

SAFETY DATA SHEET

Section 1: Identification of the Substance/Mixture and of the Company/Undertaking

Product identifier: LeadCare® Blood Lead Controls

Relevant identified uses of the substance or mixture and uses advised against:
For quality control of LeadCare Analyzers

Details of the supplier of the Safety Data Sheet:

United States:

Magellan Diagnostics, Inc.
101 Billerica Ave., Bldg 4
North Billerica, MA 01862 US
Phone: (800) 275-0102
Fax: (978) 600-1480
Info: bloodleadtechsupport@magellandx.com

Europe:

Ichor Technologies Ltd
1 Paper Mews
300 High Street
Dorking, Surrey, RH4 2TU UK
Phone: +44 (0) 1372 377 754
Fax: +44 (0) 1372 388 282
Info: bloodleadtechsupport@magellandx.com

Emergency telephone number:

(800) 535-5053 (24-hour, US only)

1 (352) 323-3500 (24-hour)

Section 2: Hazards Identification

Classification of the substance or mixture:

While this product may not be classified as hazardous, this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Label elements:

Not applicable

European Classification:

Mixture does not meet the hazard categories' classification criteria of Regulation (EC) No 1272/2008.

This preparation is not classified as dangerous according to Directive 1999/45/EC.

U.S.A.:

This material is not considered hazardous by the OSHA Hazard Communication Standard (29CFR 1910.1200). Animals maintained at State and Federally regulated farms are used to provide blood for these controls. These animals are maintained disease-free and also used to provide blood products for clinical laboratory use.

SAFETY DATA SHEET

Section 2: Hazards Identification, continued

Canada:

This is a controlled product under WHMIS. Classification D3– Biohazardous Infectious Material



Other hazards: Not applicable

Section 3: Composition/Information on Ingredients

Hazardous Substances: 100% Freeze-dried bovine blood. No known hazardous substances at concentration greater than 0.1%.

Section 4: First Aid Measures

Description of first aid measures:

Inhalation: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Obtain medical advice.

Eye Contact: Rinse cautiously with lukewarm, gently flowing water or neutral saline solution for 5 minutes, while holding the eyelid(s) open.

Skin Contact: Flush skin with plenty of water or gently wash with soap and water.

Ingestion: Call a POISON CENTER or doctor/physician if you feel unwell.

Most important symptoms and effects, both acute and delayed:

Inhalation: No immediate adverse health effects are expected from exposure.

Eye Contact: No immediate adverse health effects are expected from exposure.

Skin Contact: No immediate adverse health effects are expected from exposure.

Ingestion: No immediate adverse health effects are expected from exposure.

Indication of any immediate medical attention and special treatment needed: Not Available.

Section 5: Fire Fighting Measures

Extinguishing media:

Product does not burn and will not support combustion. Use extinguishing agents appropriate for the surrounding fire conditions.

Special hazards arising from the substance or mixture:

Not applicable

Advice for firefighters:

No special measures are recommended.

SAFETY DATA SHEET

Section 6: Accidental Release Measures

Personal precautions, protective equipment and emergency procedures:

Wear water-impermeable protective gloves appropriate for the workplace or laboratory where this product is handled.

Environmental precautions:

Prevent release of product to the environment.

Methods and material for containment and cleaning up:

Disinfect the spill area using a solution of 5-7% sodium hypochlorite (bleach) solution. Contain and soak up spilled product and bleach solution with a suitable absorbent (e.g. cloth or papertowel). Place any absorbent and waste product in suitable, covered, labeled containers for proper disposal as a biohazardous waste product. Do not return the spilled product to original containers. Follow applicable laboratory practices for cleaning of spills.

Reference to other sections:

See Section 8 for information on selection of personal protective equipment.
See Section 13 for information on disposal of spilled product and contaminated absorbents.

Section 7: Storage and Handling

Precautions for safe handling:

All blood products must be treated as potentially infectious and users of these products must be properly trained in safe handling procedures. Users of this product must follow all applicable regulations regarding blood borne pathogens and practice universal precautions.

Wear personal protective equipment required for the workplace. Guidelines for selection of protective equipment are described in Section 8.

Wash hands thoroughly immediately after exposure to product and at the end of the work-shift. Workers whose clothing has been contaminated by product should change into clean clothing promptly. Do not eat, smoke or drink where product is handled, processed, or stored. Keep contaminated clothing in closed containers. Discard or launder before rewearing. Inform laundry personnel of contaminant's hazards.

Conditions for safe storage, including any incompatibilities:

Reagents must be stored according to label directions in tightly-closed containers. Store at 2 - 8 °C.

Specific end use(s):

For quality control of LeadCare Analyzers

Section 8: Exposure Controls / Personal Protection

Control parameters:

Consult regional/local authorities for acceptable exposure limits.

<u>Ingredient</u>	<u>Ontario TWAEV</u> (ppm)	<u>ACGIH TLV</u> (8-hr. TWA) (ppm)	<u>U.S. OSHA PEL</u> (8-hr. TWA) (ppm)	<u>U.K. WEL</u> (8-hr. TWA) (ppm)
Freeze dried bovine blood	Not established	Not established	Not established	Not established

Exposure controls:

Engineering Controls: No special requirements.

Personal Protection: Workers must comply with the Personal Protective Equipment requirements of the workplace in which this product is handled.

Eye/Face Protection: Wear laboratory safety glasses, goggles or other eye protection appropriate for the workplace.

Skin Protection: Wear water-impermeable protective gloves and other skin protection appropriate for the workplace.

SAFETY DATA SHEET

Section 8: Exposure Controls / Personal Protection, continued

Respiratory Protection: Respiratory protection is not required when product is used as directed, for its intended purpose. If respiratory protection is required, institute a complete respiratory protection program including selection, fit testing, training, maintenance and inspection.

A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements or European Standard EN 149 or Canadian Standards Association (CSA) Standard Z94.4-2002 must be followed whenever workplace conditions warrant a respirator's use.

Other: Workplaces should have a safety shower, hand-wash station and eye-wash fountain readily available in the immediate work area.

Section 9: Physical and Chemical Properties

Information on basic physical and chemical properties:

Appearance:	Dark, freeze-dried powder
Odor:	Odorless
Odor threshold:	Not applicable
pH:	Not applicable
Melting point/freezing point:	Not applicable
Initial boiling point and boiling range:	Not applicable
Flash point:	Not applicable, product is not flammable or combustible.
Auto-ignition temperature:	Not applicable
Upper/lower flammability or explosive limits:	Not applicable
Explosive properties:	Not applicable
Oxidising properties:	Not applicable
Sensitivity to mechanical impact:	Not applicable
Sensitivity to static discharge:	Not applicable
Vapor pressure:	Not available
Vapor density:	Not available
Relative density:	Not available
Solubility (ies):	Not available
Partition coefficient (n-octanol/water):	Not available
Decomposition temperature:	Not available
Viscosity:	Not available
Other information:	Not available

Section 10: Stability and Reactivity

Reactivity:

Not classified as dangerously reactive.

Chemical Stability:

Normally stable.

Possibility of Hazardous Reactions:

Hazardous polymerization does not occur.

Conditions to Avoid:

Not available

Incompatible Materials:

Not applicable

Hazardous Decomposition Products:

Not applicable

SAFETY DATA SHEET

Section 11: Toxicological Information**Information on toxicological effects:****Acute Health Effects:**

Relevant Route(s) of Exposure: Skin contact, inhalation of dust

Inhalation: No acutely toxic effects are expected exposure by inhalation of dust. Product may contain blood-borne pathogens which may be transmitted by inhalation of airborne dust.

Ingestion: Not an expected route of exposure. No acutely toxic effects are expected from a single exposure, if swallowed. Product may contain blood-borne pathogens which may be transmitted by swallowing.

Skin: No adverse health effects are expected from direct contact with the product.

Eye: No adverse health effects are expected from direct contact with the product. Product may contain blood-borne pathogens which may be transmitted by contact with the eyes.

Acute Toxicity Data

Acute toxicology data is not available for this product.

Chronic Health Effects:

No data is available for the product. No long-term health effects are expected from occupational exposures to this product. Product may contain blood-borne pathogens which may be transmitted by occupational exposures by inhalation, ingestion, eye and skin contact.

Sensitization:

Not applicable

Neurological Effects:

Not applicable

Genetic Effects:

Not applicable

Reproductive Effects:

Not applicable

Developmental Effects:

Not applicable

Target Organ Effects:

Not applicable

Carcinogenicity:

This product does not contain any component that is considered a human carcinogen by IARC (International Agency for Research on Cancer), ACGIH (American Conference of Governmental Industrial Hygienists), OSHA (Occupational Safety and Health Administration) or NTP (National Toxicology Program).

Medical Conditions Aggravated by Exposure:

Not available

Interactions With Other Chemicals:

Not available

SAFETY DATA SHEET

Section 12: Ecological Information

Toxicity:	No toxic effects are expected.
Persistence and degradability:	Substances are not persistent.
Bioaccumulative potential:	Substances are not bioaccumulative.
Mobility in soil:	Not available
Results of PBT and vPvB assessment:	Not available
Other adverse effects:	Not available

Section 13: Disposal Considerations

Waste treatment methods:

Follow all applicable regulations regarding disposal of blood borne pathogens. Store material for disposal in covered, labeled bio-hazard containers.
 Follow applicable laboratory practices for disposing of potentially hazardous waste. Dispose of contents/container in accordance with local/regional/national/ international regulations.

Section 14: Transport Information

UN Number:	Not regulated as dangerous good for transport.
UN proper shipping name:	Not applicable
Transport hazard class(es):	Not applicable
Packing group:	Not applicable
Environmental hazards:	Not applicable
Special precautions for user:	Not available
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code:	Not applicable

Section 15: Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture:

USA

Toxic Substances Control Act 8(b) Inventory: Not available

SARA Title III:

Sec. 302/304: Not applicable
 Sec. 311/312: Not applicable
 Sec. 313: Not applicable
 CERCLA RQ: Not applicable

Canada

This product has been classified in accordance with the hazard criteria of the *Controlled Products Regulations* and the MSDS contains all the information required by the *Controlled Products Regulations*.

WHMIS Classification: D3; based on bovine blood content which may contain pathogens.

New Substance Notification Regulations: Naturally occurring product.

National Pollutant Release Inventory: Not applicable

EU

EINECS Inventory: Not applicable

SAFETY DATA SHEET

Section 15: Regulatory Information, continued**Other National Inventories****Australia:** Not applicable**China:** Not applicable**Japan:** Not applicable**Korea:** Not applicable**New Zealand:** Not applicable**Philippines:** Not applicable**Chemical safety assessment:**

Not applicable

Section 16: Other Information**References and sources for data:**

HSDB – Hazardous Substances Data Bank; US National Library of Medicine
Cheminfo – Canadian Centre for Occupational Health and Safety
RTECS – Registry of Toxic Effects of Chemical Substances
Supplier MSDSs for component substances.

Methods for classification of mixtures:

Does not meet the criteria for classification as hazardous according to Regulation EC No 1272/2008 Annex I.

Full text of risk/hazard statements under Section 3:

Not applicable

Legend to abbreviations:

WHMIS – Workplace Hazardous Materials Information System.
SARA - Title III of the Superfund Amendments and Reauthorization Act of 1986
CERCLA RQ - Comprehensive Environmental Response, Compensation, and Liability Act of 1980
PBT Persistent, Bioaccumulative and Toxic substances
vPvB Very Persistent, very Bioaccumulative substances
TWAEV – Time weighted average exposure value
TWA – Time weighted average
TLV - Threshold Limit Value
WEL – Workplace exposure limit
PEL – Permissible exposure limit
ACGIH – American Conference of Governmental Industrial Hygienists
OSHA - Occupational Safety and Health Administration

Supplier Note:

Product is intended for use by qualified professionals experienced in handling potentially hazardous chemicals and trained in good laboratory practices. The above information is believed to be correct but does not purport to be all inclusive. All materials may present unknown hazards and should be used with caution. Magellan Diagnostics shall not be held liable for any damage resulting from handling or contact with above product.

Prepared by:

Magellan Diagnostics, Inc.