Technical Data Sheet

NutriSelect® prime
Tryptic Soy Agar halal with Lecithin and Polysorbate 80 acc. EP, USP, JP, EN 17141 and ISO 21149

Ordering number: 1.04323.0500

For enumeration and detection of aerobic mesophilic microorganisms (Total aerobic microbial count) present in cosmetics, pharmaceutical and other products containing preservatives and for determining the sanitation efficiency of containers, equipment, and work area (environmental monitoring).

Tryptic Soy Agar (TSA) with Lecithin and Polysorbate 80 is also known as Microbial Content Test (MCT) Agar and as Soybean-casein-digest-lecithin-polysorbate 80 agar medium (SCDLPA).

This culture medium complies with the specifications given by the harmonized methods of EP, USP, JP for Microbial Examination of Non-sterile Products: Tests for Specified Microorganisms and the specifications given by EN 17141 and EN ISO 21149.

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.

This modification of Tryptic Soy Agar contains lecithin and polysorbate 80 (also known as Tween® 80) to inactivate residual disinfectants when sampling. EP, JP, USP, EN 17141 and EN ISO 21249 recommend to incorporate lecithin to neutralize quaterny ammonium compounds (QACs), para-hydroxybenzoates (parabens) and bis-biguanides and to add polysorbate 80 to neutralize QACs, iodine and parabens. Polysorbate 80 is reported as well for neutralizing phenols, hexachlorophene and formalin.

Tryptic Soy Agar (TSA) with Lecithin and Polysorbate 80 can be used to prepare plates for different usage, e.g. contact plates for surface-sampling, plates for surface-plating and air-sampling techniques, for membrane filtration and for pour-plating technique.

Typical Composition

Specified by EP/USP/JP, and EN 17414		Specified by ISO 21149		NutriSelect® prime Tryptic Soy Agar halal with Lecithin and Polysorbate 80 acc. EP, USP, JP, EN 17141 and ISO 21149	
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	Soy bean 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
Lecithin***	(0.7 g/l)	Egg lecithin***	1.0 g/l	Lecithin	0.7 g/l
Polysorbate 80	(5.0 g/l)	Polysorbate 80	5.0 g/l	Polysorbate 80	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 a Casein peptone.
** Papaic digest of soya bean is a papaic digest of soya peptone.
*** EP/JP/USP and EN 17141 specify no exact composition for the neutralizers Lecithin and Polysorbate 80.
**** Agar-Agar is equivalent to other different terms of agar.

Preparation

Dissolve 45.7 g in 1 liter of purified water. Heat in boiling water and agitate frequently until completely dissolved. Autoclave (15 minutes at 121 °C). Cool the medium to about 45 °C, mix well and pour to plates.

The dehydrated medium is a powder with brown colour.

The prepared medium is clear to opalescent 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.

Inoculate the medium by surface-plating technique, by using membrane filters with the membrane filter technique, air-sampling technique or by pour-plating technique.

For testing the cleanliness and disinfection efficiency of surfaces, press the contact plate with even pressure onto the surface. Avoid rubbing to prevent damage of the agar bed.

Clean the surface afterwards to remove any agar residues.

Incubation: 24-48 hours at 35 °C aerobically or according to the applicable specification.

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 32,5 ± 2,5 °C, aerobic	≤ 100 cfu	Quantitative by surface plating	Recovery rate ≥70 %
Staphylococcus aureus ATCC® 6538 [WDCM 00032]		≤ 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		
Staphylococcus aureus ATCC® 6538 [WDCM 00032]	Test for neutralizing capacity			Passes test
Pseudomonas aeruginosa ATCC® 9027 [WDCM 00026]				

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.

Literature

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CEN European Committee for Standardisation. Cleanrooms and associated controlled environments – biocontamination control. EN 17141:2020.

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. Cosmetics - Microbiology — Enumeration and detection of aerobic mesophilic bacteria. EN ISO 21149:2017.

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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.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program. Parenteral Drug Association, Bethesda, MD, USA.

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Ordering Information

Product	Cat. No.	Pack size
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
NutriSelect® prime Tryptic Soy Agar halal acc. EP, USP, JP, ISO and FDA-BAM	1.04317.0500	500 g

MilliporeSigma