

Instructions for Use

TRYPTIC SOY BROTH (TSB) WITH LECITHIN AND TWEEN[®] 20, USP

Cat. no. U241	TSB with Lecithin and Tween [®] 20, USP, 240ml Wide Mouth Jar, 90ml	12 jars/box
Cat. no. U261	TSB with Lecithin and Tween [®] 20, USP, 240ml Wide Mouth Jar, 100ml	12 jars/box

INTENDED USE

IFU

Hardy Diagnostics Tryptic Soy Broth (TSB) with Lecithin and Tween[®] 20, USP, aids in neutralizing disinfectants and emulsifying oil and water mixtures. TSB is also known as Soybean-Casein Digest Medium and conforms to the formula given by the U.S. Pharmacopeia. TSB with Lecithin and Tween[®] 20, USP, is recommended for the cultivation of microorganisms from environmental surfaces and for sterility testing various products.

This product is not intended to be used for the diagnosis of human disease.

SUMMARY

The formulation of TSB with Lecithin and Tween[®] 20 is prepared according to the United States Pharmacopeia (USP) standards formula for Soybean-Casein Digest Medium.⁽⁴⁾ It is also included in approved procedures in the *Compendium* of Methods for the Microbiological Examination of Foods and Standard Methods for the Examination of Water and Wastewater.^(1,3)

Hardy Diagnostics TSB with Lecithin and Tween[®] 20, USP, contains digests of soybean meal and casein to provide amino acids and other nitrogenous compounds. Sodium chloride is added to help cells maintain osmotic equilibrium. Lecithin and Tween[®] 20 are added to neutralize germicidal or disinfectant residues found on sanitized surfaces. Quaternary ammonium compounds are neutralized by lecithin while phenolic disinfectants and hexachlorophene are neutralized by Tween[®] 20. Together, lecithin and Tween[®] 20 neutralize ethanol.^(1,3) Tween[®] 20 also aids as an emulsifier and stabilizer for oil and water mixtures to improve sterility testing of oil-based products.

FORMULA

Ingredients per liter of deionized water:*

Tryptic Soy Broth (TSB) with Lecithin and Tween [®] 20, USP				
Tween [®] 20	40.0gm			
Pancreatic Digest of Casein	17.0gm			
Sodium Chloride	5.0gm			
Papaic Digest of Soybean Meal	3.0gm			
Dextrose	2.5gm			

Dipotassium Phosphate	2.5gm
Lecithin	5.0gm

Final pH 7.3 +/- 0.2 at 25°C.

* Adjusted and/or supplemented as required to meet performance criteria.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 2-25°C. away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing.

The expiration date applies to the product in its intact packaging when stored as directed.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these products be treated as potentially infectious, and handle observing the usual universal blood precautions. Do not ingest, inhale, or allow to come into contact with skin.

This product is for laboratory use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "<u>Guidelines for Isolation</u> <u>Precautions</u>" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections*.

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

Specimen Collection: TSB with Lecithin and Tween[®] 20, USP, is not recommended for primary isolation. Consult listed references for information on specimen collection.^(1,3,4)

Method of Use: Allow medium to warm to room temperature prior to inoculation. Consult listed references for information concerning testing procedures.^(1,3,4)

Data should be collected and recorded according to a designed monitoring system that statistically provides for the accurate acquisition of data.

INTERPRETATION OF RESULTS

Consult listed references for more detailed information concerning plate count methods.^(1,3,4)

LIMITATIONS

It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification of bacteria and/or fungi.

Results can be uninterpretable or misleading unless a statistical method for monitoring is designed.

Microbial contamination on a surface cannot be completely characterized by a single assay.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, swabs, applicator sticks, other culture media, incinerators, and incubators, etc., as well as serological and biochemical reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

Test Organisms	Inoculation Method*	Incubation			Results
		Time	Temperature	Atmosphere	Kesuits
Staphylococcus aureus ATCC [®] 6538	J	24-72 hrs	30-35°C	Aerobic	Growth
Pseudomonas aeruginosa ATCC [®] 9027	J	24-72 hrs	30-35°C	Aerobic	Growth
Bacillus subtilis ATCC [®] 6633	J	24-72 hrs	30-35°C	Aerobic	Growth
Bacillus subtilis ATCC [®] 6633	J	24-72 hrs	20-25°C	Aerobic	Growth
Candida albicans ATCC [®] 10231	J	3-5 days	20-25°C	Aerobic	Growth
Aspergillus brasiliensis ATCC [®] 16404	J	5 days	20-25°C	Aerobic	Growth

* Refer to the document "Inoculation Procedures for Media QC" for more information.

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics <u>Certificate of Analysis</u> website. Also refer to the document "<u>Finished Product</u> <u>Quality Control Procedures</u>," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

PHYSICAL APPEARANCE

Tryptic Soy Broth (TSB) with Lecithin and Tween[®] 20, USP, should appear clear to hazy, and light amber in color.

REFERENCES

1. American Public Health Association. *Standard Methods for the Examination of Water and Wastewater*, APHA, Washington, D.C.

2. *Quality Assurance for Commercially Prepared Microbiological Culture Media*, M22. Clinical and Laboratory Standards Institute (CLSI - formerly NCCLS), Wayne, PA.

3. APHA Technical Committee on Microbiological Methods for Foods. *Compendium of Methods for the Microbiological Examination of Foods*, APHA, Washington, D.C.

4. The Official Compendia of Standards. USP-NF. United States Pharmacopeial Convention, Rockville, MD.

ATCC is a registered trademark of the American Type Culture Collection. Tween is a registered trademark of ICI Americas, Inc.

IFU-10823[C]



1430 West McCoy Lane, Santa Maria, CA 93455, USA Phone: (805) 346-2766 ext. 5658 Fax: (805) 346-2760 Website: <u>HardyDiagnostics.com</u> <u>Email: TechnicalServices@HardyDiagnostics.com</u> <u>Ordering Information</u>

Distribution Centers: California · Washington · Utah · Arizona · Texas · Ohio · New York · Florida · North Carolina

The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

Copyright© 2020 by Hardy Diagnostics. All rights reserved.

HDQA 2207F [D]