



## INSTRUCTIONS FOR USE

**DERMATOPHYTE SELECTIVE MEDIUM - DTM - (TAPLIN)  
DERMATOPHYTE ANTIMICROBIC SUPPLEMENT**

Dehydrated culture medium and selective supplement

*Trichophyton mentagrophytes* on DTM**1 - INTENDED USE***In vitro* diagnostic. Selective and differential medium for the detection of dermatophytic fungi from cutaneous specimens.**2 - COMPOSITION****DERMATOPHYTE SELECTIVE MEDIUM-DTM-(TAPLIN)****TYPICAL FORMULA (AFTER RECONSTITUTION WITH 1 L OF WATER) \***

Soy peptone	11.0 g
Glucose	10.0 g
Phenol red	0.2 g
Cycloheximide	0.5 g
Gentamicin sulphate	0.1 g
Agar	15.0 g

\*the formula may be adjusted and/or supplemented to meet the required performances criteria.

**DERMATOPHYTE ANTIMICROBIC SUPPLEMENT****(VIAL CONTENTS FOR 500 ML OF MEDIUM)**

Chlortetracycline HCl	50 mg
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**3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE**

The dermatophyte fungi are classified in three genera: *Epidermophyton* spp., *Microsporum* spp. and *Trichophyton* spp. The most common dermatophyte infections are *tinea pedis* (athlete's foot), *tinea unguium* (nail infection) in adults and *tinea capitis* (scalp ringworm) in children.<sup>1</sup>

Dermatophyte Test Medium or DTM has been formulated by Taplin, Zaias and Rebell<sup>2</sup> in 1969; the dehydrated medium Dermatophyte Selective Medium and the supplement Dermatophyte Antimicrobial Supplement are prepared according to the formula of Taplin *et al.* and are intended for selective isolation and differentiation of dermatophyte fungi responsible for lesions of the skin, nails, hair.<sup>1</sup>

Soy peptone provide the nutrients for microbial growth. Glucose is a source of carbon and energy for enhancing dermatophytes growth. Phenol red is a pH indicator, used to detect acid/alkaline production and to differentiate dermatophytes that cultivate with a change to red of the medium because of the production of basic metabolites. 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.

The medium allows the diagnosis of dermatophytes after at least 48 hours of incubation.

Allen<sup>3</sup> reported an accuracy of 97% in the identification of dermatophytes with the DTM medium; several authors<sup>4-7</sup> reported that DTM is an effective and convenient medium for confirming dermatophyte infections in Laboratory and in-office.

**4- DIRECTIONS FOR MEDIUM PREPARATION**

Suspend 18.4 g in 500 mL of cold distilled water, heat to boiling and sterilize by autoclaving at 115°C for 10 minutes. Cool to 47-50°C and aseptically add the contents of one vial of Dermatophyte Antimicrobial Supplement reconstituted with 5 mL of sterile distilled water, under aseptic conditions. Mix well and distribute into sterile Petri dishes or distribute into sterile screw cap bottle/tubes and cool in a slanted position.

**5 - PHYSICAL CHARACTERISTICS****Dermatophyte Selective Medium**

Dehydrated medium appearance	yellow, fine, homogeneous, free-flowing powder
Solution and prepared plates/tubes appearance	orange, limpid
Final pH at 20-25 °C	5.5 ± 0.1

**Dermatophyte Antimicrobial Supplement**

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

**6 - MATERIALS PROVIDED - PACKAGING**

Product	Type	REF	Pack
Dermatophyte Selective Medium - DTM- (Taplin)	Dehydrated medium	40136912	500 g (13,6 L) CND:W0104030101; EDMA 14.03.01.01; RDM: 1444002/R
Dermatophyte Antimicrobial Supplement	Freeze-dried supplement	4240024	10 vials, each for 500 mL of medium CND: W0104010104; EDMA: 14.01.01.04; RDM: 1892722/R

**7 - MATERIALS REQUIRED BUT NOT PROVIDED**

Autoclave, water-bath, incubator and laboratory equipment as required, Erlenmeyer flasks, Petri dishes, tubes, bottles, sterile loops and swabs, 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.<sup>1</sup> Collect specimens before antimicrobial therapy where possible. Good laboratory practices for collection, transport and storage of the specimens should be applied.<sup>1</sup>

## 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.<sup>1</sup>

## 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, it is responsibility of the end-user to perform 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
<i>T.mentagrophytes</i> ATCC 28185	23-27°C / 94-96h / A	growth, the medium turns red-violet
<i>C.albicans</i> ATCC 18804	23-27°C / 94-96h / A	good partially inhibited
<i>A.brasiliensis</i> ATCC 9642	23-27°C / 94-96h / A	good partially inhibited
<i>E.coli</i> ATCC 25922	23-27°C / 94-96h / A	inhibited

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

## 12 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of dehydrated Dermatophyte Selective Medium-DTM- (Taplin), supplemented with Dermatophyte Antimicrobial Supplement, is tested for productivity and selectivity by comparing the results with a 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 28185. After incubation at 23-27°C for 96 hours, typical colonies develop white aerial hyphae with an alkalisation 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 18804, *A.brasiliensis* ATCC 9642, *S.cereviciae* ATCC 9763, *E.coli* ATCC 25922, *S.aureus* ATCC 25923. *C.albicans* and *A.brasiliensis* are 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.<sup>8</sup>
- Disregard any colour after 10 days of incubation; it may be due to growth of contaminants.<sup>8</sup>
- A medium containing cycloheximide should not be used when infection with a non-dermatophyte mould is likely or suspected.<sup>1</sup>
- 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 medium base and the supplement are qualitative *in vitro* diagnostics, for professional use only; they are to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- The medium base and the supplement shall be used in association according to the described directions.
- Dehydrated media and antibiotics containing supplements must be handled with suitable protection. Before use, consult the Material Safety Data Sheets.
- 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 the 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](http://www.biolifeitaliana.it), describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- Many fungi are known to have allergenic effects so care should be taken to limit dissemination of fungal spores.<sup>1</sup>
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as medium powder and supplement or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and supplement and the inoculated plates with samples or microbial strains in accordance with current local legislation.





- Do not use the culture medium and the supplements 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 are available on the website [www.biolifeitaliana.it](http://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.

### 15 - STORAGE CONDITIONS AND SHELF LIFE

- **Dehydrated medium:** upon receipt, store at 10-30°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 were damaged or in case of evident deterioration of the powder (colour changes, hardening, presence of large lumps).
- **Selective supplement:** upon receipt store at 2-8°C until the expiry date. Do not use beyond this date. Once opened and reconstituted, the vial contents must be used immediately.

### 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, Rebell G, Blank H. Isolation and recognition of dermatophytes on a new medium (DTM) Arch Derm 1969; 99:203-209.
3. Allen AM, Drewry RA, Weaver RE. Evaluation of Two New Color Indicator Media for Diagnosis of Dermatophytosis. Arch Dermatol. 1970;102(1):68-70
4. Elewski BE, Leyden J, Rinaldi MG, Atillasoy E. Office practice-based confirmation of onychomycosis: a US nationwide prospective survey. Arch Intern Med. 2002;162(18):2133-2138.
5. Jennings MB, Rinaldi MG. Confirmation of dermatophytes in nail specimens using in-office dermatophyte test medium cultures. Insights from a multispecialty survey. J Am Podiatr Med Assoc. 2003;93(3):195-202.
6. Rahman MA, Chowdhury OA, Debnath MR, et al. Comparison among Different Culture Media for the Detection of Dermatophytes. Mymensingh Med J. 2018;27(3):626-630.
7. Rich P, Harkless LB, Atillasoy ES. Dermatophyte test medium culture for evaluating toenail infections in patients with diabetes. Diabetes Care. 2003;26(5):1480-1484.
8. MacFaddin JF. Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria. Baltimore: Williams & Wilkins; 1985.

## 40136912 - DERMATOPHYTE SELECTIVE MEDIUM –DTM-(TAPLIN)

**Hazardous ingredient: cycloheximide**

### Classification according to Regulation (EC) No 1272/2008

Acute toxicity, Oral (Category 3), H301

Germ cell mutagenicity (Category 2), H341

Reproductive toxicity (Category 1B), H360D

Chronic aquatic toxicity (Category 3), H412

For the full text of the H-Statements mentioned in this Section, see Section 16.

### Labelling according Regulation (EC) No 1272/2008 [CLP]

Pictogram



Signal word

Danger

Hazard statement(s)

H301

Toxic if swallowed

H341

Suspected of causing genetic defects

H360D

May damage the unborn child.

H412

Suspected of causing genetic defects

Precautionary statement(s)

P201

Obtain special instructions before use

P273

Avoid release to the environment

P281

Use personal protective equipment as required

P301 + P310

IF SWALLOWED: Immediately call a POISON CENTER/doctor

P308 + P313

IF exposed or concerned: Get medical advice/ attention.

Supplemental Hazard Statements

none

## 4240024 - DERMATOPHYTE ANTIMICROBIC SUPPLEMENT



**Hazardous ingredient: chlortetracycline hydrochloride**
**Classification according to Regulation (EC) No 1272/2008**

Skin irritation (Category 2), H315

Eye irritation (Category 2), H319

Specific target organ toxicity - single exposure (Category 3), Respiratory system, H335

For the full text of the H-Statements mentioned in this Section, see Section 16.

**Labelling according Regulation (EC) No 1272/2008**

Pictogram



Signal word Warning

Hazard statement(s)

H315

Causes skin irritation.

H319

Causes serious eye irritation.

H335

May cause respiratory irritation.

Precautionary statement(s)

P261

Avoid breathing dust.

P305 + P351 + P338

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

**TABLE OF APPLICABLE SYMBOLS FOR DEHYDRATED MEDIUM**

<b>REF</b> or <b>REF</b> Catalogue number	<b>LOT</b> Batch code	<b>IVD</b> <i>In vitro</i> Diagnostic Medical Device	Manufacturer	Use by
Temperature limitation	Contents sufficient for <n> tests	Consult Instructions for Use	Keep away from direct light	Store in a dry place

**TABLE OF APPLICABLE SYMBOLS FOR SELECTIVE SUPPLEMENT**

<b>REF</b> or <b>REF</b> Catalogue number	<b>LOT</b> Batch code	<b>IVD</b> <i>In vitro</i> Diagnostic Medical Device	Manufacturer	Use by
Temperature limitation	Contents sufficient for <n> tests	Consult Instructions for Use	Store away from direct light	Fragile, handle with care

**REVISION HISTORY**

Version	Description of changes	Date
Revision 2	Updated layout and content	2020/06

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