

SAFETY DATA SHEET

Version	2.0	Issue Date	15 Jul 2011
Revision Date	06 Apr 2011		
Supersedes	21 Jun 2001	According to Regulation (EC) No. 1907/2006	

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
Telephone	001 843 402 4900
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SECTION 2: HAZARDS IDENTIFICATION

Classification	Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008.
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 - For in vitro purposes only, not for use in humans.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	Limulus Amebocyte Lysate (LAL) and Lipopolysaccharides (LPS) co-lyophilized in a buffered medium.
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Components	CAS#	RTECS#	EC#	Concentration
Hemocyte, 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

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

SECTION 5: FIRE-FIGHTING MEASURES

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

SECTION 6: ACCIDENTAL RELEASE MEASURES

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

SECTION 7: HANDLING AND STORAGE

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

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering measures	Contains no substances with occupational exposure limit values
Respiratory protection	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).
Eye protection	Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
Skin and body protection	Wear appropriate protective gloves and clothes to prevent skin exposure.
Hygiene measures	Handle in accordance with good industrial hygiene and safety practices.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

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

SECTION 10: STABILITY AND REACTIVITY

Stability	Stable under recommended storage conditions
Materials to avoid	Strong acids, bases and oxidizers
Conditions to avoid	Heat
Hazardous polymerization	Will not occur
Hazardous decomposition	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

PBT and vPvB assessment Not available

SECTION 13: DISPOSAL CONSIDERATIONS

Product Observe all federal, state, and local environmental regulations

Contaminated packaging Dispose of as unused product.

SECTION 14: TRANSPORT INFORMATION

ADR\RID Not dangerous goods

IATA Not dangerous goods

IMDG 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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