

## SAFETY DATA SHEET

<b>Version</b>	2.0	<b>Issue Date</b>	15 Jul 2011
<b>Revision Date</b>	16 Dec 2010		
<b>Supersedes</b>	21 Jun 2001	<b>Generic GHS format – No country specific data</b>	

### SECTION 1: IDENTIFICATION OF THE SUBSTANCE AND COMPANY

**Product Name** POSITIVE PRODUCT CONTROL (PPC)  
**Brand** Endosafe  
**Product Codes** PC100, PC200

**Intended Use** R&D/Experimental use only

**Manufacturer** Charles River  
**Division** Endotoxin and Microbial Detection  
**Address** 1023 Wappoo Rd  
 Suite 43-B  
 Charleston, SC 29407

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### SECTION 2: HAZARDS IDENTIFICATION

**Classification** Not a dangerous substance or mixture according to GHS criteria.

**Label elements** None

**Hazard statements** None

**Other hazards** Lipopolysaccharides are highly pyrogenic. Administered intravenously, the minimal pyrogenic dose in humans has been estimated at 4 ng/kg. Their toxicological properties have not been fully investigated.

### SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

**Chemical Name** Limulus Amebocyte Lysate (LAL) and Lipopolysaccharides (LPS) co-lyophilized in a buffered medium.

Components	CAS#	RTECS#	EC#	Concentration
Hemocyt, limulus polyphemus, lysate	68606-22-4	-	271-731-2	< 1mg
Lipopolysaccharides, from Escherichia coli 055:B5	93572-42-0	JZ2650000	297-473-0	0.05 µg

#### SECTION 4: FIRST AID MEASURES

<b>Eye contact</b>	Flush eyes with plenty of water.
<b>Skin contact</b>	Rinse immediately with soap and plenty of water.
<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Rinse mouth with water.
<b>Inhalation</b>	Move person into fresh air. If not breathing give artificial respiration consult a physician

#### SECTION 5: FIRE-FIGHTING MEASURES

<b>Flash point</b>	Not available
<b>Ignition temperature</b>	Not available
<b>Extinguishing media</b>	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
<b>Additional information</b>	This material is assumed to be combustible. Burning may produce irritating fumes.

#### SECTION 6: ACCIDENTAL RELEASE MEASURES

<b>Personal precautions</b>	Use personal protective equipment. Avoid dust formation. Avoid breathing dust. Ensure adequate ventilation.
<b>Environmental precautions</b>	Prevent product from entering drains.
<b>Methods for cleaning</b>	Use a wet sponge or damp cloth. Keep in suitable, closed containers for disposal

#### SECTION 7: HANDLING AND STORAGE

<b>Handling</b>	Wear personal protective equipment and avoid contact with skin and eyes. Good laboratory technique should be used in handling product.
<b>Storage</b>	Recommended storage temperature: 2 - 8 °C

#### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

<b>Engineering measures</b>	Contains no substances with occupational exposure limit values
<b>Respiratory protection</b>	Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multipurpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering

controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

<b>Eye protection</b>	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
<b>Skin and body protection</b>	Wear appropriate protective gloves and clothes to prevent skin exposure.
<b>Hygiene measures</b>	Handle in accordance with good industrial hygiene and safety practices.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

<b>Physical state</b>	Powder, lyophilized
<b>Odor</b>	Not available
<b>pH</b>	Not available
<b>Melting/freezing point</b>	Not available
<b>Boiling point</b>	Not available
<b>Flash point</b>	Not available
<b>Evaporation rate</b>	Not available
<b>Flammability</b>	Not available
<b>Upper/lower flammability limits</b>	Not available
<b>Vapor pressure</b>	Not available
<b>Vapor density</b>	Not available
<b>Specific gravity</b>	Not available
<b>Water solubility</b>	Soluble
<b>Partition coefficient: n-octanol/water</b>	Not available
<b>Decomposition temperature</b>	Not available
<b>Viscosity</b>	Not applicable

## SECTION 10: STABILITY AND REACTIVITY

<b>Stability</b>	Stable under recommended storage conditions
<b>Materials to avoid</b>	Strong acids, bases and oxidizers
<b>Conditions to avoid</b>	Heat

<b>Hazardous polymerization</b>	Will not occur
<b>Hazardous decomposition</b>	Hazardous decomposition products formed under fire conditions – Carbon oxides

## SECTION 11: TOXICOLOGICAL INFORMATION

### Acute toxicity (LD50)

**Oral** Studies with a similar E. coli serotype report a dose of 48.3 mg/kg [Rat]

**Intraperitoneal** 7.6 mg/kg [Rat]

**Chronic exposure** Not available

**Irritation and corrosion** Not available

### Carcinogenic effects

**IARC** No components of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**Mutagenic effects** Not available

**Reproductive toxicity** Studies of pregnant rats treated intraperitoneally with similar E. coli endotoxin showed an increase in fetal hydrocephalus and neuronal necrosis. Intravenous doses up to 1000 µg resulted in resorptions and dead fetuses but no increase in congenital defects. Similar studies involving guinea pigs showed an increase in malformations and resorptions when given doses of 10 to 20 µg/kg intravenously.

**Specific target organ systemic toxicity (single exposure)** Not available

**Specific target organ systemic toxicity (repeated exposure)** Not available

**Aspiration hazard** Not available

## SECTION 12: ECOLOGICAL INFORMATION

**Toxicity** Not available

**Persistence/degradability** Not available

**Bioaccumulative potential** Not available

**Mobility in soil** Not available

**Other adverse effects** Not available

## SECTION 13: DISPOSAL CONSIDERATIONS

<b>Product</b>	Observe all federal, state, and local environmental regulations
<b>Contaminated packaging</b>	Dispose of as unused product.

## SECTION 14: TRANSPORT INFORMATION

<b>ADR\RID</b>	Not dangerous goods
<b>IATA</b>	Not dangerous goods
<b>IMDG</b>	Not dangerous goods

## SECTION 15: REGULATORY INFORMATION

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

No data available

## SECTION 16: OTHER INFORMATION

Although the information and recommendations set forth herein (hereinafter "information") are presented in good faith and believed to be correct as of the date hereof, Charles River Endosafe makes no representations as to the completeness or accuracy thereof. Information is supplied upon the condition that the persons receiving same will make their own determination as to its safety and suitability for their purposes prior to use. In no event will Charles River Endosafe be responsible for damages of any nature whatsoever resulting from the use of or reliance upon information.

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