contact:

Short Term Exposure: No information available

Long Term Exposure: No information available

Eye Contact:

Short Term Exposure: No information available

Long Term Exposure: No information available

Ingestion:

Short Term Exposure: No information available

Long Term Exposure: No information available

Carcinogen Status:

OSHA: No

NTP: No

IARC: No

33X PBS Wash Concentrate (Sodium Chloride)

Inhalation:

Short Term Exposure: Irritation

Long Term Exposure: No information available

Skin Contact:

Short Term Exposure: Irritation

Long Term Exposure: Irritation



Product Number(s): 023-001, 023-002, 026-001, 026-006

Eye Contact:

Short Term Exposure: Irritation

Long Term Exposure: Irritation

Ingestion:

Short Term Exposure: Fever, nausea, vomiting, diarrhea, disorientation, lung congestion, effects on the brain, convulsions, and coma.

Long Term Exposure: No information on significant adverse effects

Carcinogen Status:

OSHA: No

NTP: No

IARC: No

Stopping Solution (0.36 N Sulfuric Acid)

Inhalation:

Short Term Exposure: No information available

Long Term Exposure: No information available

Skin Contact:

Short Term Exposure: Irritation

Long Term Exposure: No information available

Eye Contact:

Short Term Exposure: No information available

Long Term Exposure: No information available

Ingestion:

Short Term Exposure: No information available

Long Term Exposure: No information available

Carcinogen Status:

OSHA: No

NTP: Yes

IARC: Yes

IgA/IgG/IgM Conjugate (HRP Conjugate Stabilizing Solution)

Inhalation:

Short Term Exposure: No information available

Long Term Exposure: No information available

Skin Contact:

Short Term Exposure: No information available

Long Term Exposure: No information available

Eye Contact:

Short Term Exposure: No information available

Long Term Exposure: No information available

Ingestion:

Short Term Exposure: No information available

Long Term Exposure: No information available



Carcinogen Status:

OSHA: No

NTP: No

IARC: No

IgA/IgG/IgM Conjugate (Glycerol)

Inhalation:

Short Term Exposure: Irritation, difficulty breathing

Long Term Exposure: No information available

Skin Contact:

Short Term Exposure: Irritation

Long Term Exposure: Irritation

Eye Contact:

Short Term Exposure: Irritation

Long Term Exposure: No information available

Ingestion:

Short Term Exposure: Fever, nausea, vomiting, diarrhea, headache, dizziness, sleep disturbances, blood disorders, kidney damage, paralysis, convulsions

Long Term Exposure: No information on significant adverse effects

Carcinogen Status:

OSHA: No

NTP: No

IARC: No

IgA/IgG/IgM Conjugate (Bovine Serum Albumin)

Inhalation:

Short Term Exposure: No information on significant adverse effects

Long Term Exposure: No information available

Skin Contact:

Short Term Exposure: Irritation

Long Term Exposure: No information available

Eye Contact:

Short Term Exposure: Irritation

Long Term Exposure: No information available

Ingestion:

Short Term Exposure: No information on significant adverse effects

Long Term Exposure: No information available

Carcinogen Status:

OSHA: No

NTP: No

IARC: No



IgA/IgG/IgM Conjugate (Chicken Serum)

Inhalation:

Short Term Exposure: No information on significant adverse effects

Long Term Exposure: No information available

Skin Contact:

Short Term Exposure: Irritation

Long Term Exposure: No information available

Eye Contact:

Short Term Exposure: Irritation

Long Term Exposure: No information available

Ingestion:

Short Term Exposure: No information on significant adverse effects

Long Term Exposure: No information available

Carcinogen Status:

OSHA: No

NTP: No

IARC: No

Normal/Positive Controls (Human Serum)

Inhalation:

Short Term Exposure: Irritation

Long Term Exposure: Irritation

Skin Contact:

Short Term Exposure: Irritation

Long Term Exposure: Irritation

Eye Contact:

Short Term Exposure: Irritation

Long Term Exposure: Irritation

Ingestion:

Short Term Exposure: May be harmful if swallowed

Long Term Exposure: May be harmful if swallowed

Carcinogen Status:

OSHA: No

NTP: No

IARC: No

IgA/IgG/IgM Calibrators (Human Serum)

See Sample Negative/Positive Controls above.

SECTION 4: FIRST AID MEASURES

INHALATION: If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. If breathing is difficult, oxygen should be administered by qualified personnel. Get immediate medical attention.

SKIN CONTACT: Wash with copious amounts of water for at least 15 minutes. Remove contaminated clothing and wash before reuse. Consult a physician.

EYE CONTACT: Immediately flush with copious amounts of water for at least 15 minutes. Consult a physician.

INGESTION: If swallowed, wash mouth with water. Consult a physician immediately. Do not give anything by mouth to unconscious or convulsive person.

SECTION 5: FIRE FIGHTING MEASURES

FIRE AND EXPLOSION HAZARDS:

All Kit Components: Slight fire hazard. Air mixtures may ignite or explode.

EXTINGUISHING MEDIA:

All Kit Components: Regular dry chemical, carbon dioxide, water, regular foam.

Large fires: Use regular foam or flood with fine water spray.

FIRE FIGHTING:

All Kit Components: Move container from fire area if it can be done without risk. Cool containers with water spray until well after the fire is out. Do not scatter spilled material with high-pressure water streams. Dike for later disposal. Use extinguishing agents appropriate for surrounding fire. Avoid inhalation of material or combustion by-products. Stay upwind and keep out of low areas.

SECTION 6: ACCIDENTAL RELEASE MEASURES

OCCUPATIONAL RELEASE: Collect spilled material in appropriate container for disposal. Keep out of water supplies and sewers. Keep unnecessary people away, isolate hazard area and deny entry. Wash hands thoroughly after cleanup of spill.

SECTION 7: HANDLING AND STORAGE

Anti-Cardiolipin IgG/IgM Test Kit and Anti-Cardiolipin IgA Test Kit: Store as a kit at 2-8° C. Keep containers tightly closed. Wash hands with soap and water after handling.

SECTION 8: EXPOSURE CONTROLS AND PERSONAL PROTECTION

EXPOSURE LIMITS:

Stopping Solution (0.36 N Sulfuric Acid):

1 mg/m³ OSHA TWA

0.2 mg/m³ ACGIH TWA (thoracic particulate)

3 mg/m³ ACGIH STEL

1 mg/m³ NIOSH recommended TWA 10 hour(s)

All Other Kit Components: No occupational exposure limits established.

PERSONAL PROTECTIVE EQUIPMENT:

Eye Protection: Wear ANSI Z87 safety glasses with side shields.

Clothing: Laboratory coat.

Gloves: Wear chemical resistant gloves.

Respirator: Not required

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Reagents aqueous (i.e., water based) solutions and are color-coded by the addition of non-hazardous coloring agents to ease identification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY: All reagents are stable under recommended storage conditions.

CONDITIONS TO AVOID: None reported

INCOMPATIBILITIES: None reported

HAZARDOUS DECOMPOSITION: Nature of decomposition products not known.

POLYMERIZATION: Will not occur

SECTION 11: TOXICOLOGICAL INFORMATION

HEALTH EFFECTS: Stopping Solution (0.36 N Sulfuric Acid):

Short Term Exposure: No information available

Long Term Exposure: No information available

Inhalation:

Acute Exposure: No information available

Chronic Exposure: No information available



Product Number(s): 023-001, 023-002, 026-001, 026-006

Skin Contact:

Acute Exposure: Irritation

Chronic Exposure: No information available

Eye Contact:

Acute Exposure: No information available

Chronic Exposure: No information available

Ingestion:

Acute Exposure: No information available

Chronic Exposure: No information available

HEALTH EFFECTS (All Other Kit Components): No information available

SECTION 12: ECOLOGICAL INFORMATION

ECOTOXICITY DATA: No information available

SECTION 13: DISPOSAL CONSIDERATIONS

Keep out of water supplies and sewers [some of the kit components contain a non-hazardous percentage of sodium azide (<1%)]. Dispose in accordance with all applicable regulations.

SECTION 14: TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION:

Stopping Solution (0.36 N Sulfuric Acid): Exempt per 49 CFR 173.136 B DOT skin corrosion test results.

All Other Kit Components: Not regulated

CANADIAN TRANSPORTATION OF DANGEROUS GOODS:

Stopping Solution (0.36 N Sulfuric Acid): Exempt per skin corrosion test results.

All Other Kit Components: Not regulated

LAND TRANSPORT ADR: Exempt

LAND TRANSPORT RID: Exempt

AIR TRANSPORT IATA:

Stopping Solution (0.36 N Sulfuric Acid): Exempt per skin corrosion test results.

All Other Kit Components: Not regulated



SECTION 15: REGULATORY INFORMATION

U.S. REGULATIONS:

CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4):

Stopping Solution (0.36 N Sulfuric Acid): 1,000 lb RQ

All Other Kit Components: Not regulated

SARA TITLE III SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.30):

Stopping Solution (0.36 N Sulfuric Acid): 1,000 lb TPQ

All Other Kit Components: Not regulated

SARA TITLE III 304 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355.40):

Stopping Solution (0.36 N Sulfuric Acid): 1,000 lb RQ

All Other Kit Components: Not regulated

SARA TITLE III SARA SECTIONS 311/312 HAZARDOUS CATEGORIES (40 CFR 370.21):

Substrate (3,3',5,5'-Tetramethylbenzidine):

Acute: No

Chronic: Yes

Fire: No

Reactive: No

Sudden Release: No

33X PBS Wash Concentrate (Sodium Chloride):

Acute: Yes

Chronic: No

Fire: No

Reactive: No

Sudden Release: No

Stopping Solution (0.36 N Sulfuric Acid):

Acute: Yes

Chronic: No

Fire: No

Reactive: No

Sudden Release: No

All Other Kit Components: Not regulated

SARA TITLE III SECTION 313 (40 CFR 372.65):

All Kit Components: Not regulated

OSHA PROCESS SAFETY (29 CFR 1910.119):

All Kit Components: Not regulated



STATE REGULATIONS:

California Proposition 65:

All Kit Components: Not regulated

CANADIAN REGULATIONS:

WHMIS CLASSIFICATION: Not determined

EUROPEAN UNION REGULATIONS:

EU RISK AND SAFETY PHRASES:

33X PBS Wash Concentrate (Sodium Chloride):

| | |
|------|---|
| R 36 | Irritating to eyes. |
| S 24 | Avoid contact with skin. |
| S 25 | Avoid contact with eyes. |
| S 26 | In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. |
| S 46 | If swallowed, seek medical advice immediately and this container or label. |

Stopping Solution (0.36 N Sulfuric Acid):

| | |
|------|--------------------------|
| S 24 | Avoid contact with skin. |
| S 25 | Avoid contact with eyes. |

All Other Kit Components: Not determined

NATIONAL INVENTORY STATUS:

U.S. INVENTORY (TSCA): All products are subject to regulation under the Federal Food, Drug and Cosmetics Act and are, therefore, exempt from the US Toxic Substances Control Act Inventory Listing requirements.

SECTION 16: OTHER INFORMATION

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Corgenix, Inc. shall not be held liable for any damages resulting from handling or from contact with the above product.