INSTRUCTIONS FOR USE

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Epower™ Certified Reference Material Microorganisms

INTENDED USE

The **Epower™ Certified Reference Material (CRM)** microorganisms are lyophilized, quantitative microorganism preparations to be used in industrial laboratories for quality control purposes. A single **Epower CRM** microorganism can be employed as an individual microorganism challenge or several **Epower CRM** microorganisms can be combined and employed as a mixed microorganism population challenge. These microorganism preparations are traceable to the American Type Culture Collection (ATCC®) or other authentic reference culture collection. CRM is recommended for validation of a new method, verification, calibration, and for quality control when a standard with known phenotypic properties is required.

SUMMARY AND HISTORY

Microbiologics became ISO Guide 34 accredited in 2009 as a qualified reference material producer. ISO Guide 34 defines reference material as material that is “sufficiently homogeneous and stable with respect to one or more properties, which has been established to be fit for its intended use in a measurement process. Properties can be quantitative or qualitative (e.g. identity of substances or species)”. Homogeneity of CRM is ensured by testing samples from each new lot for purity, concentration, and morphological characteristics. In order for the new lot of CRM to be released for sale, all samples must be free from contamination, demonstrate morphological characteristics typical for the strain, and be at the required concentration for the product.

FORMULA COMPONENTS

The lyophilized preparation consists of an enumerated microorganism population, skim milk (bovine - USA origin), a carbohydrate, gelatin (porcine - USA or Canada origin), ascorbic acid, and charcoal. The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and a carbohydrate protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage. The charcoal is included to neutralize any toxic substances formed during the lyophilization process.

Epower CRM microorganisms conform with Article 5 of EC 1069/2009 as they have reached the endpoint in the manufacturing chain and are no longer subject to the requirements of EC 1069/2009. The products are considered derived products per Article 36 of EC 1069/2009 and do not pose any significant risk to public or animal health.

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SPECIFICATIONS AND PERFORMANCE

Epower™ CRM microorganisms are packaged in a kit configuration. Each kit consists of:

- 1 vial containing 10 lyophilized pellets of an individual microorganism strain
- Detailed instructions
- Certificate of Analysis

Epower CRM microorganisms are available at a variety of challenge concentrations. These concentrations are identified by the code at the end of the catalog number.

For Example:

Catalog number 0392E3-CRM identifies a challenge concentration of 103 CFU per pellet. This means each E3 pellet will contain 1,000 – 9,999 CFU.

Catalog number 0392E6-CRM identifies a challenge concentration of 106 CFU per pellet. This means each E6 pellet will contain 1,000,000 – 9,999,999 CFU.

Pellet Concentration	**Examples of Concentration** (CFU/ml) in Specified Hydrating Fluid Volume		
	1 ml	**10 ml**	**100 ml**
E2	100 – 999	10 – 99	1 – 9
E3	1000 – 9999	100 – 999	10 – 99
E4	10,000 – 99,999	1000 – 9999	100 – 999
E6	1,000,000 – 9,999,999	100,000 – 999,999	10,000 – 99,999
E7	10,000,000 – 99,999,999	1,000,000 – 9,999,999	100,000 – 999,999
E8	100,000,000 – 999,999,999	10,000,000 – 99,999,999	1,000,000 – 9,999,999

Quality control documentation includes, but is not limited to, a Certificate of Analysis stating:

- The identity of the microorganism
- The traceability of the microorganism to a reference culture
- That the microorganism is 1 passage from the reference culture
- The certified value for the microorganism preparation
- The expanded uncertainty

Microbiologics Recommended Growth Requirements Technical Information Bulletin (TIB.081) lists the recommended media and incubation requirements for strains. This TIB, along with many others, are available on our website.

INSTRUCTIONS FOR USE

1. Remove the vial of pellets from refrigerated storage and allow to equilibrate to room temperature.
2. Prior to use, warm hydrating and dilution fluids to 34°C–38°C. Sterile pH 7.2 phosphate buffer is recommended for hydration of the lyophilized preparation.
3. With sterile forceps, transfer the **Epower CRM** microorganism pellet(s) to the hydrating fluid. Do not remove the desiccant from vial. Immediately stopper and recap the vial and return to 2°C–8°C.
4. Place the microorganism suspension into a 34°C–38°C incubator for 30 minutes to assure complete hydration.
5. Immediately following incubation, mix hydrated material until a homogeneous suspension is achieved.

6. Proceed with the challenge according to laboratory protocol. The challenge must be completed within 30 minutes of the hydration process to avoid a change in the challenge suspension concentration.

PRECAUTIONS AND LIMITATIONS

- Not intended for clinical use.
- Not intended for human, animal or pet consumption.
- **Epower™ CRM** microorganisms do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- Refer to the SDS for more detailed information. The SDS can be located on our website at **www.microbiologics.com** or by contacting Technical Support at **320.229.7045**.
- These products, and growth of these microorganisms, are considered biohazard material.
- These products contain viable microorganisms that may produce disease. Proper techniques must be employed to avoid exposure and contact with any microorganism growth.
- The microbiology laboratory must be equipped, and have the facilities to receive, process, maintain, store and dispose of biohazard material.
- Only trained laboratory personnel should use these products.
- Agencies and statutes regulate the disposal of all biohazard materials. Each laboratory must be aware of, and comply with, the proper disposal of biohazard materials.
- **Epower CRM** microorganisms are not made with natural rubber latex.
- Possible microorganism degradation may occur over time and may affect the certified value.

TECHNICAL NOTES

Certified Value

- The certified value obtained at Microbiologics was calculated using well proven statistical methods. As part of Microbiologics' quality control procedure, pellets from each **Epower CRM** microorganism lot are hydrated in pH 7.2 phosphate buffer. Replicate colony counts are performed on non-selective agar media and enumerated using an automated colony counting device. Results may differ from the certified value due to different materials and methods used.
- Variability of hydrating fluid, sampling, different colony counting techniques, incubation and the use of selective agar media will produce colony counts that vary from the stated mean certified value.

Shelf Life and Stability

- Exposure to heat, moisture, and oxygen can adversely affect the stability of the microorganism. Both reproducibility and stability are predicated on proper storage of the lyophilized preparations in the original desiccant-containing vial.
- Hydration activates the respiration and metabolic activity of the lyophilized microorganism. In the absence of critical growth requirements (i.e. nutrients and incubation conditions), the stability of the microorganism population can be affected.

Analyte Challenge

- If the application requires a food sample, do not add the food sample to the hydrated suspension until immediately before processing and testing.
- The potential exposure of moisture and oxygen in the food sample can have a profound influence on the stability of the microorganisms.
- Food samples can also introduce inhibitory or toxic properties that adversely influence the recovery of microorganism populations.
- A food sample can also introduce an intrinsic population of microorganisms which can produce an inhibitory or toxic influence on the remaining microorganisms in the population.

Hydrating Fluid and Hydration

- Lyophilized microorganisms must be hydrated to achieve viability. The intrinsic properties of hydrating fluids can influence recovery and anticipated assay values.
- The structure of the lyophilized pellet is provided by gelatin, which liquefies when warmed. To liquefy the gelatin, and ensure complete hydration and a uniform suspension of the microorganism population, follow the Instructions for Use.

STORAGE AND EXPIRATION

Store **Epower CRM** microorganisms at 2°C–8°C in the original, sealed vial. Stored as directed, the lyophilized microorganism preparation is warranted to retain, until the last day of the month of the expiration date stated on the product label, its specifications and performance within the stated limits.

Epower CRM microorganisms should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The expiration date has passed

MATERIALS REQUIRED BUT NOT PROVIDED

- **Sterile forceps or tweezers–** required for the removal of an individual pellet and placement into the primary dilution fluid.
- **Enrichment broths, dilution fluids, and required testing materials–** for qualitative or quantitative test methods in accordance with each individual laboratory's SOP.

KEY OF SYMBOLS

	Batch Code (Lot)		Manufacturer
	Biological Risks		Temperature Limitation
	Catalog Number		Use By
	Caution, Consult Accompanying Documents; Attention, see instructions for use		

PRODUCT WARRANTY

These products are warranted to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature. The warranty, expressed or implied, is limited when:

- The procedures employed in the laboratory are contrary to printed and illustrated directions and instructions
- The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature

- If the resuscitated culture is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

WEBSITE

Visit our website, **www.microbiologics.com**, for current technical information, product availability, biohazard cleanup, growth requirements, and Certificate of Analysis.

ACKNOWLEDGEMENTS

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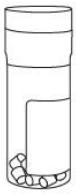
ILLUSTRATED INSTRUCTIONS

If using the Membrane Filtration Method for water testing, please refer to the Illustrated Instructions (LIT.248) located at www.microbiologics.com.

1



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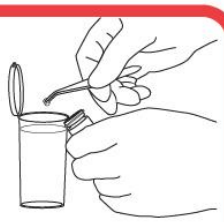

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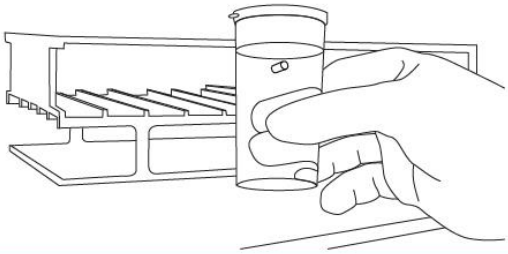

5

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