



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

Responsible Name: Diazyme Administration
Effective 08/06/08

SECTION 1: PRODUCT and COMPANY IDENTIFICATION

PRODUCT NAME:
LDL-Cholesterol Assay
HDL/LDL Calibrator

CATALOG #
DZ128A-KY1
DZ130A-CAL

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

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
Reagent R1	MES (4-Morpholineethansulfonic acid monohydrate; 2-(N-Morpholino) ethanesulfonic acid)	10%	4432-31-9	NA	NA
Reagent R2	Triton	2%	127087870	NA	NA

NOTE: Physical and health hazard information on reagent mixtures has not been determined. 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.

Product	Ingredient	Amount	CAS #	EINECS #	Symbols
Calibrator	Human serum	>99%	NA	NA	NA

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 component 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: The LDL-Cholesterol R1 solution of this product is a clear, odorless liquid. R2 solution is a light yellow odorless liquid.

Health Hazards: The components of this product may irritate contaminated tissues by inhalation, skin, or eye contact.

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.

MES:

Emergency Overview WARNING! TOXICOLOGICAL PROPERTIES UNKNOWN. MAY BE HARMFUL IF SWALLOWED, INHALED OR ABSORBED THROUGH SKIN. MAY CAUSE IRRITATION TO SKIN, EYES, AND RESPIRATORY TRACT.

SAF-T-DATA^(tm) Ratings (Provided here for your convenience)

Health Rating: 1 - Slight
Flammability Rating: 1 - Slight
Reactivity Rating: 0 - None
Contact Rating: 2 - Moderate
Lab Protective Equip: GOGGLES; LAB COAT; PROPER GLOVES
Storage Color Code: Green (General Storage)

Potential Health Effects

The toxicological properties of this material have not been investigated.

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Inhalation: No information found, but compound should be handled as a potential health hazard. May cause irritation to the respiratory tract. Symptoms may include coughing, sore throat, labored breathing, and chest pain.

Ingestion: No information found, but compound should be handled as a potential health hazard. May cause irritation to the gastrointestinal tract. Symptoms may include nausea, vomiting and diarrhea.

Skin Contact: No information found, but compound should be handled as a potential health hazard. May cause irritation with redness and pain. May be absorbed through the skin with possible systemic effects.

Eye Contact: No information found, but compound should be handled as a potential health hazard. May cause irritation, redness and pain.

Chronic Exposure: No information found.

Aggravation of Pre-existing Conditions: No information found.

Triton:
LD50 LC50 Mixture:ORAL LD50 (RAT): 1310 MG/KG
Routes of Entry: **Inhalation:Yes Skin:Yes Ingestion:Yes**
Reports of Carcinogenicity:NTP:No IARC:No OSHA:No
Health Hazards Acute and Chronic:Harmful if swallowed, inhaled, or absorbed through eyes/skin: severe irritant. Inhalation : irritation to mucous membranes & upper respiratory tract.
Explanation of Carcinogenicity:None

SECTION 4: FIRST AID MEASURES

After Inhalation: Supply fresh air; consult doctor in case of complaints.

After Skin Contact: Wash with soap and water and rinse thoroughly. Remove solid clothing.

After Eye Contact: Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

After Swallowing: Wash out mouth and then drink plenty of water. Consult a doctor for instructions.

SECTION 5: FIRE FIGHTING MEASURES

Suitable Extinguishing Agents: CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam. Use fire-fighting measures that suits the environment.

Special Hazards Caused by the Material, its Products of Combustion or Resulting Gases: In case of fire, the following can be released:
Nitrogen oxides (NO_x)
Sulfur oxides (SO_x)
Carbon monoxides (CO)

Protective Equipment: Wear full protective suit and self-contained respiratory protective device.

SECTION 6: ACCIDENTAL 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 reagent enters drain, flush with a large volume of water.

Measures for Cleaning/Collecting: Clean up spills immediately, observing precautions in the Protective Equipment section. Sweep up or absorb material, then place into a suitable clean, dry, closed container for disposal. Avoid generating dusty conditions.

SECTION 7: HANDLING AND STORAGE

Handling: Wash thoroughly after handling. Remove contaminated clothing and wash before reuse. Use with adequate ventilation. Avoid contact with eyes, skin, and clothing. Keep container tightly closed. Avoid ingestion and inhalation. Discard contaminated shoes.

Storage: Store in original container at 2-8°C, protect from direct sunlight.

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: Respiratory: Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU). Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks.

Hand: Protective gloves

Eye: Chemical safety goggles.

GENERAL HYGIENE MEASURES

Wash thoroughly after handling.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Appearance: R1- Clear; R2- Light yellow
Odor: Odorless
Boiling Point: N/A
Melting Point: N/A
Freezing Point: N/A
Specific Gravity: N/A
Vapor pressure: N/A
Vapor Dendity: N/A
Solubility: Water soluble
pH: 6.20-6.60

MES:
Appearance: White crystalline powder.
Odor: Odorless.
Solubility: Soluble in water.
Density: No information found.
pH: No information found.
% Volatiles by volume @ 21C (70F): 0
Boiling Point: No information found.
Melting Point: > 300C (> 572F)
Vapor Density (Air=1): No information found.
Vapor Pressure (mm Hg): No information found.
Evaporation Rate (BuAc=1): No information found.

Triton:
Vapor Pres: 0
Spec Gravity: 1.068
Solubility in Water: Dispersable
Appearance and Odor: Liquid
Percent Volatiles by Volume: 0

SECTION 10: STABILITY AND REACTIVITY

Chemical Stability: Stable under ordinary conditions of use and storage.
Conditions to Avoid: Avoid heat, flames, sparks, and ignition sources. Excessive heat may damage the product. Avoid prolonged exposure to direct sunlight.
Incompatibilities with Other Materials: Avoid strong oxidizing agents, strong acids.
Hazardous Decomposition Products: None expected under normal conditions of use.
Hazardous Polymerization: Will not occur.

SECTION 11: TOXICOLOGICAL INFORMATION

Acute Effects: For the calibrator, the human serum in this preparation presents a risk for exposure to infectious agents.

Chronic Effects: Data indicating the presence or absence of chronic effects from repeat long-term occupational exposure to this preparation is not yet available.

MES:

No LD50/LC50 information found relating to normal routes of occupational exposure.

-----\Cancer Lists\-----
---NTP Carcinogen---
Ingredient Known Anticipated IARC Category

4-Morpholineethanesulfonic Acid No No None
(4432-31-9)

SECTION 12: ECOLOGICAL INFORMATION

Ecotoxicity: No information available for product.

SECTION 13: DIAPOSAL 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



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precautions.
Packaging: Containers of the calibrator 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.

MES:
Whatever cannot be saved for recovery or recycling should be managed in an appropriate and approved waste disposal facility. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations. Dispose of container and unused contents in accordance with federal, state and local requirements.

SECTION 14: TRANSPORTATION INFORMATION

Basic Shipping Description: Contact Diazyme Laboratories for shipping information.

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATORY INFORMATION

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

CANADA REGULATORY INFORMATION

WHMIS Status: Non-controlled.

MES:

-----\Chemical Inventory Status - Part 1\-----
Ingredient TSCA EC Japan Australia

4-Morpholineethanesulfonic Acid (4432-31-9) Yes Yes No Yes

-----\Chemical Inventory Status - Part 2\-----
--Canada--
Ingredient Korea DSL NDSL Phil.

4-Morpholineethanesulfonic Acid (4432-31-9) Yes Yes No No

-----\Federal, State & International Regulations - Part 1\-----
-SARA 302- -----SARA 313-----
Ingredient RQ TPQ List Chemical Catg.

4-Morpholineethanesulfonic Acid (4432-31-9) No No No No

-----\Federal, State & International Regulations - Part 2\-----
-RCRA- -TSCA-
Ingredient CERCLA 261.33 8(d)

4-Morpholineethanesulfonic Acid No No No
(4432-31-9)

Chemical Weapons Convention: No TSCA 12(b): No CDTA: No
SARA 311/312: Acute: Yes Chronic: No Fire: No Pressure: No
Reactivity: No (Pure / Solid)

SECTION 15: OTHER INFORMATION

PREPARED BY: Diazyme Administration
PHONE NO: 858-455-4754
DATE PREPARED: 1 April 2008

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.