PRODUCT SPECIFICATION SHEET

Letheen Broth, Modified (Modified Letheen Broth) (DM312)

Intended Use

Letheen Broth, Modified (Modified Letheen Broth) (DM312) is recommended for screening cosmetic products for microbial contamination.

Product Summary and Explanation

In 1948, Weber and Black described the value of a highly nutritional solid medium containing lecithin and polysorbates to neutralize the antimicrobial action of quaternary ammonium compounds in sanitizers.[1] In 1965, AOAC accepted this methodology for the antimicrobial assays and extended their use to all the cationic detergents. In 1978, the FDA incorporated it as pre-enrichment medium for every microbial examination of cosmetics.

The addition of Lecithin and Polysorbate 80 to Tryptone Glucose Extract (TGE) Agar resulted in a medium that effectively neutralizes quaternary ammonium compounds in testing of germicidal activity. Total neutralization of disinfectants is critical. Disinfectant residues can result in a false negative (no-growth) test.

Letheen Broth, Modified is prepared as per FDA[2] for screening cosmetic products for microbial contamination. There are great chances of altering the chemical composition of cosmetics by the metabolism of organism s thereby spoiling and causing harm to the users.[3-5] Direct colony counts and enrichment culturing are the methods of choice for isolating microorganisms from cosmetic products. The word Letheen represents a combination of lecithin and polysorbate 80.

Principles of the Procedure

Letheen Broth, Modified contains peptic digest of animal tissue, casein enzymic hydrolysate, beef extract and yeast extract which provides nitrogenous nutrients, carbon compounds and trace elements for the metabolism of microorganisms. Incorporation of lecithin and polysorbate 80 to the medium enables the recovery of bacteria from materials containing residues of disinfectant compounds or preservatives used in cosmetics. Polysorbate 80 is added to nullify phenolic compounds, hexachlorophene, formalin and along with lecithin neutralizes ethyl alcohol. Lecithin also neutralizes quaternary ammonium compounds present in the cosmetics. Sodium chloride maintains the osmotic balance of the medium.

Formula / Liter

Ingredients	Gms / Liter
Peptic digest of animal tissue	20.00
Casein enzymic hydrolysate	5.00
Beef extract	5.00
Yeast extract	2.00
Sodium chloride	5.00
Sodium bisulphite	0.10
Lecithin	0.70
Polysorbate 80	5.00
Final pH: 7.0 ± 0.2 at 25°C	
Formula may be adjusted and/or supplemented as required to meet performance specifications	

Precautions

1. For Laboratory Use only.
2. IRRITANT. Irritating to eyes, respiratory system, and skin.

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Directions

1. Suspend 42.8 grams of the medium in one liter of distilled water.
2. Heat if necessary to dissolve the medium completely.
3. Autoclave at 121°C, 15 psi pressure, for 15 minutes / validated cycle.
4. Mix well and dispense as desired.

Quality Control Specifications

Dehydrated Appearance	Cream to yellow homogeneous free flowing powder
Prepared Medium	Yellow coloured, clear solution in tubes
Reaction of 4.28% Solution	pH : 7.0 ± 0.2 at 25°C
Gel Strength	Not Applicable

Expected Cultural Response: Cultural characteristics observed after an incubation at 35-37°C for 24-48 hours.

Sr. No.	Organisms	Results to be achieved	
		Inoculum (CFU)	Growth
1.	*Escherichia coli ATCC 25922*	50 -100	good-luxuriant
2.	*Staphylococcus aureus ATCC 25923*	50 -100	good-luxuriant
3.	*Staphylococcus aureus ATCC 6538*	50 -100	good-luxuriant

The organisms listed are the minimum that should be used for quality control testing.

Test Procedure

1. Prepare and dilute samples in Letheen Broth, Modified in accordance with established guidelines.
2. Enrichment in this medium should be done for 7 days at 30-32°C and then subcultured on Letheen Agar, Modified (DM724) and/or MacConkey Agar (DM143).
3. Refer to appropriate references for standard test procedures.

Results

Refer to appropriate references and test procedures for interpretation of results.

Storage

Store the sealed bottle containing the dehydrated medium at 10 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light.

Expiration

Refer to the expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if the appearance has changed from the original color. Expiry applies to medium in its intact container when stored as directed.

Limitations of the Procedure

1. For identification, organisms must be in pure culture. Morphological, biochemical and/or serological tests should be performed for final identification.
2. Consult appropriate texts for detailed information and recommended procedures.

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Packaging
Product Name : Letheen Broth, Modified (Modified Letheen Broth)
Product Code : DM312
Available Pack sizes : 500gm

References

1. Weber and Black, 1948, Soap Sanitary Chem., 24:134-139.
2. Bacteriological Analytical Manual, 1995, Food and Drug Administration, 8th Ed., AOAC International, Gaithersburg, MD, U.S.A.
3. Dunningan A. P., 1968, Drug Cosmet. Ind., 102:43.
4. Smart R. and Spooner D. F., 1972, J. Soc. Cosmet. Chem., 23:721.
5. Wilson L. A. and Ahearn D. G., 1977, Am. J. Opthalmol., 84:112.

Further Information

For further information please contact your local MICROMASTER Representative.

MICROMASTER LABORATORIES PRIVATE LIMITED
Unit 38/39, Kalpataru Industrial Estate,
Off G.B. Road, Near 'R-Mall' , Thane (W) – 400607. M.S. INDIA.
Ph: +91-9320126789/9833630009/9819991103
Email: sales@micromasterlab.com

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