Technical Data Sheet

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

Ordering number: 1.04317.0500

For the isolation and cultivation of a wide range of microorganisms from different material.

Tryptic Soy Agar is also known as TSA, Trypticase (Tryptic) Soy Agar, Casein Soya-bean Digest (CASO) Agar and as Soybean-Casein Digest Agar (SCDA).

This culture medium complies with the specifications given by the harmonized methods of EP, USP, JP for Microbial Examination of Non-sterile Products: Microbial Enumeration Test and Tests for Specified Microorganisms.
It complies with the specifications given by EN ISO 11133 for the usage as a reference medium during performance testing of culture media and with those given by EN ISO 22964, FDA-BAM Medium M152, USDA-FSIS, GB 4789.40, GB 4789.43 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 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 agar-agar is the solidifying agent.

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Typical Composition

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

Specified by EP/USP/JP, ISO 22964, GB 4789.40, GB 4789.43		Specified by FDA-BAM Medium M152 and USDA-FSIS		NutriSelect® prime Tryptic Soy Agar halal acc. EP, USP, JP, ISO and FDA-BAM	
Pancreatic digest of casein*	15.0 g/l	Trypticase peptone	15.0 g/l	Pancreatic digest of casein*	15.0 g/l
Papaic digest of soya bean	5.0 g/l	Phytone peptone	5.0 g/l	Papaic digest of soya bean**	5.0 g/l
NaCl	5.0 g/l	NaCl	5.0 g/l	NaCl	5.0 g/l
Agar	15.0 g/l	Agar	15.0 g/l	Agar-Agar***	15.0 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 4789.40 and GB 4789.43 specify Tryptone.
** Papaic digest of soya bean is equivalent to phytone peptone and to plant peptone. GB 4789.40 specifies plant peptone, GB 4786.43 specifies soy peptone.
*** Agar-Agar is equivalent to other different terms of agar.
***** GB 4789.40 specifies pH 7.3 ± 0.2 before autoclaving, GB 4789.43 specifies pH 7.2 ± 0.2 before autoclaving.

Preparation

Dissolve 40 g in 1 l of purified water. Heat in boiling water and agitate frequently until completely dissolved. Autoclave (15 min at 121 °C). Cool the medium to about 45 °C, mix well and pour to plates according to the intended usage.

The dehydrated medium is a powder with brownish colour.

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

Before inoculation, allow the prepared medium to equilibrate at room temperature if it was stored at a lower temperature.

There should be no visible moisture on the plates before use. When moisture is present, the plates should be dried for the minimum time required to remove visible moisture, following the procedure as described by EP, JP, USP or by EN ISO 11133.

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.

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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® 8739 [WDCM 00012]	24 ± 3 h at 37 ± 1 °C, aerobic	≤ 100 cfu	Quantitative by surface plating	Recovery rate ≥70 %
Escherichia coli ATCC® 25922 [WDCM 00013]		≤ 100 cfu		
Bacillus cereus ATCC® 11778 [WDCM 00001]		≤ 100 cfu		
Listeria monocytogenes ATCC® 13932 [WDCM 000021]		≤ 100 cfu		
Staphylococcus aureus ATCC® 25923 (WDCM 00034)		≤ 100 cfu		
Staphylococcus aureus ATCC® 6538 [WDCM 00032]	24 ± 2 h at 30 – 35 °C, aerobic	10 – 100 cfu	Quantitative by surface plating	Recovery rate 50 – 150%
Bacillus subtilis ATCC® 6633 [WDCM 00003]		10 – 100 cfu		
Escherichia coli ATCC® 8739 (WDCM 00012)		10 – 100 cfu		
Pseudomonas aeruginosa ATCC® 9027 [WDCM 00026]		10 – 100 cfu		
Candida albicans ATCC® 10231 [WDCM 00054]	up to 5 days at 30 – 35 °C, aerobic	10 – 100 cfu		
Aspergillus brasiliensis ATCC® 16404 [WDCM 00053]		10 – 100 cfu		

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

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.

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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 2.6.12 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 (2016, 2017): Chapter No. 12: *Staphylocooccus aureus* and Chapter 20A: Inhibitory Substances in Milk. U.S. Food and Drug Administration - Bacteriological Analytical Manual.

FDA-BAM (2018): Media Index for BAM - BAM Medium M152: Trypticase (Tryptic) Soy Agar. Food and Drug Administration - Bacteriological Analytical Manual.

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: Food microbiological examination: Examination of *Cronobacter* (*Enterobacter sakazakii*). GB 4789.40-2016.

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: Food microbiological examination: Determination of antibacterial activity of microbial-enzyme preparations. GB 4789.43-2016.

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 *Cronobacter* spp. EN ISO 22964:2017.

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. 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 non-sterile products: Microbial enumeration tests and Chapter <62> Microbiological examination of non-sterile products: Test for specified products. Rockville, Md., USA.

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

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

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Ordering Information

Product	Cat. No.	Pack size
NutriSelect® prime Tryptic Soy Agar halal acc. EP, USP, JP, ISO and FDA-BAM	1.04317.0500	500 g
NutriSelect® prime Tryptic Soy Agar halal with Lecithin and Polysorbate 80 acc. EP, USP, JP, EN 17141 and ISO 21149	1.04323.0500	500 g

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