# PRODUCT SPECIFICATION

**Product PN** *10496146*

**Mod. 984**

**Rev. 02**

**Description** Cetrimide Broth- Ampoules 50x2ml Ampoules

## Cetrimide Broth- Ampoules



| | |
|---|---|
| **PRODUCT DESCRIPTION** | AMP Cetrimide 2ml, (50pk)<br><br>Cetrimide broth is a pale amber nutrient liquid media used to detect *Pseudomonas aeruginosa*. Cetrimide (N-cetyl-N,N,N-trimethylammonium bromide) is added to inhibit bacteria other than *Ps. aeruginosa*. Its action as a quaternary ammonium cationic detergent causes nitrogen and phosphorous to be released from bacterial cells other than *Ps. aeruginosa*. *Ps. aeruginosa* is characterized by the production of pyocyanin (a blue green, water soluble, non-fluorescent, phenazine pigment) which is stimulated by the inclusion of magnesium chloride and potassium sulfate in the broth. |
| **MANUFACTURER NAME** | **GVS North America**<br>**63 Community Drive**<br>**Sanford, Me 04073**<br>Phone: +1.866.736.1250<br>eMail: CustomerCareGVSLS@gvs.com - Website: www.gvs.com |
| **INTENDED USE / APPLICATION** | Cetrimide Broth is selective for *Pseudomonas aeruginosa*. |
| **MATERIALS** | **Media:** cetrimide broth<br><br>**Color:** Pale amber nutrient liquid<br><br>**Ampoules**: polypropylene<br><br>**Regulatory Documentation Required:**<br>☐Biocompatibility according ISO 10993-1<br>☐IMDS<br>☒Rohs, directive 2002/95/CE<br>☐BSE/TSE, directive 2003/32/<br>☐DEHP plasticizer Free and latex free<br>☐Aging<br>☒Reach 1907/2006/CE (hazardous substances regulation)<br>☐Dir. 67/548/CE and Reg. 1272/2008/CE (medical sector dangerous substances)<br>☒Conflict minerals |

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## PRODUCT CHARACTERISTIC

**Pale amber 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

| | |
|---|---|
| Enzymatic Digest of Gelatin | 20.0 gm |
| Magnesium Chloride | 1.4 gm |
| Potassium Sulfate | 10.0 gm |
| Cetrimide | 0.3 gm |
| Glycerol | 10.0 ml |

** Adjusted and/or supplemented as required to meet performance requirements*
*pH: 7.2 ± 0.2*

## INSTRUCTIONS

## WARNINGS

Product is temperature sensitive.
Store at recommended temperature.

## PRODUCT SHELF LIFE

12 months when stored properly

## STERILIZATION

Product is sold sterilized

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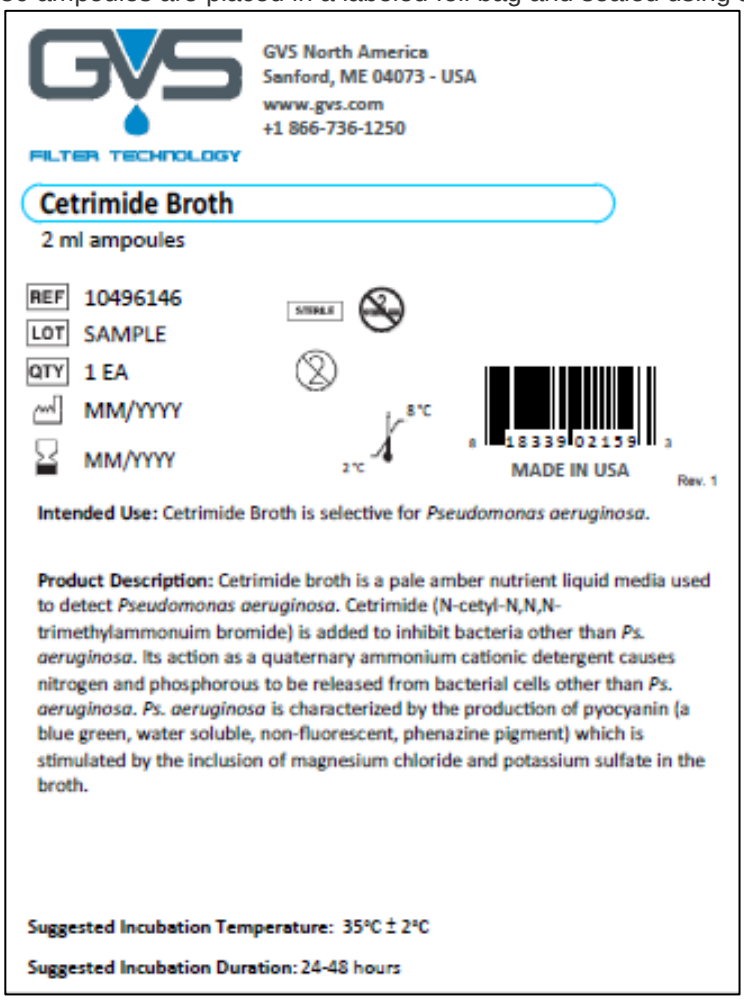
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## PACKAGING AND LABELLING

**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 amber | all | 100% |
| 2 | Ampoule appearance – no misshapen or leaking ampoules | none | |

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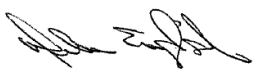
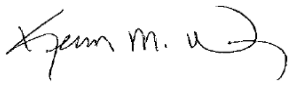
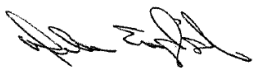
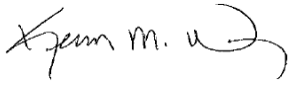
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**PERFORMANCE REQUIREMENTS**

| Acceptance Requirement | | | Sampling Plan |
|---|---|---|---|
| | **Parameter** | **Specification** | ISO 11133:2014 |
| 1 | Recovery (Measured against control) | ≥ 85% | ISO 11133:2014 |
| 2 | Test Organism | *Ps. aeruginosa* ATCC 10145 | ISO 11133:2014 |
| 3 | Negative Test Organism | *E. coli* ATCC 25922 | ISO 11133:2014 |
| 4 | pH at 25°C | 7.2 ± 0.2 | ISO 11133:2014 |
| 5 | Sterility | Zero Growth | ISO 11133:2014 |
| 6 | Media Color | Pale Amber | ISO 11133:2014 |
| 7 | Colony Color | *Ps. aeruginosa:* Blue-Green pigmentation and fluorescent<br>*E. coli:* cream to yellow in color and no fluorescence | ISO 11133:2014 |
| 8 | 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.*