

## TM 159 – LETHEEN BROTH, MODIFIED (as per FDA)

### INTENDED USE

For screening cosmetic products to check microbial contamination.

### PRODUCT SUMMARY AND EXPLANATION

In the early 40s, Weber and Black recommended the use of lecithin and polysorbates to neutralize the antimicrobial action of the quaternary ammonium compounds. In 1965, the methodology was accepted by AOAC 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.

Letheen Broth, Modified is prepared as per FDA for screening cosmetic products for microbial contamination. There are great chances of altering the chemical composition of cosmetics by the metabolism of organisms thereby spoiling and causing harm to the users. 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 (tween) 80.

### COMPOSITION

Ingredients	Gms / Ltr
Peptone	20.000
Tryptone	5.000
Beef extract	5.000
Yeast extract	2.000
Sodium chloride	5.000
Sodium bisulphite	0.100
Lecithin	0.700
Polysorbate 80	5.000

### PRINCIPLE

This medium consists of Peptone, tryptone, Beef extract and yeast extract which provide nitrogenous nutrients, carbon compounds, long chain amino acids and trace elements to the 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. Enrichment in this medium should be done for 7 days at 30-32°C and then subcultured on Letheen Agar, Modified and/or MacConkey Agar.

### INSTRUCTION FOR USE

- Dissolve 42.80 grams in 1000 ml distilled water.
- Heat if necessary to dissolve the medium completely.
- Dispense into tubes or flasks as desired and Sterilize by autoclaving at 15 psi pressure (121°C) for 15 minutes. Cool to 45-50°C.

### QUALITY CONTROL SPECIFICATIONS



**Appearance of Powder** : Cream to yellow homogeneous free flowing powder.  
**Appearance of prepared medium** : Yellow coloured clear solution in tubes.  
**pH (at 25°C)** : 7.0 ± 0.2

## INTERPRETATION

Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
<i>Escherichia coli</i>	25922	50-100	Luxuriant	35-37°C	24-48 Hours
<i>Staphylococcus aureus subsp. aureus</i>	25923	50-100	Luxuriant	35-37°C	24-48 Hours
<i>Staphylococcus aureus subsp. aureus</i>	6538	50-100	Good-luxuriant	35-37°C	24-48 Hours

## PACKAGING:

In pack size of 500 gm bottles.

## STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 2-8°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.

**Product Deterioration:** Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

## DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

## REFERENCES

1. Bacteriological Analytical Manual, 1995, Food and Drug Administration, 8th Ed., AOAC International, Gaithersburg, MD, U.S.A.
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3. Favero (Chm.), 1967, A State of the Art Report, Biological Contamination Control Committee, American Association for Contamination Control.
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
5. Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock, D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
6. Smart R. and Spooner D. F., 1972, J. Soc. Cosmet. Chem., 23:721.
7. Weber and Black, 1948, Soap Sanitary Chem., 24:134-139.
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**GMP**  
 Good Manufacturing  
 Practices Certified


  
 Best Before

  
**QTY.**  
 Quantity

  
**REF**  
 Catalogue Number

  
 Manufacturer

  
 Temperature Unit

  
**LOT/  
B. NO.**  
 Lot / Batch Number

  
 Consults Instructions  
 for Use

  
 QR  
 Code

**NOTE:** Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

\*For Lab Use Only  
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