



Conforms to 93/112/EC and ISO 11014-1

Responsible Name: Diazyme Administration
Effective: 05/05/10

SECTION 1: PRODUCT and COMPANY IDENTIFICATION

| <u>PRODUCT NAME:</u> | <u>PART #</u> |
|---------------------------------------|---------------|
| Homocysteine 2 PT Calibrator | DZ568A-CAL |
| Homocysteine 3 PT Calibrator | DZ568B-CAL |
| Homocysteine 5 PT Calibrator | DZ568A-CA5 |
| Homocysteine 4 Level Control | DZ568A-CON |
| Roche Partner Channel 2 Level Control | DZ568CL2 |
| Roche Partner Channel 4 Level Control | DZ568CON |
| Roche Partner Channel Calibrator | DZ568CAL |

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| Supplier: Diazyme Laboratories 12889 Gregg Court Poway, CA 92064, USA 858-455-4754 | Manufacturer: Diazyme Laboratories 12889 Gregg Court Poway, CA 92064, USA 858-455-4754 | Authorized Representative: MDSS GmbH Schiffgraben 41 30175 Hannover Germany |
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In case of Emergency: Call Diazyme Laboratories (858-455-4754)

Intended Use: Refer to the instruction booklet for proper and intended use. Otherwise, contact supplier for specific applications.

SECTION 2: HAZARDOUS INGREDIENTS

| Product | Ingredient | Amount | CAS # | EINECS # | Symbols |
|---------|------------|--------|-------|----------|---------|
| All | N/A | N/A | N/A | N/A | N/A |

NOTE: Any physical and health information noted is based on 1) evaluation of data for the pure ingredients, and 2) concentration of ingredients as packaged. To the best of our knowledge, this product contains no hazardous ingredients as defined by OSHA, or WHMIS.

Emergency Overview: The chemical, physical and toxicological properties of this preparation, pertaining directly to occupational exposures, have not been thoroughly characterized.

Precautionary Statements: Avoid contact with eye and skin. Do not ingest or inhale. The human serum in the preparation was tested by FDA-approved methods and found to be negative for the presence of hepatitis B virus surface antigen (HBsAg), human immunodeficiency virus (HIV) 1&2 and hepatitis C virus (HCV). However, because no test method can provide complete assurance that infectious agents are absent, this product should be handled as a potentially biohazardous material in accordance with Universal/Standard Precautions.

Regulatory Status: This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; EC. Directive 1999/45/EC; Canadian R.S. 1985. c.H-3; U.K. CHIPS 2002No. 1689; or U.N. GHS ST/SG/AC 10/30. None of the components present in this preparation at concentration equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

SECTION 3: HAZRAD IDENTIFICATION

Emergency Overview: This component contains human serum. Material is a Biohazards, and it is recommended that the material be handled using universal precautions.

Health Hazards: The serum-based components of this product have no known potential effects in acute or chronic exposure.

Flammability Hazards: The components of this product are not flammable.

Emergency

Recommendations: Emergency responders must wear personal protective equipment suitable for situation to which they are responding.

SECTION 4: FIRST AID MEASURES

After Inhalation: Not applicable

After Skin Contact: Wash with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes and wash before wearing.

After Eye Contact: Flush eyes with plenty of water for at least 15 minutes. Separate eyelids with fingers in order to ensure complete flushing. Consult a physician.

Ingestion: Wash mouth out with water provided the person is conscious. Consult a physician.

SECTION 5: FIRE FIGHTING MEASURES

Suitable Extinguishing Agents: Not applicable

Special Hazards Caused by the Material, its Products of Combustion or Resulting Gases: Not applicable

Protective Equipment: Not applicable

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SECTION 6: ACCIDENTIAL RELEASE MEASURES

Personal Precautions: Wear Personal Protective Equipment (PPE) as indicated in Section 8. Avoid physical contact with material. Wash hands thoroughly after handling.

Environmental Handling: If the calibrators or controls enter drain, flush with a large volume of water.

Measures for Cleaning/Collecting: Place absorbent and used material into a properly labeled leak-proof container. Container must be labeled according to CFR 29 1910.1030(g)(1)(i). Consult local authorities before disposal.

SECTION 7: HANDLING AND STORAGE

Handling: Handle as if capable of transmitting diseases. Wash hands with soap and water after handling this material. Do not eat, drink, smoke, apply cosmetics or lip balm, or handle contact lenses with working with this material. All procedures involving this product must be done in ways that minimize splashing, spraying, spattering, and generation of droplets of this substance.

Storage: Containers must be kept closed when not in use. Store in original container at 2-8 °C.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines: There are no ACGIH, NIOSH, OSHA or country specific occupational exposure limits currently established for components present in this preparation at concentration equal to or greater than 1% (0.1% if carcinogen).

Engineering Controls: Preparation and handling of this material should be performed in accordance with Universal/Standard Precautions. Facilities storing or utilizing this preparation should be equipped with an eyewash fountain and a safety shower.

PERSONAL PROTECTIVE EQUIPMENT

Respiratory: Not normally needed.

Skin: Protective gloves. Disposable gloves must be replaced as soon as practical whenever contamination occurs.

Eye: Masks in combination with goggles or glasses with solid side shields should be worn whenever eye contamination can be reasonably anticipated.

Protective Clothing: Appropriate protective clothing such as gowns, aprons, lab coats, and clinic jackets should be worn in occupational exposure situations.

GENERAL HYGIENE MEASURES

Wash thoroughly after handling.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Straw to amber color

Odor: Odorless

Boiling Point: Not available

Melting Point: Not available

Freezing Point: Not available

Specific Gravity: Not available

Vapor pressure: Not available

Vapor Density: Not available

Solubility: Not available

pH: Not available

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability: Stable under ordinary conditions of use and storage.

Conditions to Avoid: None known

Incompatibilities with Other Materials: None known

Hazardous Decomposition Products: None expected under normal conditions of use.

Hazardous Polymerization: Will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute Effects: May be harmful by inhalation, ingestion, or skin absorption. May cause irritation. The toxicological properties of the material are not known.

Chronic Effects: None known for this product.

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: No information available for product.

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SECTION 13: DISPOSAL CONSIDERATIONS

Method of Disposal: If the preparation enters drain, flush with a large volume of water. Remaining unused material and product waste should be treated as biohazardous/infectious waste and contaminated instruments and surfaces should be disinfected in accordance with your employer's Universal/Standard precautions. Observe all federal, state and local environmental regulations.

Packaging: Containers of the calibrator and control may retain product residues. Handle contaminated packaging in the same way as the substance itself and dispose according to instructions. If not officially specified differently, non-contaminated packaging may be treated like household waste or recycled.

Water Classification: Biological/chemical waste generators must refer to the relevant waste regulations to ensure complete and accurate classification. Disposal regulations may vary according to geographic location.

SECTION 14: TRANSPORTATION INFORMATION

Basic Shipping Description: Contact Diazyme Laboratories for shipping information.

SECTION 15: REGULATORY INFORMATION**UNITED STATES REGULATORY INFORMATION**

This preparation (calibrators and controls) is a component of an FDA-regulated in vitro diagnostic device.

CANADA REGULATORY INFORMATION

WHMIS Status: Non-controlled.

WHMIS:

This MSDS has been prepared according to the hazard criteria of the Controlled Products Regulations (CPR) and the MSDS contains all of the information required by the CPR.

SECTION 16: OTHER INFORMATION

PREPARED BY: Diazyme Administration

PHONE NO: 858-455-4754

DATE PREPARED: 26-04-2010

The information provided on this Material Safety Data Sheet is provided in the interest of promoting safe handling of the material. While this information is believed to be correct Diazyme makes no warranty in respect to any of the information disclosed. Observe all federal, provincial, state and local laws concerning health and pollution.