

LPT DILUTION BROTH

Dehydrated and ready-to-use culture medium

1 - INTENDED USE

For the samples suspension and dilution in the microbiological examination of cosmetics.

2 - COMPOSITION - TYPICAL FORMULA *

(AFTER RECONSTITUTION WITH 1 L OF WATER)

DEHYDRATED MEDIUM AND READY-10-USE FLASKS	
Lecithin	3.0 g
Sodium thiosulphate	5.0 g
Tryptic digest of casein	1.0 g
Sodium chloride	8.5 g
Disodium hydrogen phosphate	8.0 g
Potassium dihydrogen phosphate	1.5 g
L-histidine HCl	1.0 g

^{*}The formula may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Preservatives are generally present in cosmetics to reduce the risk of microbial contamination and to ensure that the product remains suitable and safe during the period of storage and consumer use.

LPT Dilution Broth is a universal diluent for the homogenisation of cosmetic samples and the preparation of decimal dilutions, with neutralizing properties against antimicrobial agents, produced according to the formulation proposed by UNIPRO.¹

Lecithin and Tween® 80 remove the antimicrobial activity of quaternary ammonium compounds and parabens, while sodium thiosulphate and L-histidine neutralize microbicidal active halogen compounds.

The low concentration of peptone, a phosphate buffer and sodium chloride, provide osmotic stability, a stable pH value and maintain the viability of microorganisms without supporting growth during sample preparation.

4 - DIRECTIONS FOR DEHYDRATED MEDIUM PREPARATION

Suspend 28 g in 1000 mL of cold purified water. Mix well and add 30 mL of Tween® 80 (REF 42120502). Heat to boiling with frequent agitation, distribute into flasks or tubes and sterilise by autoclaving at 121°C for 15 minutes. Mix well after sterilisation.

5 - PHYSICAL CHARACTERISTICS

Dehydrated medium appearance beige, fine, homogeneous, free-flowing powder

Solution and prepared medium appearance pale yellow, slightly opalescent

Final pH at 20-25 °C 7.0 ± 0.2

6 - MATERIAI S PROVIDED - PACKAGING

- IMATERIALS PROVIDED - PACKAGING					
Product	Туре	REF	Pack		
LPT Dilution Broth	Dehydrated medium	4016392	500 g (17.8 L)		
		4016394	5 kg (178 L)		
LPT Dilution Broth	Ready-to-use flasks	5116392	6 x 90 mL		

7 - MATERIALS REQUIRED BUT NOT PROVIDED

Autoclave, water-bath, sterile loops and pipettes, incubator and laboratory equipment as required, Erlenmeyer flasks, microbiological tubes and flasks, Tween® 80 (REF 42120502), ancillary culture media and reagents.

8 - SPECIMENS

Cosmetic products. When collecting, storing, transporting and preparing samples, follow the rules of good laboratory practice and refer to applicable International Standards and regulations.

9 - TEST PROCEDURE, READING AND INTERPRETATION

The initial suspension is prepared from a sample of at least 1 g-mL or 10 g-mL of the well-mixed product under test, depending of the expected level of contamination.

Transfer the sample of product to an appropriate volume (e.g. 9 mL or 90 mL) of LPT Dilution Broth.

If needed, additional serial dilutions (e.g. 1:10 dilution) may be performed from the initial suspension using the same diluent. For pour-plate enumeration method, within 45 minutes add 1 mL of the initial suspension and/or sample dilutions into two sterile Petri dishes

and pour 15 mL to 20 mL of the melted agar medium.

If an enrichment procedure is needed, incubate the initial suspension and the dilutions at 30-35 °C for at least 20 hours and observe for

If an enrichment procedure is needed, incubate the initial suspension and the dilutions at 30-35 °C for at least 20 hours and observe for growth. Using a sterile loop, streak an aliquot of the incubated LPT Dilution Broth on the surface of a Petri dish with the specific medium for the target organism.

10 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory.

CONTROL STRAINS INCUBATION $T^{\circ}/T/ATM$ EXPECTED RESULTS S. aureus ATCC 25923 35-37°C / 18-24H / A good growth P. aeruginosa ATCC 27853 35-37°C / 18-24H / A good growth

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection



11 - PERFORMANCES CHARACTERISTICS

Prior to release for sale representative samples of all lots of ready-to-use and dehydrated LPT Dilution Broth, are tested for neutralising properties of a quaternary ammonium base by comparing the results with a previously approved Reference Batch (RB) and with a general-purpose medium without neutralising properties (Tryptic Soy Broth).

The above characteristic is tested with the following strains: *E. coli* ATCC 25922, *P. aeruginosa* ATCC 27853, *S. aureus* ATCC 6538. After incubation at 37°C for 24 hours, good growth of the tested organisms is obtained with LPT Dilution Broth supplemented with quaternary ammonium base, whereas growth is totally or partially inhibited in TSB supplemented in the same way.

12 - PRECAUTIONS AND WARNINGS

- This culture medium is for microbiological control and for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- Dehydrated media must be handled with suitable protection. Before use, consult the Safety Data Sheet.
- This culture medium contains raw materials of animal origin. The ante and post mortem controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that this product doesn't contain any transmissible pathogen. Therefore, it is recommended that the culture medium be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- Apply Good Manufacturing Practice in the production process of prepared media.
- Be careful when opening screw cap flasks to prevent injury due to breakage of glass.
- Ready-to-use flasks are subject to terminal sterilization by autoclaving
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as medium powder or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and the sterilized medium inoculated with samples or microbial strains in accordance with current local legislation.
- Do not use the culture medium as active ingredient for pharmaceutical preparations or as production material intended for human and animal consumption
- The Certificates of Analysis and the Safety Data Sheets of the products are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

13 - STORAGE CONDITIONS AND SHELF LIFE

Ready-to-use medium in flasks

Upon receipt, store flasks in their original pack at +2°C /+8°C away from direct light. If properly stored, the flasks may be used up to the expiration date. Do not use the flasks beyond this date. Flasks from opened secondary packages can be used up to the expiration date. Opened flasks must be used immediately. Before use, check the closing and the integrity of the screw cap. Do not use flasks with signs of deterioration (e.g., microbial contamination, abnormal turbidity, precipitate, atypical colour).

Dehydrated medium

Upon receipt, store at +10°C /+30°C away from direct light in a dry place. If properly stored, it may be used up to the expiration date. Do not use beyond this date. Avoid opening the bottle in humid places. After use, the container must be tightly closed. Discard the product if the container and/or the cap are damaged, or if the container is not well closed, or in case of evident deterioration of the powder (colour changes, hardening, large lumps).

The user is responsible for the manufacturing and quality control processes of prepared media and the validation of their shelf life, according to the type and the applied storage conditions (temperature and packaging).

14 - REFERENCES

1. La Microbiologia nell'Industria Cosmetica. UNIPRO, aprile 1990, vol. 1. Ricerche e Tecnologie Cosmetiche.

®Tween is a trademark of ICI Americas Inc.

TABLE OF APPLICABLE SYMBOLS

TABLE OF AFF EIGABLE STIMBOLS					
REF or REF Catalogue number	LOT Batch code	Manufacturer	This side up	Store in a dry place	Fragile
Temperature limitation	Content sufficient for <n> tests</n>	Consult Instructions for Use	Use by	Keep away from direct light	For single use only

REVISION HISTORY

I	Version	Description of changes	Date
Ī	Revision 1	Updated layout and content	2022/08

Note: minor typographical, grammatical, and formatting changes are not included in the revision history

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