# PRODUCT SPECIFICATION

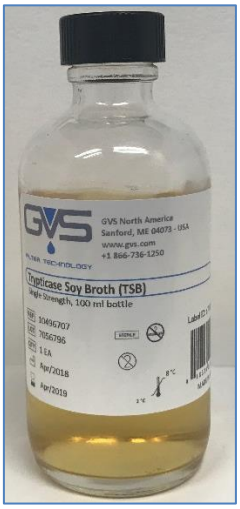
**Product PN** *10496707*

**Mod. 984**

**Rev. 02**

**Description** **Trypticase Soy Broth Single Strength - Bottle**

## Trypticase Soy Broth Single Strength - Bottle




| | |
|---|---|
| **PRODUCT DESCRIPTION** | BRO TSB Single 100ml 1/pk<br><br>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 single strength solution. |
| **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** | TSB is a general purpose nutritious liquid medium that supports the cultivation of a wide variety of microorganisms. |
| **MATERIALS** | **Media:** Trypticase soy broth<br><br>**Color:** Yellow nutrient liquid<br><br>**Bottle**: clear soda lime glass<br>**Cap:** Black phenolic with rubber liner<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 |

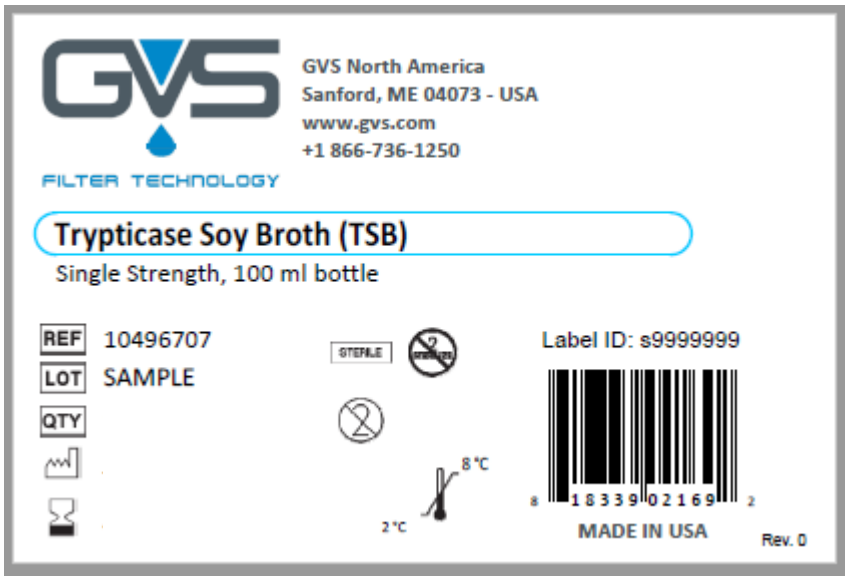
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| **PRODUCT CHARACTERISTIC** | **Yellow colored liquid media dispensed in glass bottle with black, rubber-lined cap**<br><br>**Physical:**<br>**Dimensions:** Bottle ( 48 x 112 mm); Cap Size: 22-400 GPI thread finish<br>**Volume/bottle:** 95-105 ml<br>**Incubation Temperature Range:** 35°C ±2°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. |
| **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. |
| **PACKAGING AND LABELLING** | **1)** Apply sealing band around cap and bottle junction<br>**2)** Label bottle.<br><br> |

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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:***<br>**Magnification:** none<br>**Light type:** normal room lighting |

| Acceptance Requirement | | | Sampling Plan |
|---|---|---|---|
| 1 | Color – yellow | 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*<br>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 | Light Yellow | 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.*