



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 |
|-----------------|-----------|----------------------------------------------------------------------------------------------------|

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] |
|-----------------|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

Ecotoxicity - Water Flea Data

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

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 |
|-----------------|-----------|-----------------------------------------------------------------|

Germany - Water Classification (VwVwS) - Annex 2 - Water Hazard Classes

| | | |
|-----------------|-----------|------------------------------------------------------|
| Sodium chloride | 7647-14-5 | ID Number 270, hazard class 1 - low hazard to waters |
|-----------------|-----------|------------------------------------------------------|

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 |
|-----------------|-----------|-------|

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 | Non-controlled |
|---------------------|----------------|

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.



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MSDS Origination Date: August 19, 2008

Version #: 2

Revision Date: September 09, 2008

Disclaimer:

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