

**SECTION 1 - IDENTITY**

NAME Cholestech GDX™ System		ADDRESS 3347 Investment Boulevard, Hayward, CA 94545-3808	
TELEPHONE NUMBER (800) 733-0404	FOR ADDITIONAL INFORMATION CONTACT Technical Service	DATE PREPARED July 10, 2002	
COMMON NAME (USED ON LABEL) Cholestech GDX A1C Controls		CHEMICAL FAMILY Does not apply	
CHEMICAL NAME Does not apply		FORMULA Does not apply	
TRADE NAME & SYNONYMS Cholestech GDX™, Trademark of Cholestech Corporation			

**SECTION 2 - HAZARDOUS INGREDIENTS**

HAZARDOUS COMPONENT	CAS #	% (wt)	TLV	PEL
Product consists of freeze-dried whole human blood. Product is reconstituted with 500 uL of purified water.				

PEL: Permissible Exposure Limit established by the Occupational Safety and Health Administration (OSHA).  
TLV: Threshold Limit Value established by the American Conference of Governmental Industrial Hygienists, 1987-88.

**SECTION 3 - PHYSICAL DATA**

BOILING POINT/ MELTING TEMPERATURE Not applicable.		SPECIFIC GRAVITY Not determined	VAPOR PRESSURE (mm Hg) Not determined
PERCENT VOLATILE BY VOLUME (%) Not determined	VAPOR DENSITY (AIR = 1) Not determined	EVAPORATION DATE ( _____ - 1) Not determined	
SOLUBILITY IN WATER Soluble – 500 uL of purified water is used to reconstitute controls prior to use.		REACTIVITY IN WATER Not applicable.	
APPEARANCE AND ODOR Form – solid powder. Color – red (stored in brown glass bottles). Odor – none.			

**SECTION 4 - FIRE AND EXPLOSION DATA**

FLASH POINT Not applicable.	FLAMMABLE LIMITS IN AIR (% by VOLUME) LOWER: Not applicable. UPPER: Not applicable.		
EXTINGUISHING MEDIA Not flammable or explosive	AUTO IGNITION TEMPERATURE Not applicable.		
UNUSUAL FIRE AND EXPLOSION HAZARDS Not flammable or explosive.			
SPECIAL FIRE FIGHTING PROCEDURES None			

## SECTION 5 - HEALTH INFORMATION

### PRIMARY ROUTES OF EXPOSURE

Skin, eye, ingestion.

### SIGNS AND SYMPTOMS OF EXPOSURE

### MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE

None

CHEMICAL/COMPONENT LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN None

NTP  
 Yes  
 No

IARC  
 Yes  
 No

OSHA  
 Yes  
 No

### OTHER EXPOSURE LIMITS

None

### EMERGENCY & FIRST AID PROCEDURES

Eye Contact – Irrigate with copious amounts of water. Seek medical advice.  
Skin Contact – Wash off thoroughly with soap and water. Seek medical advice.  
Ingestion – Wash out mouth thoroughly with water. Seek medical advice.  
Inhalation – Not applicable.

## SECTION 6 - REACTIVITY DATA

### STABILITY

Unstable  Stable   
Non-reactive.

### CONDITIONS TO AVOID

Not determined

### INCOMPATIBILITY (MATERIALS TO AVOID)

Not determined

### HAZARDOUS DECOMPOSITION PRODUCTS

Not determined

### HAZARDOUS POLYMERIZATION

May Occur   
Will Not Occur

### CONDITIONS TO AVOID

Not applicable.

## SECTION 7 - SPILL OR LEAK PROCEDURES

### STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED

Clean up spills with an absorbant material. Dispose of this material in a biohazard container. Wipe down the area of the spill with 10% bleach. All cleaning items and gloves should be discarded into a biohazardous container.

### ECOLOGICAL INFORMATION

No environmental hazard is anticipated provided the materials are handled and disposed of with due care and attention.

### WASTE DISPOSAL METHOD

Dispose in a biohazardous waste container for collection by waste contractor. Additional items that have come into contact with the controls (e.g. pipette tips, test cartridges) should also be disposed of in a biohazardous waste container.

## SECTION 8 - PERSONAL PROTECTION INFORMATION

### RESPIRATORY PROTECTION

Not required under normal and intended uses.

### VENTILATION

Not applicable.

### PROTECTIVE GLOVES

Wear protective gloves during reconstitution and testing.

### EYE PROTECTION

Not required

### OTHER PROTECTIVE CLOTHING OR EQUIPMENT

Wear laboratory coat for personal protection.

## SECTION 9 - SPECIAL PRECAUTIONS

### PRECAUTIONS TO BE TAKEN IN HANDLING & STORING

Controls should be transported unopened at 2 – 8°C.  
Store unopened controls at 2 – 8°C. Expiration date is shown on the outside of the box. After reconstitution the controls are stable for up to five days at 2 – 8°C.

### OTHER PRECAUTIONS

All donors have been screened by Food and Drug Administration USA (FDA) approved tests and found to be negative for HbsAg, HCA and HIV Antibodies. However as no testing can claim total absence of infectious agents they should be handled as though they are capable of transmitting an infectious disease. Very slight risk of biological infection.