INSTRUCTIONS FOR USE

Custom Solutions for Growth Promotion Testing

INTENDED USE

Growth promotion microorganisms are lyophilized, enumerated microorganism preparations to be used in laboratories for quality control purposes. Processed as directed, these preparations provide a challenge of 10-100 CFU per 0.1 ml on non-selective media.

FORMULA COMPONENTS

The lyophilized preparation consists of:

An enumerated microorganism population	Skim milk (Bovine – USA origin)	Carbohydrate
Gelatin (Porcine – USA or Canada origin)	Ascorbic acid	

The hydrating fluid is a working solution of pH 7.2 phosphate buffer. The fluid contains:

Monobasic potassium phosphate	Deionized water
Sodium hydroxide	Magnesium chloride as required

Growth promotion microorganisms conform with Article 5 of EC 1069/2009 as they have reached the end point 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.

PRECAUTIONS AND LIMITATIONS

- This product is not intended to diagnose, treat, cure or prevent any disease.
- Not intended for human, animal or pet consumption.
- Growth promotion microorganisms do not contain any hazardous substances listed in 67/548/EEC or listed in 1272/2008/EC.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located on our website at **www.microbiologics.com** or by contacting Technical Support at **1.320.229.7045**
- These devices, and growth of these microorganisms, are considered biohazard material.
- These devices contain viable microorganisms that may produce disease. Proper techniques must be employed to avoid exposure and contact with any microorganism growth.

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- 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 devices.
- 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.

KEY OF SYMBOLS

	Batch Code (Lot)		Manufacturer
	Biological Risks		Temperature Limitation
	Catalog Number		Use By
	Caution, Consult Accompanying Documents		

STORAGE AND EXPIRATION

Custom Solutions GPT products have a standard expiration date of 2-years from the time of manufacture. Because we have no prior experience with your specific in-house isolate, the performance date could be less than 2 years. As Microbiologics gains experience with your specific in-house isolates, the expiration date may be adjusted. If the product does not perform as described in this IFU up to the expiration date, please contact Microbiologics Technical Support for assistance and resolution.

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 and biohazard cleanup.

ACKNOWLEDGEMENTS

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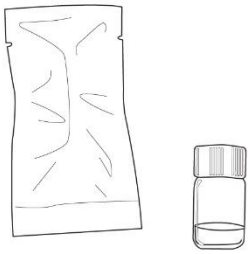
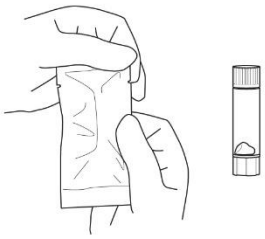
ILLUSTRATED INSTRUCTIONS

This kit was assembled with the correct volume of hydrating fluid and number of pellets per vial to deliver a concentration of 10-100 CFU per 0.1 ml. The hydrating fluid in this kit is only intended for use with this lot.

1 Remove 1 vial of hydrating fluid and 1 foil pouch from refrigerated storage. Allow unopened pouch and hydrating fluid to equilibrate to room temperature (about 30 minutes)



2

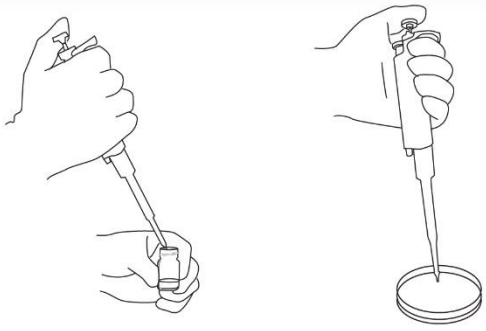


Tear open the foil pouch and remove the pellet vial.

3 Remove the caps from the pellet vial and the hydrating fluid vial. Tip entire contents of the pellet vial into the hydrating fluid vial.

4 Vortex the hydrated material until the pellet has completely dissolved and the suspension is homogeneous.

5 With a sterile pipette, transfer 0.1 ml of the suspension to the material being challenged (0.1 ml contains 10-100 CFU).



6 Proceed with the challenge procedure according to laboratory protocol. Discard any remaining hydrating material in accordance with the laboratory protocol for disposal of biohazard material. If the resuscitated culture is frozen, Microbiologics cannot guarantee the state characteristics of the product

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A safer, healthier world.