

Product PN **10496164**

Mod. 984

Description **Heterotrophic Plate Count Broth without Indicator - Ampoules – 50x 2ml Ampoules**

Rev. 02

Heterotrophic Plate Count Broth without Indicator - Ampoules



PRODUCT DESCRIPTION	<p>AMP HPC 2ml, (50pk)</p> <p>Heterotrophic Plate Count Broth (HPC) without indicator is a pale yellow colored microbiology nutrient liquid media used to detect heterotrophic bacteria in water. The broth contains gelatin and should be warmed above 28°C to melt the gelatin before dispensing.</p>
MANUFACTURER NAME	<p>GVS North America 63 Community Drive Sanford, Me 04073 Phone: +1.866.736.1250 eMail: CustomerCareGVSLs@gvs.com - Website: www.gvs.com</p>
INTENDED USE / APPLICATION	<p>Heterotrophic Plate Count Broth (HPC) without indicator is a used to detect heterotrophic bacteria in water using the membrane filtration technique.</p>
MATERIALS	<p>Media: Heterotrophic Plate Count Broth (HPC) without indicator</p> <p>Color: Pale yellow nutrient liquid</p> <p>Ampoules: polypropylene</p> <p>Regulatory Documentation Required:</p> <ul style="list-style-type: none"> <input type="checkbox"/> Biocompatibility according ISO 10993-1 <input type="checkbox"/> IMDS <input checked="" type="checkbox"/> RoHS, directive 2002/95/CE <input type="checkbox"/> BSE/TSE, directive 2003/32/ <input type="checkbox"/> DEHP plasticizer Free and latex free <input type="checkbox"/> Aging <input checked="" type="checkbox"/> Reach 1907/2006/CE (hazardous substances regulation) <input type="checkbox"/> Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) <input checked="" type="checkbox"/> Conflict minerals

PRODUCT SPECIFICATION

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<p>PRODUCT CHARACTERISTIC</p>	<p>Pale yellow colored liquid media dispensed in plastic ampoules.</p> <p>Physical: Ampoule Dimensions: 57.9 mm x 8.4mm (at cap)/22 mm (at seal) Volume/ampoule: 2 - 2.4 ml</p> <p>Incubation Temperature Range: 35°C ± 2°C Storage temperature Range: From 2°C to 8°C</p> <p>Biological: Product is sold sterilized. Toxicity: See SDS for further information.</p> <p>Media Formulation: Approximate formula* per liter of water</p> <table border="1" data-bbox="327 929 1029 1030"> <tr> <td>Peptone</td> <td>30 gm</td> </tr> <tr> <td>Gelatin</td> <td>15 gm</td> </tr> <tr> <td>Glycerol</td> <td>15 ml</td> </tr> </table> <p><i>* Adjusted and/or supplemented as required to meet performance requirements pH: 7.1 ± 0.2</i></p>	Peptone	30 gm	Gelatin	15 gm	Glycerol	15 ml
Peptone	30 gm						
Gelatin	15 gm						
Glycerol	15 ml						
<p>INSTRUCTIONS WARNINGS</p>	<p>Product is temperature and light sensitive. Store at recommended temperature protected from light.</p>						
<p>PRODUCT SHELF LIFE</p>	<p>12 months when stored properly</p>						
<p>STERILIZATION</p>	<p>Product is sold sterilized.</p>						

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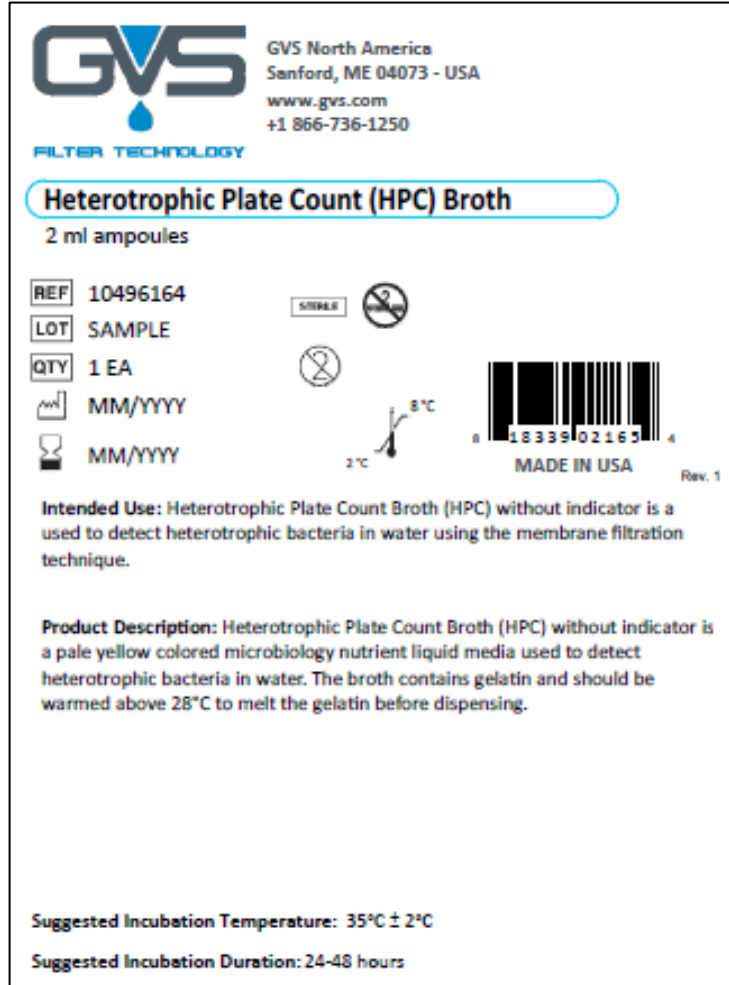
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PACKAGING AND LABELLING

Primary: 50 ampoules are placed in a labeled foil bag and sealed using a heat sealer.



CERTIFICATE OF COMPLIANCE

With each shipment, GVS NA will provide the CoC with item number, lot number and expiration date. The Quality management system is in compliance with ISO 9001.

VISUAL REQUIREMENTS

Visual acceptance requirements apply when inspected under below conditions:

Magnification: none

Light type: normal room lighting

Acceptance Requirement			Sampling Plan
1	Color – pale yellow	all	100%
2	Ampoule appearance – no misshapen or leaking ampoules	none	

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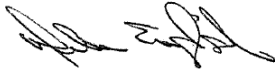
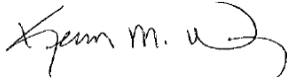
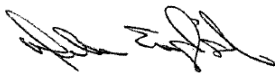
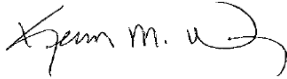
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PERFORMANCE REQUIREMENTS	Acceptance Requirement		Sampling Plan
	Parameter	Specification	
1	Recovery (Measured against control)	≥ 85%	ISO 11133:2014
2	Test Organism	<i>E. coli</i> ATCC 25922	ISO 11133:2014
3	pH at 25°C	7.1 ± 0.2	ISO 11133:2014
4	Sterility	Zero Growth	ISO 11133:2014
5	Media Color	Pale Yellow	ISO 11133:2014
6	Colony Color	Organism Dependent <i>E. coli</i> is cream-yellow	ISO 11133:2014
7	Incubation	35°C ±2°C for 24-48 Hours	ISO 11133:2014

This material specification describes the properties of product above indicated.
This document contains general requirements, material description, drawing references, defect specification, biological material requirements.

REVISIONS AND APPROVALS:

DATE	REV.	REASON FOR CHANGE	ISSUED AND CONTROLLED BY: (name /function and signature)	APPROVED BY: (name /function and signature)
11/7/18	0	Initial release	Debra English/Manager Biochemistry Applications 	Kevin Wrigley/Director, Quality 
7/28/2021	1	Update description, label, ampoule dimension & add media formulation	Debra English/Manager Biochemistry Applications 	Kevin Wrigley/Director, Quality 

Customer Approval:



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We accept this material specification as a part of the agreed terms of delivery

Company name _____

Approved by: _____
(Name, Function) (Signature)

Date _____
(Company stamp)

Please send back this document signed for approval. If we will not receive this specification signed, we consider the first order placed as implicit approval.