



MATERIAL SAFETY DATA SHEET

Genzyme Cystatin C Reagent 1

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Genzyme Cystatin C Reagent 1

Product Number: 80-7145-00; 80-7139-00

Synonym(s): Reagent 1

Product Use: Component of Genzyme Cystatin C Reagent kit (catalog # 80-7136-00 & 80-7143-00). For the quantitative measurement of cystatin C concentration in human serum, heparinized plasma, or EDTA plasma. Cystatin C measurements are used as an aid in the diagnosis and treatment of renal disease. For In Vitro Diagnostic Use Only.

Description: Buffered aqueous solution containing salts, emulsifier, preservative, glycol, and rabbit polyclonal antibody.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Distributor

Genzyme Diagnostics

31 New York Avenue
Framingham, MA 01701-9322
USA

Phone: 800-332-1042

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.): 703-527-3887

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, colorless to faint yellow liquid.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation	No data available. Inhalation is not expected to produce adverse health effects.
Eye	No data available. Eye exposure may cause irritation, redness and watering.
Skin	No data available. Skin contact may cause irritation, dryness and redness.
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. CHIP 2002 No. 1689; 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	> 79
EC R-Phrases: None	EC Hazard Class: None		
Bis(2-hydroxyethyl)iminotris(hydroxymethyl)methane (Bis-Tris Buffer)	6976-37-0	230-237-7	< 9
EC R-Phrases: None	EC Hazard Class: None		
Sodium chloride	7647-14-5	231-598-3	< 6
EC R-Phrases: None	EC Hazard Class: None		
Polyethylene glycol (PEG) 20000	25322-68-3	500-038-2	< 4
EC R-Phrases: None	EC Hazard Class: None		
Rabbit polyclonal antibody	Not Assigned	Not Assigned	< 4
EC R-Phrases: None	EC Hazard Class: None		
Polyoxyethylene lauryl ether	9002-92-0	500-002-6	< 1
EC R-Phrases: None	EC Hazard Class: None		
Ethylenediaminetetraacetic acid, disodium, dihydrate	6381-92-6	Not Assigned	< 1
EC R-Phrases: None	EC Hazard Class: None		
Disodium dodecyl(sulphonatophenoxy)benzenesulphonate	28519-02-0	Not Assigned	< 1
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	< 0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		

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:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

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 - 8°C (36 - 46°F). Do not freeze. Do not store with incompatible substances; see Section 10.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Guidelines:

There are no ACGIH, NIOSH, or OSHA 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 safety eye glasses or goggles.



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Personal Protective Equipment (PPE):

Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Clear, colorless to faint yellow liquid	pH:	6.65 - 6.75
Odor:	Odorless	Solubility:	Water-soluble
Boiling Point:	Not available	Vapor Pressure:	Not available
Melting Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Freezing Point:	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 oxidizers, strong acids and bases, heavy metals and their salts.

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

Polyethylene glycol (PEG) 20000	25322-68-3	Oral LD50 Rat: 28 g/kg; Dermal LD50 Rabbit: >20 g/kg
Sodium chloride	7647-14-5	Inhalation LC50 Rat: >42 g/m ³ /1H; Oral LD50 Rat: 3 g/kg; Dermal LD50 Rabbit: >10 g/kg

Local Effects:

No data available.

Chronic Effects:

No data available.



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Genzyme Cystatin C Reagent 1

Carcinogenicity:

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.

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.

12. ECOLOGICAL INFORMATION

Ecotoxicity:**Ecotoxicity - Freshwater Fish Species Data**

Polyethylene glycol (PEG) 20000	25322-68-3	24 Hr LC50 Carassius auratus: >5000 mg/L (PEG 200, 400, 800)
Sodium chloride	7647-14-5	96 Hr LC50 Lepomis macrochirus: 9675 mg/L [flow-through]; 96 Hr LC50 Lepomis macrochirus: 12946 mg/L [static]; 96 Hr LC50 Pimephales promelas: 7650 mg/L [static]

Ecotoxicity - Microtox Data

Polyethylene glycol (PEG) 20000	25322-68-3	15 min EC50 Photobacterium phosphoreum: 100000 mg/L (polymer unspecified)
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Ecotoxicity - Water Flea Data

Sodium chloride	7647-14-5	48 Hr EC50 Daphnia magna: 1000 mg/L
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Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. 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.



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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)

Bis(2-hydroxyethyl)iminotris(hydroxymethyl)methane (Bis-Tris Buffer)	6976-37-0	Present
Disodium dodecyl(sulphonatophenoxy)benzenesulphonate	28519-02-0	Present
Polyethylene glycol (PEG) 20000	25322-68-3	XU
Sodium chloride	7647-14-5	Present



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Genzyme Cystatin C Reagent 1

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

Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
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Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Polyethylene glycol (PEG) 20000	25322-68-3	ID Number 279, hazard class 1 - low hazard to waters (footnote 11)
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Sodium chloride	7647-14-5	ID Number 270, hazard class 1 - low hazard to waters
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Inventory - Australia - Inventory of Chemical Substances (AICS)

Bis(2-hydroxyethyl)iminotris(hydroxymethyl)methan€ (Bis-Tris Buffer)	6976-37-0	Present
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Disodium	28519-02-0	Present
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dodecyl(sulphonatophenoxy)benzenesulphonate		
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Polyethylene glycol (PEG) 20000	25322-68-3	Present
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Sodium chloride	7647-14-5	Present
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Sodium chloride	7647-14-5	Present
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Inventory - Canada - Domestic Substances List (DSL)

Disodium	28519-02-0	Present
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dodecyl(sulphonatophenoxy)benzenesulphonate		
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Polyethylene glycol (PEG) 20000	25322-68-3	Present
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Sodium chloride	7647-14-5	Present
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Inventory - Canada - Non-Domestic Substances List (NDSL)

Bis(2-hydroxyethyl)iminotris(hydroxymethyl)methan€ (Bis-Tris Buffer)	6976-37-0	Present
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Bis(2-hydroxyethyl)iminotris(hydroxymethyl)methan€ (Bis-Tris Buffer)	6976-37-0	Present
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Inventory - China

Disodium	28519-02-0	Present
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dodecyl(sulphonatophenoxy)benzenesulphonate		
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Polyethylene glycol (PEG) 20000	25322-68-3	Present
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Sodium chloride	7647-14-5	Present
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Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

Bis(2-hydroxyethyl)iminotris(hydroxymethyl)methan€ (Bis-Tris Buffer)	6976-37-0	230-237-7
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Disodium	28519-02-0	249-063-8
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dodecyl(sulphonatophenoxy)benzenesulphonate		
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Sodium chloride	7647-14-5	231-598-3
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Sodium chloride	7647-14-5	231-598-3
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Inventory - Japan Existing and New Chemical Substances (ENCS)

Polyethylene glycol (PEG) 20000	25322-68-3	2-441; 7-129; 8-429
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Sodium chloride	7647-14-5	1-236
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Inventory - Korea - Existing and Evaluated Chemical Substances

Bis(2-hydroxyethyl)iminotris(hydroxymethyl)methan€ (Bis-Tris Buffer)	6976-37-0	KE-20636
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Disodium	28519-02-0	KE-13026
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dodecyl(sulphonatophenoxy)benzenesulphonate		
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Polyethylene glycol (PEG) 20000	25322-68-3	KE-20228
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Sodium chloride	7647-14-5	KE-31387
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Sodium chloride	7647-14-5	KE-31387
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Canadian Hazardous Products:

WHMIS Status	Non-controlled
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European Communities Dangerous Substances/Preparations:

EC Hazard Class	None
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Risk Phrases	None
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Safety Phrases	None
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16. OTHER INFORMATION



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Genzyme Cystatin C Reagent 1

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.

MSDS Origination Date: August 19, 2008

Version #: 2

Revision Date: September 09, 2008

Disclaimer:

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MATERIAL SAFETY DATA SHEET

Genzyme Cystatin C Reagent 2

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Genzyme Cystatin C Reagent 2

Product Number: 80-7147-00; 80-7141-00

Synonym(s): Reagent 2

Product Use: Component of Genzyme Cystatin C Reagent kit (catalog # 80-7136-00 & 80-7143-00). For the quantitative measurement of cystatin C concentration in human serum, heparinized plasma, or EDTA plasma. Cystatin C measurements are used as an aid in the diagnosis and treatment of renal disease. For In Vitro Diagnostic Use Only.

Description: Buffered aqueous solution containing antibody-coated colloidal gold particles, salts, bovine serum albumin and preservative.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Distributor

Genzyme Diagnostics

31 New York Avenue
Framingham, MA 01701-9322
USA

Phone: 800-332-1042

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.): 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. The bovine serum albumin (BSA) in this product is of US origin and meets the current standards for reduction of TSE (Transmissible Spongiform Encephalopathy) risk. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: opaque, dark purple liquid.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation	No data available. Inhalation is not expected to produce adverse health effects.
Eye	No data available. Eye exposure may cause irritation, redness and watering.
Skin	No data available. Skin contact may cause irritation, dryness and redness.
Ingestion	No data available.
Chronic Effects	No data available.
Target Organs	Unknown.



MATERIAL SAFETY DATA SHEET

Genzyme Cystatin C 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. CHIP 2002 No. 1689; 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	> 54
EC R-Phrases: None	EC Hazard Class: None		
Colloidal gold particles coated with anti-cystatin C polyclonal antibodies	Mixture	Mixture	< 41
EC R-Phrases: None	EC Hazard Class: None		
D-Mannitol	69-65-8	200-711-8	< 6
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	< 0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		
HEPES, Free Acid	7365-45-9	230-907-9	< 0.1
EC R-Phrases: None	EC Hazard Class: None		
Bovine serum albumin	9048-46-8	232-936-2	< 0.1
EC R-Phrases: None	EC Hazard Class: None		
EDTA-CuNa2	14025-15-1	237-864-5	< 0.1
EC R-Phrases: None	EC Hazard Class: None		

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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Genzyme Cystatin C 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:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

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 universal/standard precautions. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at 2 - 8°C (36 - 46°F). Do not freeze. 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 safety eye glasses or goggles.
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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Genzyme Cystatin C Reagent 2

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:	Opaque, dark purple liquid	pH:	7.3 - 7.5
Odor:	Odorless	Solubility:	Water-soluble
Boiling Point:	Not available	Vapor Pressure:	Not available
Melting Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Freezing Point:	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 oxidizers, strong acids and bases, heavy metals and their salts.

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**

D-Mannitol

69-65-8

Oral LD50 Rat: 13500 mg/kg

Local Effects:

No data available.

Chronic Effects:

No data available.

Carcinogenicity:

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.

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.



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Genzyme Cystatin C Reagent 2

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:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. 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)

D-Mannitol	69-65-8	Present
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Genzyme Cystatin C Reagent 2

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

D-Mannitol	69-65-8	Uncontrolled product according to WHMIS classification criteria
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Inventory - Australia - Inventory of Chemical Substances (AICS)

D-Mannitol	69-65-8	Present
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Inventory - Canada - Domestic Substances List (DSL)

D-Mannitol	69-65-8	Present
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Inventory - China

D-Mannitol	69-65-8	Present
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Inventory - European Union - European Inventory of Existing Commercial Chemical Substances (EINECS)

D-Mannitol	69-65-8	200-711-8
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Inventory - Japan Existing and New Chemical Substances (ENCS)

D-Mannitol	69-65-8	8-49; 9-1375
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Inventory - Korea - Existing and Evaluated Chemical Substances

D-Mannitol	69-65-8	KE-23061
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Canadian Hazardous Products:

WHMIS Status	Non-controlled
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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.

MSDS Origination Date: August 19, 2008

Version #: 2

Revision Date: September 09, 2008



MATERIAL SAFETY DATA SHEET

Genzyme Cystatin C Reagent 2

Disclaimer:

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MATERIAL SAFETY DATA SHEET

Genzyme Cystatin C Calibrator Set

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name: Genzyme Cystatin C Calibrator Set

Product Number: 80-7151-00; 80-7153-00; 80-7155-00; 80-7157-00; 80-7159-00; 80-7161-00

Synonym(s): Genzyme Cystatin C Calibrator 1; Genzyme Cystatin C Calibrator 2; Genzyme Cystatin C Calibrator 3; Genzyme Cystatin C Calibrator 4; Genzyme Cystatin C Calibrator 5; Genzyme Cystatin C Calibrator 6

Product Use: The six Genzyme Cystatin C Calibrators are components of the Genzyme Cystatin C Calibrator Set (catalog # 80-7149-00). For the calibration of the Genzyme cystatin C assay. For In Vitro Diagnostic Use Only.

Description: Buffered aqueous solution containing recombinant human cystatin C, bovine serum albumin, salt, and preservative.

Corporate Headquarters

Genzyme Corporation

500 Kendall Street
Cambridge, MA 02142
USA

Phone: 617-252-7500

Distributor

Genzyme Diagnostics

31 New York Avenue
Framingham, MA 01701-9322
USA

Phone: 800-332-1042

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.): 703-527-3887

2. HAZARDS IDENTIFICATION

Precautionary Statements:

The chemical, physical and toxicological properties of this preparation have not been thoroughly characterized. The bovine serum albumin (BSA) in this product is of US origin and meets the current standards for reduction of TSE (Transmissible Spongiform Encephalopathy) risk. Avoid contact with eyes and skin. Do not ingest or inhale. Preparation appearance: clear, colorless to faint yellow liquid.

Routes of Exposure:

Occupational exposure routes may include eye and skin contact.

Potential Health Effects:

Inhalation	No data available. Inhalation is not expected to produce adverse health effects.
Eye	No data available. Eye exposure may cause irritation, redness and watering.
Skin	No data available. Skin contact may cause irritation, dryness and redness.
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. CHIP 2002 No. 1689; 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	> 94
EC R-Phrases: None	EC Hazard Class: None		
Bovine serum albumin	9048-46-8	232-936-2	< 4
EC R-Phrases: None	EC Hazard Class: None		
HEPES, Free Acid	7365-45-9	230-907-9	< 2
EC R-Phrases: None	EC Hazard Class: None		
Sodium chloride	7647-14-5	231-598-3	< 1
EC R-Phrases: None	EC Hazard Class: None		
Sodium azide	26628-22-8	247-852-1	< 0.1
EC R-Phrases: R28, R32, R50, R53	EC Hazard Class: T+, N		
Recombinant human cystatin C	Not Assigned	Not Assigned	0 - 0.0008
EC R-Phrases: None	EC Hazard Class: None		

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.

Suitable Extinguishing Media:

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



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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:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. Follow proper disposal procedures.

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 universal/standard precautions. See Section 8, Engineering Controls. Minimize contact and contamination of personal clothing and skin. Wash hands thoroughly after handling.

Storage:

Store at 2 - 8°C (36 - 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 safety eye glasses or goggles.
Skin	Wear lab coat or other protective garments. Remove contaminated clothing promptly.
Gloves	Wear chemical resistant protective gloves.
General	Follow company-specific safety procedures.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: Clear, colorless to faint yellow liquid **pH:** 7.35 - 7.45



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Odor:	Odorless	Solubility:	Water-soluble
Boiling Point:	Not available	Vapor Pressure:	Not available
Melting Point:	Not applicable	Partition Coefficient (n-octanol/water):	Not available
Freezing Point:	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 oxidizers, strong acids and bases, heavy metals and their salts.

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**

Sodium chloride	7647-14-5	Inhalation LC50 Rat: >42 g/m ³ /1H; Oral LD50 Rat: 3 g/kg; Dermal LD50 Rabbit: >10 g/kg
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Local Effects:

No data available.

Chronic Effects:

No data available.

Carcinogenicity:

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.

Mutagenicity:

No data available.

Teratogenicity:

No data available.

Reproductive Effects:

No data available.

Sensitization:

No data available.



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12. ECOLOGICAL INFORMATION

Ecotoxicity:**Ecotoxicity - Freshwater Fish Species Data**

Sodium chloride	7647-14-5	96 Hr LC50 Lepomis macrochirus: 9675 mg/L [flow-through]; 96 Hr LC50 Lepomis macrochirus: 12946 mg/L [static]; 96 Hr LC50 Pimephales promelas: 7650 mg/L [static]
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Ecotoxicity - Water Flea Data

Sodium chloride	7647-14-5	48 Hr EC50 Daphnia magna: 1000 mg/L
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Persistence and Degradability:

No data available.

Bioaccumulative Potential:

No data available.

Mobility in Environmental Media:

No data available.

13. DISPOSAL CONSIDERATIONS

Methods of Disposal:

This preparation contains a small amount of sodium azide which can react with copper, lead, brass or solder in plumbing systems and form potentially explosive metal azides. If preparation enters drain, flush with a large volume of water to prevent azide build-up. 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)

Bovine serum albumin	9048-46-8	XU
HEPES, Free Acid	7365-45-9	Present
Sodium chloride	7647-14-5	Present



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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

Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
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Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

Sodium chloride	7647-14-5	ID Number 270, hazard class 1 - low hazard to waters
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Inventory - Australia - Inventory of Chemical Substances (AICS)

Bovine serum albumin	9048-46-8	Present
HEPES, Free Acid	7365-45-9	Present
Sodium chloride	7647-14-5	Present

Inventory - Canada - Domestic Substances List (DSL)

Bovine serum albumin	9048-46-8	Present
HEPES, Free Acid	7365-45-9	Present
Sodium chloride	7647-14-5	Present

Inventory - China

Bovine serum albumin	9048-46-8	Present
HEPES, Free Acid	7365-45-9	Present
Sodium chloride	7647-14-5	Present

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

Bovine serum albumin	9048-46-8	232-936-2
HEPES, Free Acid	7365-45-9	230-907-9
Sodium chloride	7647-14-5	231-598-3

Inventory - Japan Existing and New Chemical Substances (ENCS)

Sodium chloride	7647-14-5	1-236
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Inventory - Korea - Existing and Evaluated Chemical Substances

Bovine serum albumin	9048-46-8	KE-05-0011
Sodium chloride	7647-14-5	KE-31387

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.



MATERIAL SAFETY DATA SHEET

Genzyme Cystatin C Calibrator Set

MSDS Origination Date: August 19, 2008

Version #: 3

Revision Date: October 29, 2008

Disclaimer:

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