PRODUCT SPECIFICATION

Product PN *10496116*

Mod. 984

Rev. 02

Description M-Green Select - Ampoules



M-Green Select - Ampoules

PRODUCT DESCRIPTION	AMP M-GREEN SELECT 2ml, (50pk) M-Green Select 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 identification easily. 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. The addition of chloramphenicol further inhibits the growth of bacteria to allow for the development and enumeration of yeast and mold.
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	M-Green Select Broth is used for the detection of fungi in the routine analysis of beverages.
MATERIALS	**Media:** M-Green Select Broth **Color:** Green 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

Green 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: 25°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 Casein	5 gm
Enzymatic Digest of Animal Tissue	5 gm
Yeast Extract	9 gm
Dextrose	50 gm
Magnesium Sulfate	2.1 gm
Potassium Phosphate	2 gm
Diastase	0.05 gm
Thiamine	0.05 gm
Bromocresol Green	0.026 gm
Chloramphenicol, 1% solution	8.5 ml

** Adjusted and/or supplemented as required to meet performance requirements*
pH 4.6 ± 0.2

INSTRUCTIONS

WARNINGS

Product is temperature.
Store at recommended temperature.

PRODUCT SHELF LIFE

12 months when stored properly

STERILIZATION

Product is sold sterilized

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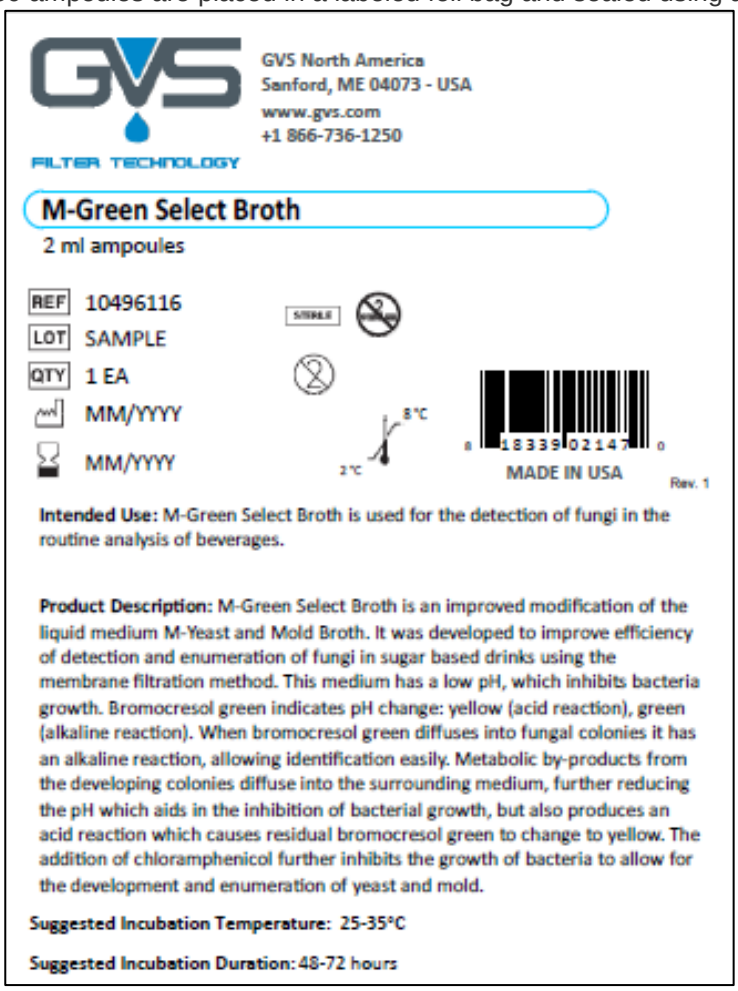
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PACKAGING AND LABELLING

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 – green	all	100%
2	Ampoule appearance – no misshapen or leaking ampoules	none	

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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	*C. albicans* ATCC 10231	ISO 11133:2014
3	Negative Test Organism	*E.coli* *ATCC* 25922 Growth Inhibited	ISO 11133:2014
4	pH at 25°C	4.6 ± 0.2	ISO 11133:2014
5	Sterility	Zero Growth	ISO 11133:2014
6	Media Color	Green	ISO 11133:2014
7	Colony Color	Organism Dependent	ISO 11133:2014
8	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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Description	**M-Green Select - Ampoules**	**Rev. 02**

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.