



# Tryptic Soy Broth

Ordering number: 1.46379.0006

Tryptic Soy Broth is a universal complex medium for the isolation and cultivation of fastidious aerobic bacteria, yeasts and molds.

The medium is used for sterility testing of substances, preparations and products as well as a preenrichment broth for the test for specified microorganisms or total viable aerobic count determinations using the MPN method within non-sterile products according to European Pharmacopoeia (EP) and the United States Pharmacopoeia (USP).

The formulation of the basic medium (Soybean-Casein Digest Broth) is prepared according to the recommendations of the current European, Japanese and United States Pharmacopoeia (EP, 2.6.12.; JP, 4.05 and USP, 61).

The TSB is available in different filling volumes and with various closure types:

- Tryptic Soy Broth (article number 146317): 125 mL-bottle **with flip cap**, filling volume 100 mL
- Tryptic Soy Broth (article number 146357): 275 mL-bottle **with wide mouth**, filling volume 100 mL
- Tryptic Soy Broth (article number 146458): 125 mL-bottle **with screw cap**, filling volume 100 mL
- Tryptic Soy Broth (article number 146380): 125 mL-bottle **with combined septum and screw cap**, filling volume 100 mL
- Tryptic Soy Broth (article number 146432): 17 mL-**tube**, filling volume 9 mL
- Tryptic Soy Broth (article number 146377): 125 mL-bottle **with screw cap**, filling volume 45 mL
- Tryptic Soy Broth (article number 146334): 275 mL-bottle **with wide mouth**, filling volume 90 mL
- Tryptic Soy Broth (article number 146335): 250 mL-bottle **with screw cap**, filling volume 100 mL
- Tryptic Soy Broth (article number 146318): 250 mL-bottle **with screw cap**, filling volume 200 mL
- Tryptic Soy Broth (article number 146342): 1000 mL-bottle **with combined septum and screw cap**, filling volume 750 mL
- Tryptic Soy Broth (article number 146379): 1000 mL-bottle **with screw cap**, filling volume 1000 mL

## Mode of Action

Tryptic Soy Broth supports the growth of a wide variety of aerobic and facultative anaerobic microorganisms including fungi by the content of two highly nutritious peptones.

## Typical Composition

|                                 |         |
|---------------------------------|---------|
| Casein Peptone                  | 17 g/L  |
| Soy Peptone                     | 3 g/L   |
| NaCl                            | 5 g/L   |
| K <sub>2</sub> HPO <sub>4</sub> | 2.5 g/L |
| Glucose Monohydrate             | 2.5 g/L |

The appearance of the medium is clear, yellowish to brownish. The pH value is in the range of 7.1-7.5. The medium can be adjusted and/or supplemented according to the performance criteria required.\*

\*For item 1463790006 the potential presence of small, chemically derived black particles does not influence the applicability of the product.

## Application and Interpretation

According to EP sterility tests may be carried out using the technique of membrane filtration or by direct inoculation.

For membrane filtration as diluents e.g. Fluid A (article number 146470) or Fluid D (article number 146397) may be used. The filter or its half is transferred into Tryptic Soy Broth or vice versa and incubated at 20-25 °C for not less than 14 days.

For direct inoculation the volume of the sample which has to be tested should not extend 10 % of the volume of the Tryptic Soy Broth and incubated at 20-25 °C for not less than 14 days.

If the material to be tested renders the medium turbid and a visual examination is not possible after 14 days of incubation, portions not less than 1 ml of the inoculated Tryptic Soy Broth are transferred into fresh Tryptic Soy Broth. The original inoculated broth as well as the freshly inoculated broth are incubated at 20-25 °C for not less than 4 days and examined again.

In case of growth it is recommended to identify the colonies using microbiological methods (e.g. selective media, biochemical methods) in order to identify and remove the source of contamination.

## Storage and Shelf life

The product can be used for tests until the expiry date if protected from light and properly sealed at +2 °C to +25 °C.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

## Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

## Quality Control

| Control Strains                 | ATCC         | Inoculum CFU | Incubation          | Expected Results                  |
|---------------------------------|--------------|--------------|---------------------|-----------------------------------|
| <i>Staphylococcus aureus</i>    | <b>6538</b>  | 10-100       | 20-24 h at 30-35 °C | good growth; pronounced turbidity |
| <i>Pseudomonas aeruginosa</i>   | <b>6538</b>  | 10-100       | 20-24 h at 30-35 °C | good growth; pronounced turbidity |
| <i>Bacillus subtilis</i>        | <b>6633</b>  | 10-100       | 20-24 h at 30-35 °C | good growth; pronounced turbidity |
|                                 |              |              | 70-74 h at 20-25 °C |                                   |
| <i>Candida albicans</i>         | <b>10231</b> | 10-100       | 44-48 h at 20-25 °C | good growth; pronounced turbidity |
| <i>Aspergillus brasiliensis</i> | <b>16404</b> | 10-100       | 70-74 h at 20-25 °C | good growth; pronounced turbidity |

Please refer to the actual batch related Certificate of Analysis.

## Literature

European Pharmacopoeia 8.0 (2014): 2.6.1. Sterility; 2.6.12. Microbial examination of non-sterile products (total viable aerobic count); 2.6.13. Microbial examination of non-sterile products (test for specified microorganisms).

Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.

Japanese Pharmacopoeia 16<sup>th</sup> edition (2011): 4.05 Microbial Limit Test.

PDA Technical Report No. 13 (2014 Revised): Fundamentals of an Environmental Monitoring Program.

United States Pharmacopoeia 38 NF 33 (2015): <71> Sterility Tests; <61> Microbial Limit Tests.

## Ordering Information

| Product                 | Cat. No.            | Pack size           |
|-------------------------|---------------------|---------------------|
| Tryptic Soy Broth       | <b>1.46379.0006</b> | 6 x 1000 mL bottles |
| Tryptic Soy Broth       | <b>1.46317.0010</b> | 10 x 100 mL bottles |
| Tryptic Soy Broth       | <b>1.46357.0006</b> | 6 x 100 mL bottles  |
| Tryptic Soy Broth       | <b>1.46458.0010</b> | 10 x 100 mL bottles |
| Tryptic Soy Broth       | <b>1.46380.0010</b> | 10 x 100 mL bottles |
| Tryptic Soy Broth       | <b>1.46432.0020</b> | 20 x 9 mL tubes     |
| Tryptic Soy Broth       | <b>1.46432.0100</b> | 100 x 9 mL tubes    |
| Tryptic Soy Broth       | <b>1.46377.0010</b> | 10 x 45 mL bottles  |
| Tryptic Soy Broth       | <b>1.46334.0006</b> | 6 x 90 mL bottles   |
| Tryptic Soy Broth       | <b>1.46334.0006</b> | 6 x 100 mL bottles  |
| Tryptic Soy Broth       | <b>1.46318.0006</b> | 6 x 200 mL bottles  |
| Tryptic Soy Broth       | <b>1.46342.0006</b> | 6 x 750 mL bottles  |
| Fluid A acc. USP Septum | <b>1.46470.0010</b> | 10 x 100 mL bottles |
| Fluid D acc. USP        | <b>1.46397.0010</b> | 10 x 100 mL bottles |

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technical assistance**

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MilliporeSigma  
400 Summit Drive  
Burlington, MA 01803

