

## Technical Data Sheet

### NutriSelect® prime

#### Casein digest Soy Lecithin Polysorbate 20 (FCDLP 20) Broth (Base)

acc. ISO 16212, ISO 18415 and ISO 21149 (TAT Broth Base)

**Ordering number: 1.11723.0500**

For the initial suspension and dilution and for the non-selective enrichment of microorganisms from cosmetic and other material.

Casein digest Soy Lecithin Polysorbate 20 (FCDLP 20) Broth (Base) acc. ISO 16212, ISO 18415 and ISO 21149 (TAT Broth Base) is also known as Tryptone-Azolectin-Tween (TAT) Broth Base and as Fluid Casein digest-soy lecithin-polysorbate 20 (FCDLP 20) medium.

This culture medium complies with the specifications given by EN ISO 16212:2017/Amd 1:2022, EN ISO 18415:2017/Amd 1:2022, EN ISO 21149:2017/Amd 1:2022 and by the current version of Microbiology Guidelines of the PCPC (Personal Care Products Council; formerly Cosmetics, Toiletries, and Fragrance Association – CTFA).

It complies with the specifications given for Fluid Casein Digest-Soy Lecithin-Polysorbate 20-Medium by 31<sup>st</sup> Edition of United States Pharmacopoeia (2007) chapter <61> Microbial Limit Tests (non-harmonised method).

The performance test of this culture medium complies with the current versions of EN ISO 11133 and EN ISO 4973.

This culture medium is released by the quality control laboratory of Merck KGaA, Darmstadt, Germany. The laboratory is accredited by the German accreditation authority DAkkS as registered test laboratory D-PL-15185-01-00 according to DIN EN ISO/IEC 17025 for the performance testing of media for microbiology according to DIN EN ISO 11133.

### Mode of Action

This culture medium contains pancreatic digest of casein, which provides nitrogen, amino acids and carbon to ensure optimal conditions for the spore germination and regeneration of microorganisms.

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Soy lecithin and polysorbate 20 neutralize preservatives in the cosmetics, personal care or pharmaceutical products. The neutralizing additives reverse the growth inhibitory effect of most disinfectants and antiseptics. Soy lecithin inactivates cetrimide, chlorohexidine, chlorinated phenols, polymyxin B and others. Polysorbate 20 inactivates phenols, phenol derivatives, benzoic acid, p-hydroxybenzoic acid, and their esters, for example. The synergistic effect of lecithin and polysorbate 20 is known to inactivate many antimicrobial compounds, such as quaternary ammonium and phosphonium compounds.

## Typical Composition

PCPC Microbiology Guidelines specifies no composition for Casein digest Soy Lecithin Polysorbate 20 (FCDLP 20) Broth.

| Specified by<br>EN ISO 16212:2017/Amd 1:2022,<br>EN ISO 18415:2017/Amd 1:2022,<br>EN ISO 21149:2017/Amd 1:2022,<br>USP 31 <sup>st</sup> ed. Chapter <61><br>(non-harmonized method) |            | NutriSelect® prime<br>Casein digest Soy Lecithin<br>Polysorbate 20 (FCDLP 20)<br>Broth (Base)<br>acc. ISO 16212, ISO 18415 and<br>ISO 21149 (TAT Broth Base) |           |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------|
| Pancreatic digest of casein                                                                                                                                                         | 20.0 g/l   | Pancreatic digest of casein                                                                                                                                  | 20.0 g/l  |
| Soy lecithin                                                                                                                                                                        | 5 g/l      | Soy lecithin                                                                                                                                                 | 5.0 g/l   |
| <b>Supplementation:</b>                                                                                                                                                             |            |                                                                                                                                                              |           |
| Polysorbate 20                                                                                                                                                                      | 40.0 ml    | Polysorbate 20                                                                                                                                               | 40.0 ml   |
| Water                                                                                                                                                                               | 960 ml/l   | Water                                                                                                                                                        | n/a       |
| pH at 25 °C                                                                                                                                                                         | 7.3 ± 0.2* | pH at 25 °C                                                                                                                                                  | 7.3 ± 0.2 |

\* USP 31<sup>st</sup> ed. Chapter <61> (non-harmonized method) specifies no pH value. EN ISO 16212:2017/Amd 1:2022 and EN ISO 21149:2017/Amd 1:2022 specify pH 7.3 ± 0.2 at 25 °C whilst EN ISO 18415:2017/Amd 1:2022 specifies pH 7.2 ± 0.2 at 25 °C.

## Preparation

Dissolve 25,0 g in 960 ml demineralized water and add 40 ml polysorbate 20, Cat. No. 817072. Heat in a water bath set at 50°C for about 30 minutes with occasional agitation to dissolve completely. Alternatively add 40 ml polysorbate 20 after the heating and dissolve it completely. Mix and dispense into suitable containers. Autoclave (15 minutes at 121°C). After autoclaving, mix again, as the polysorbate 20 may have settled at the bottom.

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The dehydrated medium is a powder with beige colour.

The prepared medium is clear to slightly turbid and yellowish to yellowish-brown.

The pH value at 25 °C is in the range of  $7.3 \pm 0.2$ .

## Experimental Procedure and Evaluation

Depending on the purpose for which the medium is used.

For the **detection of specified and non-specified microorganisms** in cosmetic products according EN ISO 18415, the initial suspension of the sample is prepared in the enrichment broth Casein digest Soy Lecithin Polysorbate 20 (FCDLP 20) Broth acc. ISO 16212, ISO 18415 and ISO 21149 (TAT Broth).

Incubate the initial suspension prepared in broth at  $(32,5 \pm 2,5)$  h for at least 20 h.

For the isolation of specified and non-specified microorganisms, streak an aliquot of the incubated suspension on the surface of a Petri dish containing an appropriate medium, e.g. Tryptic soy agar (TSA).

Invert the inoculated dishes and incubate at  $(32,5 \pm 2,5)$  °C for (48 – 72) h. Proceed with suitable identifications tests and expression of results.

For the **enumeration of yeasts and mould** in cosmetic products according EN ISO 16212, the initial suspension of the sample is prepared in the neutralizing diluent Casein digest Soy Lecithin Polysorbate 20 (FCDLP 20) Broth acc. ISO 16212, ISO 18415 and ISO 21149 (TAT Broth). If needed, additional serial dilutions may be performed from the initial suspension using the same diluent (according to the expected level of contamination of the product).

Use pour-plate, surface-spread or membrane filtration method to inoculate an appropriate medium, e.g. Sabouraud dextrose chloramphenicol agar medium (SCDA) or Potato dextrose agar medium with chloramphenicol.

Invert the inoculated dishes and incubate at  $(25 \pm 2,5)$  °C for (3 - 5) d or appropriate other condition. After incubation, the dishes shall, if possible, be examined immediately. Alternatively, they may be stored, unless otherwise specified, for up to a maximum of 24 h in the refrigerator at  $(5 \pm 3)$  °C. An intermediate check can be performed where both yeast and mould are suspected. Proceed with counting and expression of results.

For the **enumeration and detection of aerobic mesophilic bacteria** in cosmetics products according EN ISO 21149, the initial suspension and, if needed, additional serial dilutions of the sample are prepared in the neutralizing diluent Casein digest Soy Lecithin Polysorbate 20 (FCDLP 20) Broth acc. ISO 16212, ISO 18415 and ISO 21149 (TAT Broth).

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**For enumeration of aerobic mesophilic bacteria**, use pour-plate, surface-spread or membrane filtration method to inoculate an appropriate medium, e.g. Tryptic soy agar (TSA). Invert the inoculated dishes and incubate at  $(32,5 \pm 2,5) ^\circ\text{C}$  for  $(72 \pm 6)$  h. After incubation, the dishes shall, if possible, be examined immediately. Otherwise, they may be stored, unless otherwise specified, for up to a maximum of 24 h in the refrigerator. Proceed with counting and expression of results.

**For enrichment of aerobic mesophilic bacteria**, incubate the initial suspension prepared in the enrichment broth Casein digest Soy Lecithin Polysorbate 20 (FCDLP 20) Broth acc. ISO 16212, ISO 18415 and ISO 21149 (TAT Broth) at  $(32,5 \pm 2,5) ^\circ\text{C}$  for at least 20 h. Subculture the incubated suspension on the surface of a Petri dish containing an appropriate medium, e.g. Tryptic soy agar (TSA).

Wait for the absorption of the incubated suspension by the agar and invert the inoculated dishes. Incubate at  $(32,5 \pm 2,5) ^\circ\text{C}$  for  $(48 - 72)$  h. Proceed with checking the agar medium surfaces on bacterial growth and record the presence or absence of growth.

### Storage

Store at  $+15 ^\circ\text{C}$  to  $+25 ^\circ\text{C}$ , dry and tightly closed. Do not use clumped or discolored medium. Protect from UV light (including sun light). For *in vitro* use only.

According to MacFaddin, self-prepared tubes can be stored at  $(5 \pm 3) ^\circ\text{C}$  in the dark and protected against evaporation for 6 – 8 weeks.

### Microbiological Performance

The performance test complies with the current versions of EN ISO 11133 and EN ISO 4973.

| Test method: Performance testing of diluents: Quantitative method                                         |                                                                                                                   |                   |                                               |                                                                          |
|-----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------|-------------------|-----------------------------------------------|--------------------------------------------------------------------------|
| Control strains                                                                                           | Incubation                                                                                                        | Method of control | Expected results                              | Specified by*                                                            |
|                                                                                                           |                                                                                                                   |                   | Growth                                        |                                                                          |
| <i>Staphylococcus aureus</i><br>ATCC® 6538™ [WDCM 00032]                                                  | 45 minutes<br>up to 1 hour<br>at $(18 - 27) ^\circ\text{C}$<br>(laboratory<br>ambient<br>temperature),<br>aerobic | Quantitative      | $\pm 30\%$ of<br>original count<br>(70-130 %) | Additional<br>control<br>strains<br>not<br>specified<br>by a<br>standard |
| <i>Pseudomonas paraeruginosa</i><br>(formerly <i>Pseudomonas aeruginosa</i> )<br>ATCC® 9027™ [WDCM 00026] |                                                                                                                   |                   | $\pm 30\%$ of<br>original count<br>(70-130 %) |                                                                          |
| <i>Escherichia coli</i><br>ATCC® 8739™ [WDCM 00012]                                                       |                                                                                                                   |                   | $\pm 30\%$ of<br>original count<br>(70-130 %) |                                                                          |
| <i>Candida albicans</i><br>ATCC® 10231™ [WDCM 00054]                                                      |                                                                                                                   |                   | $\pm 30\%$ of<br>original count<br>(70-130 %) |                                                                          |

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**Test method: Qualitative single tube method (turbidity) for performance testing of liquid media**

| Control strains                                                                                                 | Inoculum  | Incubation                                      | Method of control | Expected results | Specified by |
|-----------------------------------------------------------------------------------------------------------------|-----------|-------------------------------------------------|-------------------|------------------|--------------|
|                                                                                                                 |           |                                                 |                   | Growth**         |              |
| <i>Staphylococcus aureus</i><br>ATCC® 6538™<br>[WDCM 00032]                                                     | ≤ 100 CFU | ≤ 20 hours<br>at<br>(32,5 ± 2,5) °C,<br>aerobic | Quantitative      | Visible growth   | EN ISO 4973  |
| <i>Pseudomonas paraeruginosa</i><br>(formerly<br><i>Pseudomonas aeruginosa</i> )<br>ATCC® 9027™<br>[WDCM 00026] | ≤ 100 CFU |                                                 |                   | Visible growth   | EN ISO 4973  |
| <i>Escherichia coli</i><br>ATCC® 8739™<br>[WDCM 00012]                                                          | ≤ 100 CFU |                                                 |                   | Visible growth   | EN ISO 4973  |
| <i>Candida albicans</i><br>ATCC® 10231™<br>[WDCM 00054]                                                         | ≤ 100 CFU |                                                 |                   | Visible growth   | EN ISO 4973  |

\* EN ISO 4973 does not specify a microbiological performance test for diluents;

EN ISO 11133 specifies the general methodology for microbiological performance testing of diluents.

\*\* 'Visible growth' is confirmed by subculturing: Bacteria on Tryptic soy agar up to 24 hours at 32,5 °C ± 2,5 °C; aerobic; *Candida* on Sabouraud Dextrose agar, up to 48 hours at 32,5 °C ± 2,5 °C.

Please refer to the actual batch related Certificate of Analysis.

## Literature

ISO International Standardization Organisation. Cosmetics — Microbiology — Quality control of culture media and diluents used in cosmetics standards. EN ISO 4973:2023.

ISO International Standardization Organisation. Microbiology of food, animal feed and water - Preparation, production, storage and performance testing of culture media + Amendment 1 + Amendment 2. EN ISO 11133:2014/Amd1:2018/Amd2:2020.

ISO International Standardisation Organisation. Cosmetics — Microbiology — Enumeration of yeast and mould + Amendment 1. EN ISO 16212:2017/Amd1:2022.

ISO International Standardisation Organisation. Cosmetics — Microbiology — Detection of specified and non-specified microorganisms + Amendment 1. EN ISO 18415:2017/Amd1:2022.

ISO International Standardisation Organisation. Cosmetics — Microbiology — Enumeration and detection of aerobic mesophilic bacteria + Amendment 1. EN ISO 21149:2017/Amd1:2022.

PCPC (Personal Care Products Council; formerly Cosmetics, Toiletries, and Fragrance Association – CTFA) (2024): Microbiology Guidelines. Washington, DC, USA.

United States Pharmacopeial Convention. (2007): The United States Pharmacopeia (USP). 31<sup>st</sup> Edition. Chapter <61> Microbiological examination of nonsterile products: Microbial Limit Tests (non-harmonised method).

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Chioro, C.O., Mambleton, R.Q., and Rigby, G. (1965) The inhibition of spores of *Bacillus subtilis* by cetrimide retained on washed membrane spores. J. Appl. Bact., **28**, pp 322-330.

Evans, W.P. (1964) The solubilisation and inactivation of preservatives by nonionic detergents. J. Pharm. Pharmacol., **16**, pp 323-331.

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Kohn, S.R., Gershenfeld, L., and Barr, M. (1963) Effectiveness of antibacterial agents presently employed in ophthalmic preparations as preservatives against *Pseudomonas aeruginosa*. J. Pharm. Sci., **52**, pp 967-974.

McFaddin, J.F. (1985): Media for isolation – cultivation – identification – maintenance of medical bacteria. Vol 1. TAT (Tryptone-Azolectin-Tween) broth base. pp. 787 - 794. Williams & Wilkins, Baltimore, MD, USA.

## Ordering Information

| Product                                                                                                                                                | Cat. No.   | Pack size |
|--------------------------------------------------------------------------------------------------------------------------------------------------------|------------|-----------|
| NutriSelect® prime<br>Casein digest Soy Lecithin Polysorbate 20 (FCDLP 20)<br>Broth (Base) acc. ISO 16212, ISO 18415 and<br>ISO 21149 (TAT Broth Base) | 1117230500 | 500 g     |
| GranuCult® prime<br>Cetrimide Agar (base) acc. ISO 22717, FDA-BAM<br>and Ph. Eur./USP/JP                                                               | 1052840500 | 500 g     |
| GranuCult® prime<br>Tryptic Soy Agar<br>acc. EP, USP, JP, ISO and FDA-BAM                                                                              | 1054580500 | 500 g     |
| GranuCult® prime<br>SABOURAUD 4% Dextrose agar<br>acc. harm. EP/USP/JP                                                                                 | 1054380500 | 500 g     |

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