



MATERIAL SAFETY DATA SHEET

Ultra N-geneous® HDL Cholesterol Reagent #1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Ultra N-geneous® HDL Cholesterol Reagent #1

Product Number: 295157; 312168; 70-5950-02; 70-5950-02/B; 70-5950-03; 70-5950-05; 70-5950-06; 80-6247-00; 80-6257-00; 80-6265-00; 80-6271-00; 80-6275-00; 80-6281-00; 80-6283-00; HDCE-70-5955-03 ; 6121; 6122; 6123R1

Synonym(s): Ultra N-geneous® HDL-c R1; Ultra N-geneous® HDL-c Reagent; HDL Ultra Cholesterol Reagent 1

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), salt, buffer, surfactant and preservative.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
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, 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.

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	90 - 97
EC R-Phrases: None	EC Hazard Class: None		
Good's Buffer	Mixture	Mixture	1 - 2
EC R-Phrases: None	EC Hazard Class: None		
Ascorbate oxidase	9029-44-1	232-852-6	1 - 3
EC R-Phrases: None	EC Hazard Class: None		
Cholesterol oxidase	9028-76-6	232-842-1	< 1
EC R-Phrases: None	EC Hazard Class: None		
Peroxidase	9003-99-0	232-668-6	< 1
EC R-Phrases: None	EC Hazard Class: None		
Proprietary non-ionic detergent	Trade Secret	Trade Secret	< 1
EC R-Phrases: R22, R38, R41, R52	EC Hazard Class: Xn, N		
N,N-bis(4-Sulphobutyl)-m-toluidine, disodium salt	Not Assigned	Not Assigned	< 0.1
EC R-Phrases: None	EC Hazard Class: None		
Proprietary preservative	Mixture	Mixture	< 0.1
EC R-Phrases: R10, R20/21/22, R34, R43, R50/53	EC Hazard Class: C, N		

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

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.

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.



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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).

Engineering Controls:

This preparation is aqueous and non-volatile and 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):

Respiratory	A respirator is not required under normal conditions of use.
Eye/Face	Wear appropriate protective chemical safety glasses.
Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.



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Personal Protective Equipment (PPE):

- Gloves** Wear chemical resistant protective gloves.
- General** Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, pale yellow liquid	pH:	6.0
Odor:	Odorless	Solubility:	Water-soluble
Boiling Point:	Not available	Evaporation Rate:	Not available
Melting Point:	Not applicable	Vapor Pressure:	Not available
Freezing Point:	Not available	Partition Coefficient (n-octanol/water):	Not available
Viscosity:	Not available	Vapor Density:	Not available
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not applicable		
Flash Point:	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:

No data available.

Local Effects:

No data available.

Chronic Effects:

No data available.

Carcinogenicity:

No data available.

Mutagenicity:

No data available.



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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)

Cholesterol oxidase	9028-76-6	XU
Peroxidase	9003-99-0	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).

Inventory - Australia - Inventory of Chemical Substances (AICS)

Cholesterol oxidase	9028-76-6	Present
Peroxidase	9003-99-0	Present

Inventory - Canada - Domestic Substances List (DSL)

Ascorbate oxidase	9029-44-1	Present
Peroxidase	9003-99-0	Present

Inventory - Canada - Organisms on the Domestic Substances List (DSL)

Cholesterol oxidase	9028-76-6	IUB #1.1.3.6
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Inventory - Canada - Organisms on the Non-Domestic Substances List (NDSL)

Peroxidase	9003-99-0	IUB #1.11.1.7
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Inventory - China

Peroxidase	9003-99-0	Present
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Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Ascorbate oxidase	9029-44-1	232-852-6
Cholesterol oxidase	9028-76-6	232-842-1
Peroxidase	9003-99-0	232-668-6

Inventory - Korea - Existing and Evaluated Chemical Substances

Ascorbate oxidase	9029-44-1	KE-01946
Cholesterol oxidase	9028-76-6	KE-05953
Peroxidase	9003-99-0	KE-28159

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).

MSDS Origination Date: December 15, 2004

Version #: 9

Revision Date: September 01, 2009



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Disclaimer:

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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

500 Kendall Street
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.



MATERIAL SAFETY DATA SHEET

Ultra N-geneous® HDL Cholesterol Reagent #2

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

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):

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



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Ultra N-geneous® HDL Cholesterol Reagent #2

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, light brown liquid	pH:	6.0
Odor:	Odorless	Solubility:	Water-soluble
Boiling Point:	Not available	Evaporation Rate:	Not available
Melting Point:	Not applicable	Vapor Pressure:	Not available
Freezing Point:	Not available	Partition Coefficient (n-octanol/water):	Not available
Viscosity:	Not available	Vapor Density:	Not available
Flammability/Explosivity Limits in Air, Lower:	Not available		
Flammability/Explosivity Limits in Air, Upper:	Not available		
Auto-Ignition Temperature:	Not applicable		
Flash Point:	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:

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

Disclaimer:

The information above is provided in good faith. It is believed to be accurate and represents the best information currently available to us. HOWEVER, WE MAKE NO WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER TYPE, EXPRESSED OR IMPLIED, WITH RESPECT TO PRODUCTS DESCRIBED OR DATA OR INFORMATION PROVIDED, AND WE ASSUME NO LIABILITY RESULTING FROM THE USE OF SUCH PRODUCTS, DATA OR INFORMATION. Users should make their own investigations to determine the suitability of the information for their particular purposes, and the user assumes all risk arising from their use of the material. The user is required to comply with all laws and regulations relating to the purchase, use, storage and disposal of the material, and must be familiar with and follow generally accepted safe handling procedures. In no event shall Genzyme be liable for any claims, losses, or damages of any individual or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if Genzyme has been advised of the possibility of such damages.