INSTRUCTIONS FOR USE

DERMATOPHYTE ANTIMICROBIC SUPPLEMENT

Freeze-dried selective supplement

1 - INTENDED USE

In vitro diagnostic. Mixture of antimicrobials to be added to Dermatophyte Selective Medium-DTM-(Taplin) for the detection of dermatophytes from cutaneous specimens.

2 - COMPOSITION - VIAL CONTENTS FOR 500 mL OF MEDIUM

Chlortetracycline HCl	50 mg

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Dermatophyte Antimicrobic Supplement is a freeze-dried mixture of antimicrobials to be used as a supplement of Dermatophyte Selective Medium -DTM- (Taplin) for selective isolation and differentiation of dermatophyte fungi responsible for lesions of the skin, nails, hair.[1,2]
The antimicrobials included in the medium base and in the supplement partially suppress the growth of bacteria and fungi: cycloheximide inhibits most saprophytic moulds, gentamicin inhibits most Gram-negative and some Gram-positive bacteria, chlortetracycline has a bacteriostatic activity against a wide range of microorganisms including Gram-positive and Gram-negative.[3]

4- DIRECTIONS

Aseptically reconstitute the contents of one vial with 5 mL of sterile purified water and mix gently to dissolve.
Prepare 500 mL of Dermatophyte Selective Medium -DTM- (Taplin) (REF 4013691), autoclaved and cooled to 47-50°C and add the contents of one vial of Dermatophyte Antimicrobic Supplement under aseptic conditions. Mix well and distribute into sterile Petri dishes.

5 - PHYSICAL CHARACTERISTICS

Freeze-dried supplement appearance	high, soft yellow pastille
Reconstituted supplement appearance	yellow, colourless

6 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
Dermatophyte Antimicrobic Supplement	Freeze-dried supplement	4240024	10 vials, each for 500 mL of medium

7 - MATERIALS REQUIRED BUT NOT PROVIDED

Dermatophyte Selective Medium -DTM- (Taplin) (REF 4013691), autoclave, water-bath, incubator and laboratory equipment as required, sterile loops and swabs, Petri dishes, Erlenmeyer flasks, ancillary culture media and reagents for the identification of the colonies.

8 - SPECIMENS

DTM is intended for the examination of cutaneous specimens such as nails, hair, skin.[1] Collect specimens before antimicrobial therapy where possible. Good laboratory practices for collection, transport and storage of the specimens should be applied.[1]

9 - TEST PROCEDURE

Allow plates/flasks or tubes to come to room temperature.
Press cutaneous specimens by gently pressing lightly the samples onto the agar surface.
Incubate aerobically, at 23-27°C for 4-7 days.
Negative cultures can be reported after 7 days, but plates should be re-incubated for a further week and examined before discarding at two weeks.[1]

10 - READING AND INTERPRETATION

After incubation observe the bacterial growth and record the specific morphological and chromatic characteristics of the colonies.
Dermatophytes produce alkaline metabolites which elevate the pH of the medium inducing a colour change of phenol red from orange to red. Examine the medium for evidence of white or light pinkish aerial growth and of a pink to red colour in medium.
For fast-growing dermatophytes, the red colour appears after 48 hours of incubation; for slow-growing dermatophytes, 3 to 7 days of incubation are required. When there are small colonies, the red colour remains limited to the area around the colony; when the growth is confluent and conspicuous, the indicator changes over the entire plate or flask or tube.

11 - 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 testing in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed some test strains useful for the quality control.

CONTROL STRAINS	INCUBATION T°/ T / ATM	EXPECTED RESULTS
T.mentagrophytes ATCC 28185	23-27°C / 94-96h / A	growth, the medium turns red-violet
C.albicans ATCC 18804	23-27°C / 94-96h / A	good partially inhibited
A.brasiliensis ATCC 9642	23-27°C / 94-96h / A	good partially inhibited
E.coli ATCC 25922	23-27°C / 94-96h / A	inhibited

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

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12 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of Dermatophyte Antimicrobic Supplement added to dehydrated Dermatophyte Selective Medium -DTM- (Taplin) is tested for productivity and selectivity by comparing the results with previously approved Reference Batch.
Productivity characteristics are tested by semi-quantitative ecometric technique with the following target strains: *Microsporum canis* ATCC 36229, *Trichophyton rubrum* ATCC 28188, *Trichophyton mentagrophytes* ATCC 9533. After incubation at 23-27°C for 96 hours, typical colonies develop white aerial hyphae with an alkalinisation of the medium that turns to red.
Selectivity is evaluated with modified Miles-Misra surface drop method by inoculating the plates with suitable decimal dilutions in saline of a 0.5 McFarland suspension of the non-target strains *C.albicans* ATCC 10231, *A.brasiliensis* ATCC 16404, *S.cereviciae* ATCC 9763, *E.coli* ATCC 25922, *S.aureus* ATCC 25923. *C.albicans* is partially inhibited, the growth of other non-target strains is totally inhibited.

13 - LIMITATIONS OF THE METHOD

- Saprophytes may redden the medium if specimen material is heavy contaminated but they can be recognized by their dark green or black hyphae; dermatophytes exhibit white aerial hyphae.[3]
- Disregard any colour after 10 days of incubation; it may be due to growth of contaminants.[3]
- A medium containing cycloheximide should not be used when infection with a non-dermatophyte mould is likely or suspected.[1]
- Even if the microbial colonies on the medium are differentiated on the basis of their morphological and chromatic characteristics, it is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on isolates, from pure culture, for complete identification. If relevant, perform antimicrobial susceptibility testing.
- The culture medium and the supplement are intended as an aid in the diagnosis of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

14 - PRECAUTIONS AND WARNINGS

- The supplement is a qualitative *in vitro* diagnostic, for professional use only; it must be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- Antibiotics containing supplements must be handled with suitable protection; consult the Safety Data Sheet before use.
- The supplement and the medium base shall be used in association according to the directions described above. Apply Good Manufacturing Practice in the production process of prepared media.
- The supplement is sterilized by membrane filtration.
- Be careful when opening the metal ring to avoid injury.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as medium powder and supplements or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused supplements and the sterilized media inoculated with samples or microbial strains in accordance with current local legislation.
- Do not use the supplement as active ingredients for pharmaceutical preparations or as production materials intended for human and animal consumption.
- The Certificates of Analysis and the Safety Data Sheet of the product are available on the website www.biolifeitaliana.it.
- Notify Biolife Italiana Srl (complaint@biolifeitaliana.it) and the relevant Authorities of any serious incident occurring in connection with the use of the *in vitro* diagnostic.
- 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.

15 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store the product in the original package at 2-8°C away from direct light. If properly stored, the product may be used up to the expiry date printed on the label; do not use beyond this date. Once the vial has been opened and the lyophilised product has been reconstituted, the resulting solution should be used immediately. Before use, examine the lyophilized and reconstituted product and discard if there are obvious signs of deterioration (e.g., contamination, atypical colour or other abnormal characteristics).
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 (plates/tubes/bottles) and the applied storage conditions (temperature and packaging).

16 - REFERENCES

1. Public Health England. Investigation of dermatological specimens for superficial mycoses. SMI B 39, Issue no: 3.1, 2016.
2. Taplin D, Zaias N, Rebbell G, Blank H. Isolation and recognition of dermatophytes on a new medium (DTM) Arch Derm 1969; 99:203-209.
3. MacFaddin JF. Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria. Baltimore: Williams & Wilkins; 1985.

4240024 DERMATOPHYTE ANTIMICROBIC SUPPLEMENT
SDS
Regulation 2020/878

Hazardous ingredient: chlortetracycline hydrochloride

Classification

Reproductive toxicity, category 2	H361fd Suspected of damaging fertility. Suspected of damaging the unborn child.
Eye irritation, category 2	H319 Causes serious eye irritation.
Skin irritation, category 2	H315 Causes skin irritation.
Specific target organ toxicity - single exposure, category 3	H335 May cause respiratory irritation.
Skin sensitization, category 1	H317 May cause an allergic skin reaction.

Labelling
Pictogram

Signal word Warning

Hazard statements:

H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.

Precautionary statements:

P280	Wear protective gloves/ protective clothing / eye protection / face protection.
P261	Avoid breathing dust / fume / gas / mist / vapours / spray.
P201	Obtain special instructions before use.
P312	Call a POISON CENTRE / doctor / . . . if you feel unwell.
P403+P233	Store in a well-ventilated place. Keep container tightly closed.
P362+P364	Take off contaminated clothing and wash it before reuse.

TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	This side up	
Temperature limitation	Content sufficient for <n> tests	Consult Instructions for Use	Use by	Keep away from direct light	Fragile

REVISION HISTORY

Version	Description of changes	Date
Revision 1	Updated layout and content	2022/02
Revision 2	Removal of obsolete classification	2023/04
Revision 3	Updated SDS's precautionary statements	2025/02

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