IFU

Instructions for Use

CRITERION™ MODIFIED LETHEEN BROTH

Cat. no. C7640	CRITERION™ Modified Letheen Broth	85.6gm
Cat. no. C7641	CRITERION™ Modified Letheen Broth	500gm
Cat. no. C7642	CRITERION™ Modified Letheen Broth	2kg
Cat. no. C7643	CRITERION™ Modified Letheen Broth	10kg
Cat. no. C7644	CRITERION™ Modified Letheen Broth	50kg

INTENDED USE

Hardy Diagnostics CRITERION™ Modified Letheen Broth is for use in microbial recovery from personal care products and for the neutralization of quaternary ammonium compounds in the testing of germicidal activity.

Dehydrated culture media is a raw material not intended for use in the diagnosis of human disease. For implementation, this product requires additional processing and supplementation of ingredients before use.

SUMMARY

Quaternary ammonium compounds are molecules which contain a nitrogen atom bonded to four other atoms. Most quaternary ammonium compounds are organic compounds that have biological activity. These compounds often work well as disinfectants, offering bactericidal and bacteriostatic effects. Modified Letheen Broth is used in the AOAC procedure for determining the effect of these bactericidal compounds.(1)

Modified Letheen Broth is formulated as described in the 7th edition of the *U.S. FDA Bacteriological Analytical Manual* and is recommended by the FDA for use in the microbiological testing of cosmetics.(1) The medium contains beef extract and peptone which provide a nutrient rich medium of vitamins, amino acids and nitrogen to support the growth of a variety of microorganisms. Yeast extract provides vitamins and co-factors which serve as additional sources of nitrogen and carbon required for bacterial growth. Modified Letheen Broth also contains lecithin and Tween® 80. Quaternary ammonia compounds are neutralized by lecithin while phenolic disinfectants and hexachlorophene are neutralized by Tween® 80. Together, lecithin and Tween® 80 neutralize ethanol.(1)

FORMULA*

Gram weight per liter:	42.8gm/L
Letheen Broth	25.7gm
Proteose Peptone No. 3	10.0gm
Casein Peptone	5.0gm
Yeast Extract	2.0gm

Sodium Bisulfite	0.1gm

Final pH 7.2 +/- 0.2 at 25ºC.

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

STORAGE AND SHELF LIFE

Store the sealed bottle(s) that contain dehydrated culture medium at 2-8ºC. Dehydrated culture medium is very hygroscopic and will clump when exposed to moisture and air. Keep lid tightly sealed. Protect dehydrated culture media from moisture and light. Dehydrated culture media should be discarded if it is not moist and lumpy or if the color has changed from its original beige.

Store the prepared culture media at 2-8ºC and do not remove the container desiccant, if applicable.

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 "Guidelines for Isolation Precautions" 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.

METHOD OF PREPARATION FOR DEHYDRATED CULTURE MEDIA

1. Suspend 42.8gm of the dehydrated culture media in 1 liter of distilled or deionized water. Stir to mix thoroughly.

2. Heat as necessary to dissolve completely.

3. Dispense into appropriate container.

4. Sterilize in the autoclave at 121ºC. for 15 minutes.

Note: The shelf life of in-house prepared media from dehydrated culture media is dependent upon preparation methods, container quality, equipment, storage conditions, and batch testing criteria and must be validated by the end user.

PROCEDURE AND INTERPRETATION OF RESULTS

For information on procedures and interpretation of results, consult listed references or refer to the prepared media Instructions for Use (IFU) for Cat. No. K293.

LIMITATIONS

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

Some formulations may require a settling period before pH testing of the prepared medium. If the pH is tested immediately after preparation and is out of specification, retest the medium after 24 hours to obtain final pH results. Always take pH reading at room temperature.

Accurate counting may be difficult with molds or spreading colonies.

Rare, fastidious microorganisms may not grow on selective media formulations.

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, tubes, other culture media, swabs, applicator sticks, autoclaves, 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	
Staphylococcus aureus ATCC® 25923	A	18-48hr	35°C	Aerobic	Growth; turbidity
Staphylococcus aureus ATCC® 6538	A	18-48hr	35°C	Aerobic	Growth; turbidity

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

USER QUALITY CONTROL

Users of dehydrated 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 Certificate of Analysis website. In addition, refer to the following document "Finished Product Quality Control Procedures," for more information on QC or see the reference(s) for more specific information.

PHYSICAL APPEARANCE

CRITERION™ Modified Letheen Broth powder should appear moist, lumpy, and beige in color. The prepared media should appear slightly opalescent, may have a slight fine precipitate, and medium-dark amber color.

REFERENCES

1. Tomlinson, L. (ed.). 1992. *FDA Bacteriological Analytical Manual*, 7th ed. AOAC International, Arlington, VA.

2. Hitchins, A.D., T.T. Tran, and J.E. McCarron. 1995. *FDA Bacteriological Analytical Manual*, 8th ed. AOAC International, Gaithersburg, MD.

3. Marshall, R.T., (ed.). 1992. *Standard Methods for the Examination of Dairy Products*, 16th ed. APHA, Washington, D.C.

4. Vanderzant, C. and D.F. Splittstoesser, (ed.). 1992. *Compendium of Methods for the Microbiological Examination of Foods*, 3rd ed. APHA, Washington, D.C.

5. Greenberg, A.E., et al. (ed.). 1992. *Standard Methods for the Examination of Water and Wastewater*, 18th ed. APHA, Washington, D.C.

6. *U.S. Pharmacopeia*, 22nd rev. 1990. U.S. Pharmacopeial Convention, Rockville, MD.

7. MacFaddin, J.F. 1985. *Media for Isolation, Cultivation, Identification, Maintenance of Bacteria*, Vol. I. Williams & Wilkins, Baltimore, MD.

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

9. Helrich, Kenneth, (ed.). 1990. *Official Methods of Analysis*, 15th ed. AOAC, Arlington, VA.

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

HDQA 2207B [D]