Letheen Agar, Modified

Intended Use
Letheen Agar, Modified is recommended for screening cosmetic products for microbial contamination.

Summary
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 a pre-enrichment medium for every microbial examination of cosmetics. Letheen Agar, Modified is used to partially inactivate the preservatives in cosmetics being analysed for the microbial content. This medium was originally recommended by APHA for use in microbial testing of water.

Principle
Peptone, tryptone and yeast extract provide nitrogenous and carbonaceous compounds, long chain amino acids, vitamins 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.

Formula*

Ingredients	g/L
Peptic Digest of Animal Tissue	10.0
Casein Enzymic Hydrolysate	10.0
Beef Extract	3.0
Lecithin	1.0
Polysorbate 80	7.0
Dextrose	1.0
Yeast Extract	2.0
Sodium Chloride	5.0
Sodium Bisulphite	0.1
Agar	15.0
Final pH (at 25°C)	7.2 ± 0.2

*Adjusted to suit performance parameters.

Storage and Stability
Store dehydrated medium below 30°C in tightly closed container and the prepared medium at 2°C-8°C. Avoid freezing and overheating. Use before expiry date on the label. Once opened keep powdered medium closed to avoid hydration.

Type of Specimen
Pharmaceutical samples – Cosmetics

Specimen Collection and Handling
Ensure that all samples are properly labelled.
Follow appropriate techniques for handling samples as per established guidelines.
Some samples may require special handling, such as immediate refrigeration or protection from light, follow the standard procedure.
The samples must be stored and tested within the permissible time duration.
After use, contaminated materials must be sterilized by autoclaving before discarding.

Directions

1. Suspend 54.10 g of the powder in 1000 mL purified / distilled water.
2. Mix thoroughly.
3. Boil with frequent agitation to dissolve the powder completely. DO NOT OVERHEAT.
4. Sterilize by autoclaving at 121°C (15 psi) for 15 minutes as per validated cycle.

Quality Control

Dehydrated Appearance: Cream to yellow coloured, homogenous free flowing powder.
Prepared Appearance: Light amber coloured, clear to slightly opalescent gel forms in petridishes.
Growth Promotion Test: Growth promotion is carried out in accordance with the harmonized method of USP/EP/JP/IP and growth was observed after an incubation at 30-35°C for 18 to 24 hours.
Growth Promoting Properties: The test results observed are within the specified temperature and shortest period of time specified in the test, inoculating ≤ 100 cfu of appropriate microorganism at 30-35°C for 18 hours.

Organism (ATCC)	**Growth**
Escherichia coli (25922)	Good
Escherichia coli (8739)	Good
Staphylococcus aureus subsp. *aureus* (25923)	Good
Staphylococcus aureus subsp. *aureus* (6538)	Good

Performance and Evaluation

Performance of the product is dependent on following parameters as per product label claim:

1. Directions
2. Storage
3. Expiry

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. Madden J. M. and Dallas W. S., 1984, Bacteriological Analytical Manual, 6th Ed., AOAC, Arlington, Va.
2. APHA, 1960, Standard Methods for the Examination of Water and Wastewater, 11th Ed., American Public Health Association, New York.
3. Weber and Black, 1948, Soap Sanitary Chem., 24:134-139.
4. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	**Product description**	**Pack Size**
201120190500	Dehydrated Culture Media	500 g