



## MATERIAL SAFETY DATA SHEET

### Ultra N-geneous® HDL Cholesterol Reagent #2

#### 1. PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Ultra N-geneous® HDL Cholesterol Reagent #2

**Product Number:** 295164; 312175; 70-5952-02; 70-5952-02/B; 70-5952-03; 70-5952-05; 70-5952-06;  
80-6241-00; 80-6261-00; 80-6269-00; 80-6273-00; 80-6277-00; 80-6279-00;  
HDCE-70-5955-03; 6121; 6122; 6123R2

**Synonym(s):** Ultra N-geneous® HDL-c R2; Ultra N-geneous® HDL-c Reagent; HDL Ultra Cholesterol Reagent 2

**Product Use:** For In Vitro Diagnostic Use Only. Component of the Ultra N-geneous® HDL Cholesterol Kit and the HDL Ultra Cholesterol Kit. For use in the direct quantitative determination of high density lipoprotein cholesterol (HDL-C) in human serum or plasma.

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

**Corporate Headquarters**

**Genzyme Corporation**

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Cambridge, MA 02142  
USA

**Phone:** 617-252-7500

**Distributor**

**Genzyme Diagnostics**

50 Gibson Drive  
Kings Hill, West Malling  
Kent, ME19 4AF

UK

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

**Emergency Telephone Numbers**

**Genzyme (U.S.):** 617-562-4555

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

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

**Distributor**

**Genzyme Diagnostics**

115 Summit Drive  
Exton, PA 19341  
USA

**Phone:** 800-999-6578

**Distributor**

**Genzyme Diagnostics**

31 New York Avenue  
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, light brown 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.

**Chronic Effects**

No data available.

**Target Organs**

Unknown.



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**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	88 - 97
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Good's Buffer	Mixture	Mixture	1 - 2
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Proprietary non-ionic detergent	Trade Secret	Trade Secret	1 - 2
<b>EC R-Phrases:</b> R22, R38, R41, R52	<b>EC Hazard Class:</b> Xn, N		
Cholesterol esterase	9026-00-0	232-808-6	1 - 2
<b>EC R-Phrases:</b> None	<b>EC Hazard Class:</b> None		
Proprietary preservative	Mixture	Mixture	< 1
<b>EC R-Phrases:</b> R10, R20/21/22, R34, R43, R50/53	<b>EC Hazard Class:</b> C, N		
4-Aminoantipyrine	83-07-8	201-452-3	< 0.1
<b>EC R-Phrases:</b> R22	<b>EC Hazard Class:</b> Xn		

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

### 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.

**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.



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**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).

**Engineering Controls:**

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

**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.



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#### 9. PHYSICAL AND CHEMICAL PROPERTIES

<b>Appearance:</b>	Clear, light brown liquid	<b>pH:</b>	6.0
<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:**

Avoid strong oxidizing agents, strong acids and bases.

**Hazardous Decomposition Products:**

None expected under normal conditions of use.

**Possibility of Hazardous Reactions:**

Hazardous polymerization will not occur.

#### 11. TOXICOLOGICAL INFORMATION

**Acute Effects:****Toxicology Data - Selected LD50s and LC50s**

4-Aminoantipyrine 83-07-8 Oral LD50 Rat: 1700 mg/kg

**Local Effects:**

No data available.

**Chronic Effects:**

No data available.

**Carcinogenicity:**

No data available.

**Mutagenicity:**

No data available.

**Teratogenicity:**

No data available.



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**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-Aminoantipyrine	83-07-8	Present
Cholesterol esterase	9026-00-0	XU



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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).

#### **Canada - WHMIS - Classifications of Substances**

4-Aminoantipyrine	83-07-8	Uncontrolled product according to WHMIS classification criteria
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#### **Inventory - Australia - Inventory of Chemical Substances (AICS)**

4-Aminoantipyrine	83-07-8	Present
Cholesterol esterase	9026-00-0	Present

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

4-Aminoantipyrine	83-07-8	Present
Cholesterol esterase	9026-00-0	Present

#### **Inventory - Canada - Organisms on the Non-Domestic Substances List (NDSL)**

Cholesterol esterase	9026-00-0	IUB #3.1.1.13
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#### **Inventory - China**

4-Aminoantipyrine	83-07-8	Present
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#### **Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)**

4-Aminoantipyrine	83-07-8	201-452-3
Cholesterol esterase	9026-00-0	232-808-6

#### **Inventory - Japan Existing and New Chemical Substances (ENCS)**

4-Aminoantipyrine	83-07-8	9-62
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#### **Inventory - Korea - Existing and Evaluated Chemical Substances**

4-Aminoantipyrine	83-07-8	KE-01297
Cholesterol esterase	9026-00-0	KE-05951

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

<b>WHMIS Status</b>	Exempt
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#### **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).

**MSDS Origination Date:** December 15, 2004

**Version #:** 8

**Revision Date:** September 01, 2009



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