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## Safety Data Sheet

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### Steriluent Process Challenge Device

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#### 1. IDENTIFICATION

**Product name:** Steriluent Process Challenge Device

**Product Synonym:** Process Challenge Device

**Product Description:** Device for monitoring hydrogen peroxide sterilization efficacy of hospital and industrial sterilization processes. Device consists of a sealed plastic tube containing a stainless steel disc inoculated with non-pathogenic test organisms and a crushable “onion skin” sealed glass ampoule of non-hazardous growth medium. Note: device contains no hazardous ingredients or pathogenic microorganisms.

**Supplier:** Steriluent, Inc.  
1400 Marshall Street NE  
Minneapolis, MN 55413  
(612) 767-3260

**Customer/Technical Service:** 1-877-721-8405

#### 2. HAZARD(S) IDENTIFICATION

The device contains glass and liquid which, upon accident, may enter the skin or eye causing minor injury and/or irritation.

#### 3. COMPOSITION / INFORMATION ON INGREDIENTS

**Growth Medium Composition:** Soybean casein digest, manufactured by BD, pH indicator, and proprietary formulation. Non-hazardous.

**Biological Information:** Bacterial spores obtained from traceable source. Naturally occurring. Non-pathogenic.

#### 4. FIRST-AID MEASURES

**Eye:** If liquid media enters the eye, flush with water. If the media ampoule is crushed outside of the plastic body, glass splinters may enter the eye. Do not rub eye. Flush with water. If glass cannot be dislodged with water, medical assistance may be required.

**Skin:** Under normal circumstances contact with the device should not result in skin irritation. If liquid media comes in contact with skin, wash with soap and water. If the media ampoule is crushed outside of the plastic body, glass splinters may enter the hands or fingers. Remove splinters with tweezers and apply disinfectant to cut areas.

**Ingestion:** Not a likely route of exposure.

**Inhalation:** Not a likely route of exposure.

Note: There are no known health hazards from exposure to the microorganisms contained in this product.

5. FIRE-FIGHTING MEASURES

N/A

6. ACCIDENTAL RELEASE MEASURES

Clean and disinfect area of spill.

7. HANDLING AND STORAGE

Store at room temperature. Keep away from sterilants as they may injure the microorganisms contained in the product, reducing its functionality.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

**Exposure Limits:** N/A

**Specific Engineering Controls:** N/A

**Personal Protective Equipment:** Appropriate gloves and safety glasses should be worn when removing this product from the sterilizer, activating (crushing media tube), or cleaning spilled media / broken glass.

9. PHYSICAL AND CHEMICAL PROPERTIES

**Odor and Appearance:** The Sterilucent Process Challenge Device consists of an inoculated stainless steel disc and glass media ampoule contained in a sealed plastic body. The device contains no hazardous ingredients or pathogenic organisms.

**Specific Gravity:** N/A

**Evaporation Rate:** N/A

**pH:** N/A

**Vapor Density:** N/A

**Boiling Point:** N/A

**Coefficient of Water/Oil Distribution:** N/A

**Odor Threshold:** N/A

**Vapor Pressure:** N/A

**Freezing Point:** N/A

**Solubility in Water:** N/A

10. STABILITY AND REACTIVITY

**Chemically Stable:** Yes

**Incompatibility:** N/A

**Reactivity:** N/A

**Hazardous Decomposition Products:** N/A

11. TOXICOLOGICAL INFORMATION

**Affects of Acute Exposure:** N/A

**Affects of Chronic Exposure:** N/A

**Irritancy of Product:** N/A

**Skin Sensitization:** N/A



**Respiratory Sensitization:** N/A  
**Carcinogenicity:** N/A  
**Reproductive Toxicity:** N/A  
**Teratogenicity:** N/A  
**Embryotoxicity:** N/A  
**Mutagenicity:** N/A  
**Synergistic Products:** N/A

**12. ECOLOGICAL INFORMATION**

This product contains no known ecological hazards. The microorganisms it contains are non-pathogenic and found in nature. The chemicals are non-toxic biological nutrients and a non-toxic pH sensitive dye.

**13. DISPOSAL CONSIDERATIONS**

Autoclave at 121°C for 30 minutes prior to disposal or incinerate.

**14. TRANSPORT INFORMATION**

No special shipping precautions.

**15. REGULATORY INFORMATION**

N/A

**16. OTHER INFORMATION**

Revision date: 2015

See instructions for use delivered in each box of product.

**Disclaimer**

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Steriluent, Inc.