PRODUCT SPECIFICATION

Product PN *10496108*

Description WL Nutrient - Ampoules

Mod. 984

Rev. 02

WL Nutrient - Ampoules



PRODUCT DESCRIPTION	AMP WALLERSTEIN WL 2ml, (50pk) WL (Wallerstein Laboratory) Nutrient Broth is for the cultivation and enumeration of yeast. Use of the medium at pH 5.5 and incubation at 25°C will give reliable counts for brewer's yeast.
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	WL Nutrient Broth is used to detect yeast, mold and bacteria present in breweries.
MATERIALS	**Media:** WL Nutrient Broth **Color:** Blue 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

Blue 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

Yeast Extract	4.0 gm
Pancreatic Digest of Casein	5.0 gm
Dextrose	50.0 gm
Monopotassium Phosphate	0.55 gm
Potassium Chloride	0.425 gm
Calcium Chloride	0.125 gm
Magnesium Sulfate	0.125 gm
Ferric Chloride	0.0025 gm
Manganese Sulfate	0.0025 gm
Bromocresol Green	0.022 gm

** Adjusted and/or supplemented as required to meet performance requirements*
pH 5.5 ± 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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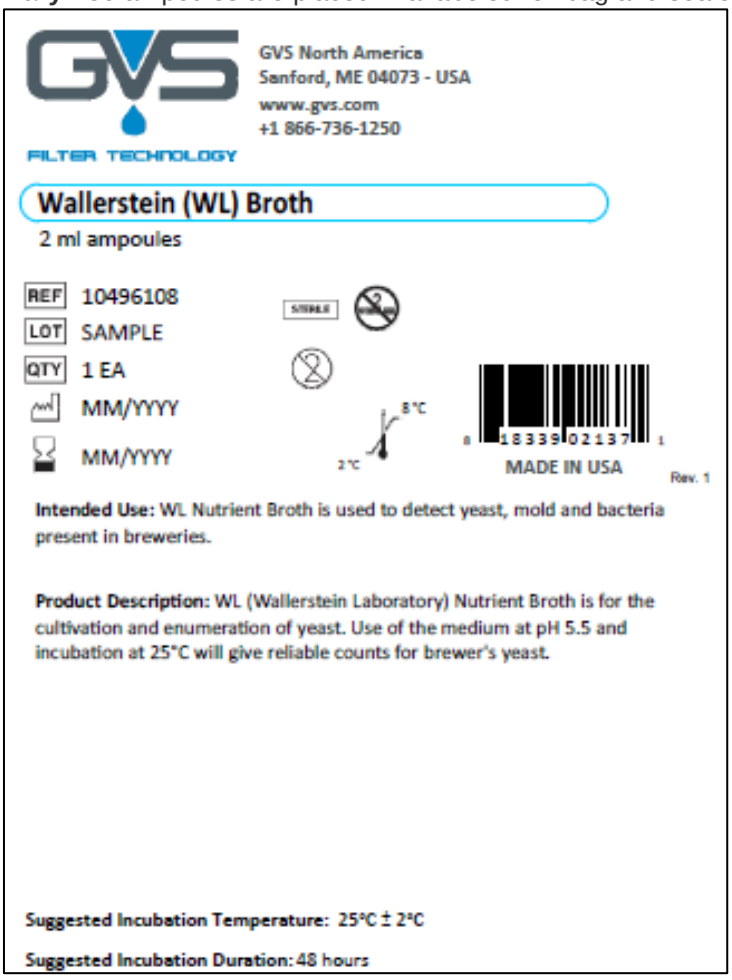
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PACKAGING AND LABELLING

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 – blue	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	*S. cerivisiae* ATTC 4098	ISO 11133:2014
3	pH at 25°C	5.5 ± 0.2	ISO 11133:2014
4	Sterility	Zero Growth	ISO 11133:2014
5	Media Color	Blue	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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Description **WL Nutrient - Ampoules**

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.