PRODUCT SPECIFICATION

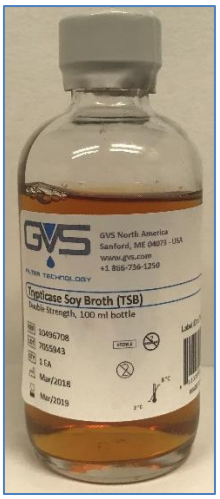
Product PN *10496708*

Mod. 984

Rev. 02

Description Trypticase Soy Broth(TSB) Double Strength - Bottle

Trypticase Soy Broth (TSB) Double Strength - Bottle



PRODUCT DESCRIPTION	BRO TSB Single 100ml 1/pk Trypticase soy broth (TSB) is a general purpose nutritious liquid medium that supports the cultivation of a wide variety of microorganisms, especially common aerobic and facultatively anaerobic bacteria. This is a double strength solution.
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	TSB is a general purpose nutritious liquid medium that supports the cultivation of a wide variety of microorganisms.
MATERIALS	**Media:** Trypticase soy broth **Color:** Amber nutrient liquid **Bottle**: clear soda lime glass **Cap:** Black phenolic with rubber liner **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	**Amber colored liquid media dispensed in glass bottle with black, rubber-lined cap.** **Physical:** **Dimensions:** Bottle (48 x 112 mm); Cap Size: 22-400 GPI thread finish **Volume/ampoule:** 95-105 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.
INSTRUCTIONS **WARNINGS**	Product is temperature sensitive Store at recommended temperature.
PRODUCT SHELF LIFE	12 months when stored properly
STERILIZATION	Product is sold sterilized.
PACKAGING AND LABELLING	**1)** Apply sealing band around cap and bottle junction **2)** Label bottle. 

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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

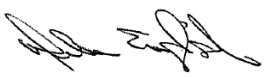
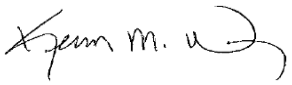
Acceptance Requirement			Sampling Plan
1	Color – amber	all	100%
2	Bottle/cap appearance – no leaking containers	none	

PERFORMANCE REQUIREMENTS

Acceptance Requirement			Sampling Plan
	Parameter	**Specification**	ISO 11133:2014
1	Positive Growth	Turbid to Highly Turbid	ISO 11133:2014
2	Test Organism	*E. coli* ATCC 25922	ISO 11133:2014
3	pH at 25°C	7.3 ± 0.2	ISO 11133:2014
4	Sterility	Zero Growth	ISO 11133:2014
5	Media Color	Amber	ISO 11133:2014
6	Colony Color	Organism Dependent	ISO 11133:2014
7	Incubation	35°C ±2°C for at 18-24 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 

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CustomerApproval:

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.