

Alere San Diego, Inc.
(MSDS) MATERIAL SAFETY DATA SHEET

MSDS-4402

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Alere Cholestech LDX[®] Controls

Section 1 - Chemical Product Identification

MSDS Name: Alere Cholestech LDX[®] Controls

Product Description: See product insert.

Common Name (Used on label)

Lipid Controls

Alere Cholestech LDX[®] Multianalyte ControlsAlere Cholestech LDX[®] Calibration Verification Materials

Chemical Name: Does not apply

Chemical Family: Does not apply

Formula: Does not apply

Trade Name & Synonyms: Alere Cholestech LDX[®], Trademark of Alere San Diego, Inc.

Company Identification: Alere San Diego, Inc. d/b/a Biosite Incorporated
 9975 Summers Ridge Road, San Diego, CA 92121
 Phone: (858) 455-4808 Fax: (858) 455-4815

Emergency Phone Number

For technical assistance please contact the Technical Services Department at Alere San Diego, Inc., at 1-877-308-8289

Section 2 - Composition, Information on Ingredients

The Alere Cholestech LDX[®] Multianalyte Controls contain human and animal constituents in an aqueous preservative medium containing antimicrobial agents. The human source material used to produce this product has been tested using FDA-accepted methods and found nonreactive for hepatitis B surface antigen (HBsAg), and for antibodies to hepatitis C (HCV) and human immunodeficiency viruses (HIV-1 and HIV-2). Because no test can offer complete assurance that infectious agents are not present, this product should be considered potentially infectious and handled with the same precautions used with patient specimens.

Section 3- Hazard Identification

HAZARDOUS COMPONENT	CAS #	% (wt)	TLV	PEL
None of these products contain hazardous chemicals at concentrations of 1 % or greater.				
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.				

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Section 4- First Aid Measures

PRIMARY ROUTES OF EXPOSURE Skin, eye, ingestion.			
SIGNS AND SYMPTOMS OF EXPOSURE Not Applicable			
MEDICAL CONDITIONS GENERALLY AGGRAVATED BY EXPOSURE None			
CHEMICAL / COMPONENT LISTED AS CARCINOGEN OR POTENTIAL CARCINOGEN None of these products contain known carcinogens at concentrations of 0.1% or greater.	NTP ___ Yes ___ No	IARC ___ Yes ___ No	OSHA ___ Yes ___ No
OTHER EXPOSURE LIMITS None			
EMERGENCY & FIRST AID PROCEDURES Eye Contact – Flush with copious amounts of water. Skin Contact – Wash off thoroughly with soap and water. Ingestion – Wash out mouth thoroughly with water. Inhalation – Not applicable.			

Section 5 - Fire Fighting Measures

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 6 - Accidental Release Measures

STEPS TO BE TAKEN IN CASE MATERIAL IS LEAKED OR SPILLED Clean up spills with an absorbent material.
ECOLOGICAL INFORMATION No environmental hazard based on the ingredients.
WASTE DISPOSAL METHOD Dispose of waste in accordance with Federal, State, and Local codes.

Section 7 - Handling and Storage

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. See product insert sheet for additional handling and storage instructions.

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Section 8 - Exposure Control, Personal Protective Equipment

RESPIRATORY PROTECTION Not required under normal and intended uses.	
VENTILATION Not applicable.	
PROTECTIVE GLOVES Wear protective gloves during testing.	EYE PROTECTION Not required
OTHER PROTECTIVE CLOTHING OR EQUIPMENT May exercise universal precautions and personal protective equipment.	

Section 9 - Physical and Chemical Properties

BOILING POINT / MELTING TEMPERATURE Not determined		SPECIFIC GRAVITY Not determined	VAPOR PRESSURE (mm Hg) Not determined
PERCENT VOLATILE BY VOLUME (%) Not determined	VAPOR DENSITY (AIR = 1) Not determined		EVAPORATION RATE (Butyl Acetate = 1) Not determined
SOLUBILITY IN WATER Reagent is aqueous based		REACTIVITY IN WATER Not applicable.	
APPEARANCE AND ODOR Form – liquid Color – colorless to amber colored Odor – none			

Section 10 - Stability and Reactivity

STABILITY Unstable ___ Stable <u>X</u> Non-reactive.	CONDITIONS TO AVOID Not determined
INCOMPATIBILITY (MATERIALS TO AVOID) Not determined	
HAZARDOUS DECOMPOSITION PRODUCTS None of these products contain hazardous chemicals at concentrations of 1% or greater.	
HAZARDOUS POLYMERIZATION May Occur ___ Will Not Occur <u>X</u>	CONDITIONS TO AVOID Not applicable.

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Section 11 – Toxicological Information

RRECS: No information available

LD 50 / LC 50: No information available

Carcinogenicity: None of these products contain known carcinogens at concentrations of 0.1% or greater

Epidemiology: No information available

Teratogenicity: No information available

Reproductive: No information available

Mutagenicity: No information available

Section 12 - Ecological Considerations

Ecotoxicology: No information available

Environmental movement and partitioning: No information available

Environmental Fate (Degradation, Transformation and Persistence): No information available

Environmental Investigations: No information available

Section 13 - Disposal Considerations

WASTE DISPOSAL METHOD

Dispose of waste in accordance with Federal, State, and Local codes.

Section 14 - Transport Information

	US DOT	IMO	IATA	RID / ADR
Shipping Name:	Not regulated as a hazardous material	Not regulated as a hazardous material	Not regulated as a hazardous material	Not regulated as a hazardous material
Hazard Class:	NA			
UN #:	NA			
Packing Group:	NA			
Note: If Alere Cholestech LDX [®] Multianalyte Controls are used and need to be shipped to another facility or returned to Alere please contact the Technical Services Department at 1-877-308-8289				

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Section 15 - Regulatory Information

US Federal TSCA: This material is not listed on the TSCA Inventory.

TSCA Section 12b: This material is not listed.

CERCLA/SARA Reportable Quantities/TPQ's: This material is not listed.

CERCLA/SARA Section 313: This material is not listed.

Clean Air Act: This material is not recognized as an air contaminant.

Clean Water Act: This material is not on any CWA list.

Section 16 - Other Information**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.

Please review product insert prior to using this product.

All individuals using this product should follow general good laboratory safety procedures as established and implemented by your institution in compliance with Federal, State and local requirements.

OTHER PRECAUTIONS: none

Effective Date: 10 November 2011

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Signature Manifest

Document Number: MSDS-4402

Revision: C

Title: Cholestech LDX® Controls

All dates and times are in US/Pacific.

DCF-0205 Update to MSDS-4402

Collaboration Step 1

Name/Signature	Title	Date	Meaning/Reason
Ed Brehm (BREHMED)		15 Nov 2011, 07:27:59 AM	Complete
Renee Wiegmann (WIEGMRE)		15 Nov 2011, 08:05:22 AM	Complete

Collaboration Step 2

Name/Signature	Title	Date	Meaning/Reason
Ed Brehm (BREHMED)			
Matt Rowe (ROWEMA)			
Renee Wiegmann (WIEGMRE)		29 Nov 2011, 08:34:03 AM	Complete

Approval Step

Name/Signature	Title	Date	Meaning/Reason
Ed Brehm (BREHMED)		29 Nov 2011, 09:54:39 AM	Approved
Matt Rowe (ROWEMA)		29 Nov 2011, 11:00:44 AM	Approved
Eric Ogg (OGGER)		29 Nov 2011, 01:59:26 PM	Approved
Robert Schmidt (SCHMIRO)		29 Nov 2011, 03:45:37 PM	Approved
Susan Moi (MOISU)	Manager, Reagent Optimization	2 Dec 2011, 10:21:48 AM	Approved

Final Release

Name/Signature	Title	Date	Meaning/Reason
Farah Shah (FARAH.SHAH)			
Erica Garcia (GARCIER)			
Deborah Phillips (PHILLDE)			
Renee Wiegmann (WIEGMRE)		2 Dec 2011, 12:06:25 PM	Approved