



**MATERIAL SAFETY DATA SHEET**  
**N-geneous® LDL Cholesterol Reagent #1**

**1. PRODUCT AND COMPANY IDENTIFICATION**

**Product Name:** N-geneous® LDL Cholesterol Reagent #1

**Product Number:** 01E3-1R1; 1E31-20R1; 80-4592-00; 80-4592-01; 80-4598-00; 80-4598-01; 80-4604-00;  
80-6415-00; 80-6415-01; 80-6418-00; 80-6480-00; 90-6706-100; 90-6706-76;  
LDCE-70-5170-04; LDLC-70-5171-01; LDLC-70-5171-02; LDLC-70-5171-03;  
LDLC-70-5171-05; LDLC-70-5171-06; 7120; 7122

**Synonym(s):** Liquid N-geneous® LDL-c R1; Liquid N-geneous® LDL-c Reagent; N-geneous® LDL Cholesterol Reagent #1; N-geneous® LDL Cholesterol R1; N-geneous® LDL Cholesterol (R1); LDL Direct Liquid Select™ Cholesterol Reagent 1

**Product Use:** Component of the N-geneous® LDL Cholesterol Reagent Kit and the LDL Direct Liquid Select™ Cholesterol Kit. For use in the direct quantitative determination of low density lipoprotein cholesterol (LDL-C) in human serum or plasma. For In Vitro Diagnostic Use Only.

**Description:** Aqueous solution containing buffer, enzymes (proteins), detergent and preservative.

**Corporate Headquarters**

**Genzyme Corporation**

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USA

**Phone:** 617-252-7500

**Distributor**

**Genzyme Diagnostics**

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**Phone:** 44 (0) 1732 220022

**Emergency Telephone Numbers**

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**CHEMTREC (U.S.):** 800-424-9300

**CHEMTREC (Outside U.S.):** +1 703-527-3887

**Distributor**

**Genzyme Diagnostics**

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USA

**Phone:** 800-999-6578

**Distributor**

**Genzyme Diagnostics**

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Framingham, MA 01701-9322  
USA

**Phone:** 800-332-1042

**2. HAZARDS IDENTIFICATION**

**Precautionary Statements:**

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, pale yellow liquid.

**Routes of Exposure:**

Occupational exposure routes may include eye and skin contact.

**Potential Health Effects:**

**Inhalation**

Although there is no evidence that the enzyme(s) in this preparation induces specific respiratory hypersensitivity, all proteins are potential respiratory allergens and may result in respiratory sensitization in certain individuals after repeated and/or prolonged inhalation exposure, producing mild to severe symptoms similar to pollen allergy or asthma, including mucous membrane or eye irritation, itching of the skin or eyes, sneezing, nasal or sinus congestion, coughing, and tightness in the chest. These symptoms may develop as late as 12 hours after exposure.

**Eye**

No data available. Eye exposure may cause irritation, redness and itching.

**Skin**

No data available. Skin contact may cause irritation, redness and discomfort.

**Ingestion**

No data available.



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### Potential Health Effects:

**Chronic Effects** No data available.

**Target Organs** Unknown.

### Regulatory Status:

This preparation is not classified as hazardous under U.S. OSHA 29 CFR 1910.1200; E.C. Directive 1999/45/EC; Canadian R.S. 1985, c. H-3; U.K. CHIPS 2009 No. 716; and/or U.N. GHS ST/SG/AC 10/30.

None of the components present in this preparation at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

### Potential Environmental Effects:

Unknown.

## 3. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredient Name	CAS #	EC #	% (wt/wt)
Water	7732-18-5	231-791-2	92 - 95
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
4-Morpholineethanesulfonic (MES) monohydrate, free acid	4432-31-9	224-632-3	1 - 2
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Ascorbate oxidase	9029-44-1	232-852-6	< 1
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Cholesterol esterase	9026-00-0	232-808-6	< 1
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Cholesterol oxidase	9028-76-6	232-842-1	< 1
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Peroxidase	9003-99-0	232-668-6	< 1
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Proprietary non-ionic detergent	Trade Secret	Trade Secret	< 1
<b>EC R-Phrases:</b> R22, R38, R41, R52	<b>EC Hazard Class:</b> Xn, N		
Proprietary preservative	Mixture	Mixture	< 0.1
<b>EC R-Phrases:</b> R10, R20/21/22, R34, R43, R50/53	<b>EC Hazard Class:</b> C, N		
4-Aminoantipyridine	83-07-8	201-452-3	< 0.1
<b>EC R-Phrases:</b> R22	<b>EC Hazard Class:</b> Xn		

NOTE - Ascorbate oxidase - Enzyme source: Curcubita sp., Enzyme Commission number: 1.10.3.3

NOTE - Cholesterol esterase - Enzyme source: Pseudomonas sp., Enzyme Commission number: 3.1.1.13

NOTE - Cholesterol oxidase - Enzyme source: Escherichia coli, Enzyme Commission number: 1.1.3.6

NOTE - Peroxidase - Enzyme source: Horseradish root, Enzyme Commission number: 1.11.1.7

## 4. FIRST AID MEASURES

### Inhalation:

If inhaled, move from exposure area to fresh air. Seek medical attention if breathing becomes difficult or if cough or other symptoms develop.



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**Eye Contact:**

Immediately flush eyes with plenty of tepid water for 15 minutes while separating eyelids with fingers. Remove contact lenses if worn. Obtain medical attention if needed or if symptoms, such as redness or irritation persist.

**Skin Contact:**

In case of contact, flush skin with copious amounts of cool water and remove contaminated clothing. Obtain medical attention if needed or if irritation or other symptoms develop.

**Ingestion:**

In case of ingestion, contact a poison control center or physician for instructions.

### 5. FIRE FIGHTING MEASURES

**Flammable Properties:**

Dilute aqueous solution not considered a fire hazard.

**Suitable Extinguishing Media:**

Use extinguishing media suitable for surrounding fire, such as carbon dioxide, chemical foam, dry chemical or water spray.

**Unsuitable Extinguishing Media:**

Unknown.

**Specific Hazards Arising from the Chemical:**

None expected.

**Standard Protective Equipment and Precautions for Firefighters:**

Firefighters should wear NIOSH-approved or equivalent Self-Contained Breathing Apparatus and full protective gear.

### 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 Precautions:**

No information available.

**Methods and Materials for Containment and Clean-Up:**

Absorb spill with inert material/sorbent. Decontaminate the spill site following standard procedures. Dispose of materials in accordance with all applicable federal, state, local and provincial environmental regulations, per Section 13.

### 7. HANDLING AND STORAGE

**Handling:**

Follow good laboratory hygiene practices. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

**Storage:**

Store at 2 to 8°C (36 to 46°F). Do not store with incompatible substances. See Section 10.

### 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 concentrations equal to or greater than 1% (0.1% if carcinogen).



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#### Engineering Controls:

This preparation is not expected to require special ventilation measures. Facilities storing or using this preparation should be equipped with an eyewash fountain.

#### Personal Protective Equipment (PPE):

<b>Respiratory</b>	A respirator is not required under normal conditions of use.
<b>Eye/Face</b>	Wear appropriate protective chemical safety glasses.
<b>Skin</b>	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
<b>Gloves</b>	Wear chemical resistant protective gloves.
<b>General</b>	Follow company-specific safety procedures.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, pale yellow liquid	<b>pH:</b>	6.4 - 6.6
<b>Odor:</b>	Odorless	<b>Solubility:</b>	Water-soluble
<b>Boiling Point:</b>	Not available	<b>Evaporation Rate:</b>	Not available
<b>Melting Point:</b>	Not applicable	<b>Vapor Pressure:</b>	Not available
<b>Freezing Point:</b>	Not available	<b>Partition Coefficient (n-octanol/water):</b>	Not available
<b>Viscosity:</b>	Not available	<b>Vapor Density:</b>	Not available
<b>Flammability/Explosivity Limits in Air, Lower:</b>	Not available		
<b>Flammability/Explosivity Limits in Air, Upper:</b>	Not available		
<b>Auto-Ignition Temperature:</b>	Not applicable		
<b>Flash Point:</b>	Not available		

### 10. STABILITY AND REACTIVITY

#### Chemical Stability:

Stable under ordinary conditions of use and storage. See Section 7.

#### Conditions to Avoid:

There are no physical conditions known to result in a hazardous situation.

#### Incompatible Materials:

Unknown.

#### Hazardous Decomposition Products:

None expected under normal conditions of use.

#### Possibility of Hazardous Reactions:

Hazardous polymerization will not occur.

### 11. TOXICOLOGICAL INFORMATION

#### Local Effects:

No data available.

#### Chronic Effects:

No data available.



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**Carcinogenicity:**

No data available.

**Mutagenicity:**

No data available.

**Teratogenicity:**

No data available.

**Reproductive Effects:**

No data available.

**Sensitization:**

No data available.

**12. ECOLOGICAL INFORMATION**

**Ecotoxicity:**

No data available.

**Persistence and Degradability:**

No data available.

**Bioaccumulative Potential:**

No data available.

**Mobility in Environmental Media:**

No data available.

**13. DISPOSAL CONSIDERATIONS**

**Methods of Disposal:**

Dispose of unused product, spilled material and waste in accordance with all applicable federal, state, local and provincial environmental and hazardous waste regulations.

**14. TRANSPORT INFORMATION**

**Basic Shipping Description:**

Not classified as dangerous goods. Not regulated per IATA and DOT regulations.

**15. REGULATORY INFORMATION**

**US Federal Regulations:**

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

**Inventory - United States - Section 8(b) Inventory (TSCA)**

4-Morpholineethanesulfonic (MES) monohydrate, 4432-31-9 Present  
free acid



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#### **International Regulations:**

If approved for European Communities use, this product is regulated under the In Vitro Diagnostic Medical Devices Directive (98/79/EC).

#### **Inventory - Australia - Inventory of Chemical Substances (AICS)**

4-Morpholineethanesulfonic (MES) monohydrate, 4432-31-9 Present  
free acid

#### **Inventory - Canada - Domestic Substances List (DSL)**

4-Morpholineethanesulfonic (MES) monohydrate, 4432-31-9 Present  
free acid

#### **Inventory - China**

4-Morpholineethanesulfonic (MES) monohydrate, 4432-31-9 Present  
free acid

#### **Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)**

4-Morpholineethanesulfonic (MES) monohydrate, 4432-31-9 224-632-3  
free acid

#### **Inventory - Korea - Existing and Evaluated Chemical Substances**

4-Morpholineethanesulfonic (MES) monohydrate, 4432-31-9 KE-25529  
free acid

#### **Canadian Hazardous Products:**

**WHMIS Status** Exempt

#### **European Communities Dangerous Substances/Preparations:**

**EC Hazard Class** None

**Risk Phrases** None

**Safety Phrases** None

## 16. OTHER INFORMATION

#### **Further Information:**

This MSDS has been prepared in accordance with the ANSI Z400.1 format. Every effort has been made to adhere to the hazard criteria and content requirements of the U.S. OSHA Hazard Communication Standard, Canadian Controlled Products Regulation (CPR), UK Chemical Hazard Information and Packaging Regulations, European Communities REACH Regulation, and UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

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**Version #:** 3

**Revision Date:** September 01, 2009



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