# PRODUCT SPECIFICATION

**Product PN** *10496101*

**Mod. 984**

**Rev. 02**

**Description** M-Green Yeast & Mold - Ampoules

## M-Green Yeast & Mold - Ampoules



| | |
|---|---|
| **PRODUCT DESCRIPTION** | AMP M-GREEN YM 2ml, (50pk)<br><br>M-Green Yeast and Mold Broth is an improved modification of the liquid medium M-Yeast and Mold Broth. It was developed to improve efficiency of detection and enumeration of fungi in sugar based drinks using the membrane filtration method. This medium has a low pH, which inhibits bacterial growth. Bromocresol green indicates pH change: yellow (acid reaction), green (alkaline reaction). When bromocresol green diffuses into fungal colonies it has an alkaline reaction, allowing easily identification. Metabolic by-products from the developing colonies diffuse into the surrounding medium, further reducing the pH which aids in the inhibition of bacterial growth, but also produces an acid reaction which causes residual bromocresol green to change to yellow. |
| **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** | M-Green Yeast and Mold Broth is used for the detection of fungi in the routine analysis of beverages. |
| **MATERIALS** | **Media:** M-Green Yeast and Mold Broth<br><br>**Color:** Green 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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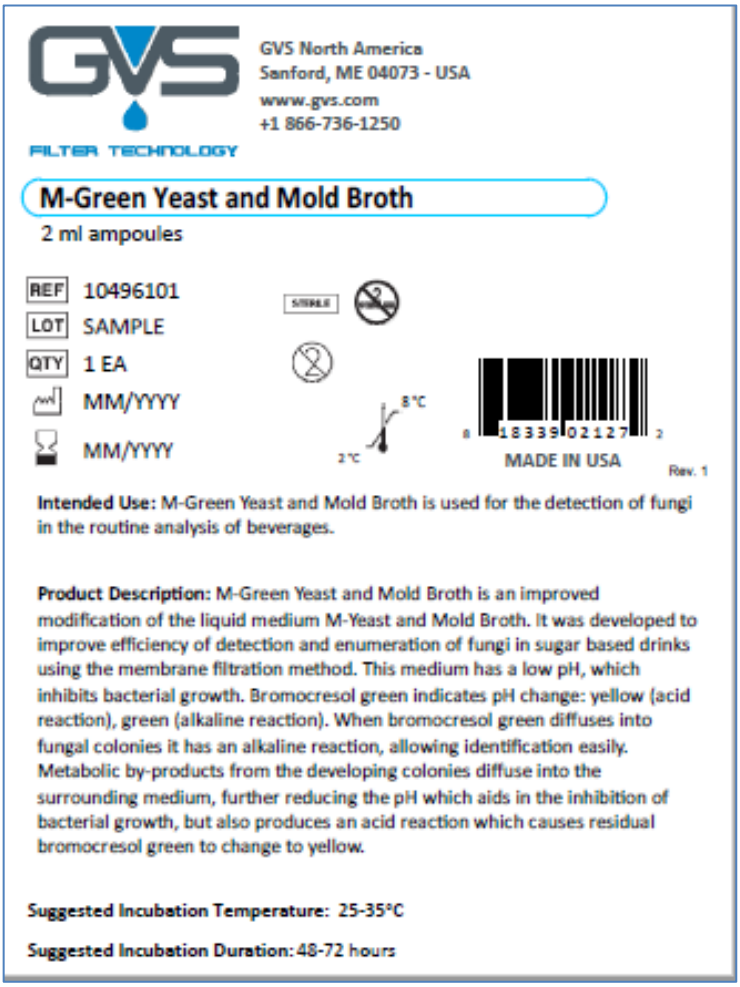
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|---|---|
| **PRODUCT CHARACTERISTIC** | **Green colored liquid media dispensed in plastic ampoules.**<br><br>**Physical:**<br>**Ampoule Dimensions:** 57.9 mm x 8.4mm (at cap)/22 mm (at seal)<br>**Volume/ampoule:** 2 - 2.4 ml<br><br>**Incubation Temperature Range:** 25-35°C<br>**Storage temperature Range:** From 2°C to 8°C<br><br>**Biological:**<br>Product is sold sterilized.<br>**Toxicity:** See SDS for further information.<br><br>**Media Formulation:**<br>Approximate formula* per liter of water<br>Yeast extract 9.0 gm<br>Dextrose (anhydrous) 50.0 gm<br>Pancreatic Digest of Casein 5.0 gm<br>Peptic Digest of Animal Tissue 5.0 gm<br>Magnesium Sulfate 2.1 gm<br>Potassium Phosphate 2.0 gm<br>Diastase 0.05 gm<br>Thiamine 0.05 gm<br>Bromocresol Green 0.026 gm<br>** Adjusted and/or supplemented as required to meet performance requirements*<br>pH 4.6 ± 0.2 |
| **INSTRUCTIONS**<br><br>**WARNINGS** | Product is temperature sensitive.<br>Store at recommended temperature. |
| **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 – green | all | 100% |
| 2 | Ampoule appearance – no misshapen or leaking ampoules | none | |

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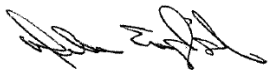
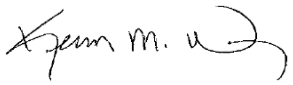
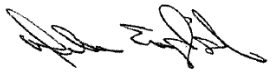
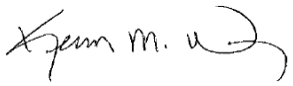
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**PERFORMANCE REQUIREMENTS**

| Acceptance Requirement | | | Sampling Plan |
|---|---|---|---|
| | **Parameter** | **Specification** | ISO 11133:2014 |
| 1 | Recovery (Measured against control) | ≥ 85% | ISO 11133:2014 |
| 2 | Test Organisms | *C. albicans* ATCC 10231<br><br>*A. brasiliensis* ATCC 16404 | ISO 11133:2014 |
| 3 | pH at 25°C | 4.6 ± 0.2 | ISO 11133:2014 |
| 4 | Sterility | Zero Growth | ISO 11133:2014 |
| 5 | Media Color | Green | ISO 11133:2014 |
| 6 | Colony Color | Organism Dependent | ISO 11133:2014 |
| 7 | Incubation | 25°C ±2°C for 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.*