PRODUCT SPECIFICATION

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	AMP HPC 2ml, (50pk) 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.
MANUFACTURER NAME	**GVS North America** **63 Community Drive** **Sanford, Me 04073** Phone: +1.866.736.1250 eMail: CustomerCareGVSLS@gvs.com - Website: www.gvs.com
INTENDED USE / APPLICATION	Heterotrophic Plate Count Broth (HPC) without indicator is a used to detect heterotrophic bacteria in water using the membrane filtration technique.
MATERIALS	**Media:** Heterotrophic Plate Count Broth (HPC) without indicator **Color:** Pale yellow nutrient liquid **Ampoules**: polypropylene **Regulatory Documentation Required:** ☐Biocompatibility according ISO 10993-1 ☐IMDS ☒Rohs, directive 2002/95/CE ☐BSE/TSE, directive 2003/32/ ☐DEHP plasticizer Free and latex free ☐Aging ☒Reach 1907/2006/CE (hazardous substances regulation) ☐Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances) ☒Conflict minerals

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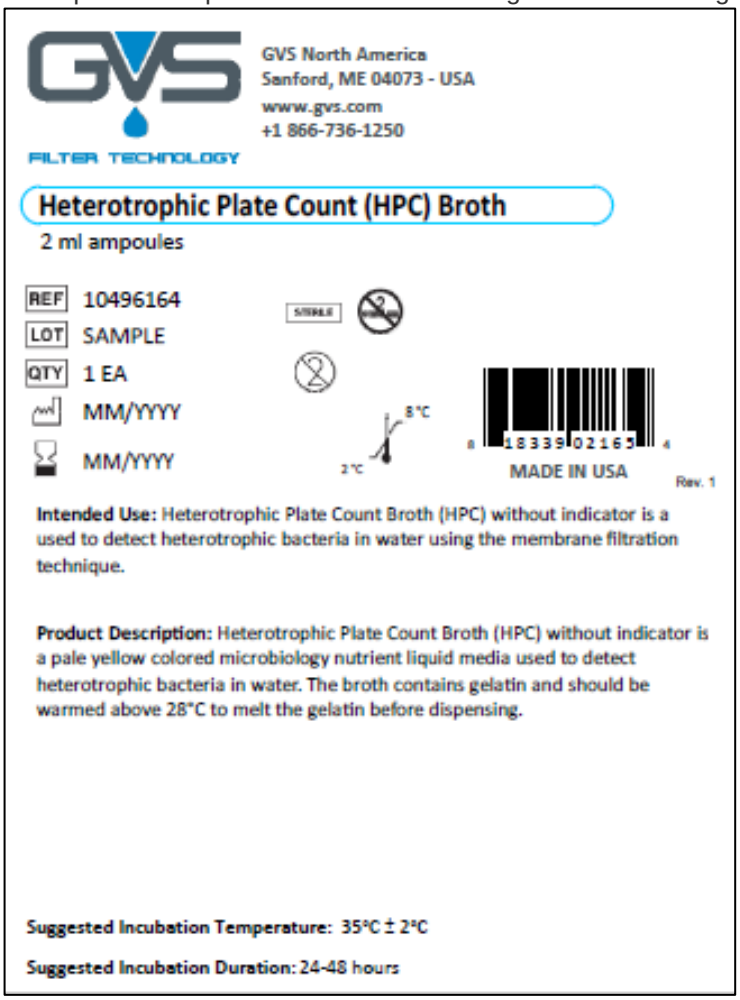
PRODUCT CHARACTERISTIC	**Pale yellow colored liquid media dispensed in plastic ampoules.** **Physical:** **Ampoule Dimensions:** 57.9 mm x 8.4mm (at cap)/22 mm (at seal) **Volume/ampoule:** 2 - 2.4 ml **Incubation Temperature Range:** 35°C ± 2°C **Storage temperature Range:** From 2°C to 8°C **Biological:**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

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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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Rev. 02

PERFORMANCE REQUIREMENTS

	Acceptance Requirement		Sampling Plan
	Parameter	**Specification**	ISO 11133:2014
1	Recovery (Measured against control)	≥ 85%	ISO 11133:2014
2	Test Organism	*E. coli* 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 *E. coli* 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

CustomerApproval:

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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.