

**Technical Data Sheet** 

EcoCult<sup>®</sup> Tryptic Soy Broth acc. EP, USP, JP, ISO, FDA-BAM

# Ordering number: 1.40143.5000 / 1.40143.9010

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 (TSB) is also known as Casein-Peptone Soymeal-Peptone (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 FDA-BAM, USDA-FSIS and APHA.

#### 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.

From EcoCult<sup>®</sup> Tryptic Soy Broth acc. EP, USP, JP, ISO, FDA-BAM, the Tryptic Soy Broth with 0.6% Yeast Extract (TSBYE, BAM M157) can be prepared by addition of 6 g/l Yeast extract granulated (article number 1.03753.0500).

From EcoCult<sup>®</sup> Tryptic Soy Broth acc. EP, USP, JP, ISO, FDA-BAM, the Tryptic Soy-Polymyxin Broth (TSPB, FDA-BAM Medium M158) can be prepared by addition of the content of one vial reconstituted Bacillus cereus Selective Supplement (article number 1.09875.0010) to 500 ml Tryptic Soy Broth.

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### **Typical Composition**

Specified by EP, USP, JP		Specified by FDA- Medium BAM M154		EcoCult <sup>®</sup> Tryptic Soy Broth acc. EP, USP, JP, ISO, FDA-BAM	
Pancreatic digest of casein	17 g/l	Trypticase peptone	17 g/l	Pancreatic digest of casein*	17 g/l
Papaic digest of soybean meal	3 g/l	Phytone peptone	3 g/l	Papaic digest of soybean meal**	3 g/l
Glucose monohydrate	2.5 g/l	Glucose	2.5 g/l	D(+)Glucose monohydrate	2.5 g/l
NaCl	5 g/l	NaCl	5 g/l	NaCl	5 g/l
K2HPO4	2.5 g/l	K <sub>2</sub> HPO <sub>4</sub>	2.5 g/l	K <sub>2</sub> HPO <sub>4</sub>	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

\* Pancreatic digest of casein is equivalent to trypticase peptone.

\*\* Papaic digest of soybean meal is equivalent to phytone peptone.

#### 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 light yellow colour.

The prepared medium is clear and yellowish-brown. The pH value at 25 °C is in the range of 7.2 – 7.5.

Tryptic Soy Broth with 0.6% Yeast Extract (TSBYE) is made by addition of 6 g/l Yeast extract granulated (article number 1.03753.0500) before autoclaving. Dissolve together with the Tryptic Soy Broth and autoclave 15 minutes at 121 °C.

Tryptic Soy-Polymyxin Broth (TSPB) is made by addition of Bacillus cereus Selective Supplement (article number 1.09875.0010) to Tryptic Soy Broth after autoclaving. At 47-50 °C add 30  $\mu$ l of the reconstituted Supplement to 15 ml Tryptic Soy Broth. The final concentration of Polymyxin B is 1,500 IU per 15 ml Tryptic Soy Broth.

#### **Experimental Procedure and Evaluation**

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

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#### Storage

Store at +10 °C to +30 °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**

Function	Control strains	Inoculum [cfu]	Incubation	Method of control	Expected results
Productivity	<i>Escherichia coli</i> ATCC <sup>®</sup> 8739 [WDCM 00012]	≤100	18-24 h at 30-35 °C	Qualitative	visible growth
	<i>Staphylococcus aureus</i> ATCC <sup>®</sup> 6538 [WDCM 00032]	≤100	18-24 h at 30-35 °C	Qualitative	visible growth
	<i>Bacillus subtilis</i> ATCC <sup>®</sup> 6633 [WDCM 0003]	≤100	18-24 h at 30-35 °C	Qualitative	visible growth
		≤100	up to 72 h at 20-25 °C	Qualitative	visible growth
	<i>Pseudomonas aeruginosa</i> ATCC <sup>®</sup> 9027 [WDCM 00026]	≤100	18-24 h at 30-35 °C	Qualitative	visible growth
	Salmonella Abony NCTC 6017 [WDCM 00029]	≤100	18-24 h at 30-35 °C	Qualitative	visible growth
	Salmonella Typhimurium ATCC <sup>®</sup> 14028 [WDCM 00031]	≤100	18-24 h at 30-35 °C	Qualitative	visible growth
	Aspergillus brasiliensis (formerly A. niger) ATCC <sup>®</sup> 16404 [WDCM 00053]	≤100	up to 5 days at 20-25 °C	Qualitative	visible growth
	Candida albicans ATCC <sup>®</sup> 10231 [WDCM 00054]	≤100	up to 5 days at 20-25 °C	Qualitative	visible growth

Please refer to the actual batch related Certificate of Analysis.

The performance test is in accordance with the current versions of EP, USP, JP and EN ISO 11133.

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#### Literature

APHA (2012): Standard Methods for the Examination of Water. 22<sup>nd</sup> ed. American Public Health Association, American Water Works Association, Water Environment Federation, Washington, D.C.

European Directorate for the Quality of Medicines and Healthcare. (2019): The European Pharmacopoeia. 10<sup>th</sup> 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 (2020): Chapter No. 5: *Salmonella*. U.S. Food and Drug Administration - Bacteriological Analytical Manual.

FDA-BAM (2017): Chapter No. 10: Detection of *Listeria monocytogenes* in Foods and Environmental Samples, and Enumeration of *Listeria monocytogenes* in Foods. U.S. Food and Drug Administration - Bacteriological Analytical Manual.

FDA-BAM (2020): Chapter No. 14: *Bacillus cereus*. U.S. Food and Drug Administration - Bacteriological Analytical Manual.

FDA-BAM (2017): Chapter No. 23: Microbiological Methods for Cosmetics. Food and Drug Administration - Bacteriological Analytical Manual.

FDA-BAM (2018): Media Index for BAM - BAM Media M154: Trypticase (Tryptic) Soy Broth. BAM Media M157: Trypticase Soy Broth with 0.6% Yeast Extract (TSBYE). BAM Media M158: Trypticase Soy-Polymyxin Broth (TSPB). Food and Drug Administration - Bacteriological Analytical Manual.

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.

Japanese Ministry of Health, Labour and Welfare. (2017): The Japanese Pharmacopoeia. 17<sup>th</sup> 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. (2020): The United States Pharmacopeia 42<sup>th</sup> Ed. 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 (2017): Microbiology Laboratory Guidebook Appendix 1.09 Media and Reagents. United States Department of Agriculture – Food Safety and Inspection Service. Athens, USA.

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## **Ordering Information**

Product	Cat. No.	Pack size
EcoCult <sup>®</sup> Tryptic Soy Broth acc. EP, USP, JP, ISO, FDA-BAM	1.40143.5000	5 kg
EcoCult <sup>®</sup> Tryptic Soy Broth acc. EP, USP, JP, ISO, FDA-BAM	1.40143.9010	5 kg
Tryptic Soy Broth (TSB), Casein-Peptone Soymeal- Peptone (CASO) Broth acc. harm. EP/USP/JP and ISO	1.05459.0500	500 g
Tryptic Soy Broth (TSB), Casein-Peptone Soymeal- Peptone (CASO) Broth acc. harm. EP/USP/JP and ISO	1.05459.5000	5 kg
(granulated medium) Tryptic Soy Broth (TSB), Casein-Peptone Soymeal- Peptone (CASO) Broth acc. harm. EP/USP/JP and ISO	1.05459.9025	25 kg
Yeast extract granulated	1.03753.0500	500 g
Bacillus cereus Selective Supplement	1.09875.0010	10 vials

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