# Technical Data Sheet

## NutriSelect® prime
## Tryptic Soy Broth halal acc. EP, USP, JP, ISO and FDA-BAM

Ordering number: 1.04326.0500

A universal culture medium free from inhibitors and indicators for the isolation and cultivation of a wide range of microorganisms from different material.

Tryptic Soy Broth is also known as TSB, Trypticase (Tryptic) Soy Broth, Casein Soya-bean Digest (CASO) Broth and as Soybean-Casein Digest Medium (SCDM).

This culture medium complies with the specifications given by the harmonized methods of EP, USP, JP for Sterility Test and for Microbial Examination of Non-sterile Products: Microbial Enumeration Test and Test for Specified Microorganisms.
It complies with the specifications given by EN ISO 11133 for cultivating test strains during performance testing of culture media and with those given by EN ISO 10273, FDA-BAM Medium M154, USDA-FSIS, GB 4789.11 and APHA.

The Halal Certificate is issued by Halal Quality Control (HQC) according to Reference Halal Standards: JAKIM MS 1500:2019, MUI HAS 23000, OIC/SMIIC1:2019, GSO 2055-1.

This culture medium is also kosher certified by Fidelity Kosher to be used for surface contact only.

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

The combination of the two peptones, enzymatic digest of casein and of soy bean provides a high nutrition by supplying organic nitrogen, amino acids and longer-chained peptides. In this complex medium the osmotic balance is supplied by sodium chloride whilst the dipotassium phosphate acts for buffering.

## Typical Composition

ISO 11133 and APHA specify no composition for Tryptic Soy Broth.

| Specified by EP/USP/JP, ISO 10273, GB 4789.11 | | Specified by FDA-BAM Medium M154 and USDA-FSIS | | NutriSelect® prime Tryptic Soy Broth halal acc. EP, USP, JP, ISO and FDA-BAM | |
|---|---|---|---|---|---|
| Pancreatic digest of casein* | 17.0 g/l | Trypticase peptone | 17.0 g/l | Pancreatic digest of casein* | 17.0 g/l |
| Papaic digest of soya bean | 3.0 g/l | Phytone peptone | 3.0 g/l | Papaic digest of soya bean** | 3.0 g/l |
| Glucose monohydrate | 2.5 g/l | Glucose | 2.5 g/l | D(+)Glucose monohydrate | 2.5 g/l |
| NaCl | 5.0 g/l | NaCl | 5.0 g/l | NaCl | 5.0 g/l |
| $K_2HPO_4$ | 2.5 g/l | $K_2HPO_4$ | 2.5 g/l | $K_2HPO_4$ | 2.5 g/l |
| Water | 1000 ml/l | Water | 1000 ml/l | Water | n/a |
| pH at 25 °C*** | 7.3 ± 0.2 | pH at 25 °C | 7.3 ± 0.2 | pH at 25 °C | 7.3 ± 0.2 |

* Enzymatic digest of casein is equivalent to trypticase peptone and to Tryptone. GB 4789.11 specifies Tryptone.
** Papaic digest of soya bean is equivalent to phytone peptone.
*** GB 4789.11 specifies pH 7.3 ± 0.2 before autoclaving.

## Preparation

Dissolve 30.0 g in 1 liter of purified water and autoclave (15 minutes at 121 °C).

The dehydrated medium is a powder with brown colour.

The prepared medium is clear and yellowish-brown. The pH value at 25 °C is in the range of 7.3 ± 0.2.

## Experimental Procedure and Evaluation

Depend on the purpose for which the medium is used, e.g. follow directions given by EP, USP, JP or by EN ISO 11133.

## Storage

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

## Quality Control

| Control strains | Incubation | Inoculum | Method of control | Expected results |
|---|---|---|---|---|
| *Escherichia coli* ATCC® 25922 [WDCM 00013] | 18 ± 2 h at 37 ± 1 °C, aerobic | ≤ 100 cfu | Qualitative | Growth (good to very good turbidity) |
| *Staphylococcus aureus* ATCC® 25923 (WDCM 00034) | | ≤ 100 cfu | | |
| *Staphylocoocus aureus* ATCC® 6538 [WDCM 00032] | ≤ 18 h at 30 – 35 °C, aerobic | ≤ 100 cfu | Qualitative | Growth (visible growth) |
| *Pseudomonas aeruginosa* ATCC® 9027 [WDCM 00026] | | ≤ 100 cfu | | |
| *Escherichia coli* ATCC® 8739 (WDCM 00012) | | ≤ 100 cfu | | |
| *Salmonella* Typhimurium ATCC® 14028 (WDCM 00031) | | ≤ 100 cfu | | |
| *Bacillus subtilis* ATCC® 6633 [WDCM 00003] | 18 – 24 h at 30 – 35 °C, aerobic | ≤ 100 cfu | Qualitative | Growth (visible growth) |
| *Staphylococcus aureus* ATCC® 6538 [WDCM 00032] | 3 days at 20 - 25 °C, aerobic | ≤ 100 cfu | Qualitative | Growth (visible growth) |
| *Bacillus subtilis* ATCC® 6633 [WDCM 00003] | | ≤ 100 cfu | | |
| *Candida albicans* ATCC® 10231 [WDCM 00054] | up to 5 days at 20 - 25 °C, aerobic | ≤ 100 cfu | Qualitative | Growth (visible growth) |
| *Aspergillus brasiliensis* ATCC® 16404 [WDCM 00053] | | ≤ 100 cfu | | |

Reference medium for bacteria: Tryptic Soy Agar, already validated.
For *Candida albicans* and *Aspergillus brasiliensis*: Sabouraud 4% Dextrose Agar, already validated.

Please refer to the actual batch related Certificate of Analysis.

The performance tests are in accordance with the current version of EN ISO 11133 and the harmonized methods of EP, USP and JP.

## Literature

APHA (2015) Compendium of Methods for the Microbiological Examination of Foods. 5th ed. American Public Health Association, Washington, D.C.

European Directorate for the Quality of Medicines and Healthcare (2022): The European Pharmacopoeia. 11th Ed. Chapter 2.6.1 Sterility, Chapter 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products. Strasbourg, France.

FDA-BAM (2021, 2022): Chapter No. 5: *Salmonella*. and Chapter No. 23: Microbiological Methods for Cosmetics. U.S. Food and Drug Administration - Bacteriological Analytical Manual.

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National Health and Family Planning Commission of the People's Republic of China. China Food and Drug Administration. National Standard of the People's Republic of China. National food safety standard Food microbiological examination Examination of β-*Streptococcus hemolyticus*. GB 4789.11-2014.

ISO International Standardisation 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. Microbiology of the food chain - Horizontal method for the detection of pathogenic *Yersinia enterocolitica*. EN ISO 10273:2017.

Japanese Ministry of Health, Labour and Welfare. (2021): The Japanese Pharmacopoeia. 18th Ed. Chapter 4.05 Microbial Limit Test I. Microbiological examination of non-sterile products: Total viable aerobic count and II. Microbiological examination of non-sterile products: Test for specified products and Chapter 4.06 Sterility test. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

United States Pharmacopeial Convention. (2022): The United States Pharmacopeia/National Formulation. Chapter ⟨61⟩ Microbiological examination of nonsterile products: Microbial enumeration tests, Chapter ⟨62⟩ Microbiological examination of nonsterile products: Test for specified micro-organisms and Chapter ⟨71⟩ Sterility tests. Rockville, Md., USA.

USDA-FSIS (2022): Microbiology Laboratory Guidebook Appendix 1.10 Media and Reagents: Tryptic Soy Broth. United States Department of Agriculture – Food Safety and Inspection Service. Athens, USA.

McFaddin J.F. (1985): Tryptic Soy Broth. In: Media for isolation – cultivation – identification – maintenance of medical bacteria. Volume I. pp. 794-802. Lippincott Williams and Wilkins, Baltimore, MD, USA.

## Ordering Information

| Product | Cat. No. | Pack size |
|---|---|---|
| NutriSelect® prime<br>Tryptic Soy Broth halal acc. EP/USP/JP, ISO and FDA-BAM | 1.04326.0500 | 500 g |





MilliporeSigma