

|                                        | Technical Data                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |                                 |       |                                 |       |             |     |                                 |       |      |     |  |  |
|----------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------|-------|---------------------------------|-------|-------------|-----|---------------------------------|-------|------|-----|--|--|
| Use in                                 | <ul style="list-style-type: none"><li>Pharmaceutical industry</li><li>For industrial, laboratory &amp; research applications only</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                 |       |                                 |       |             |     |                                 |       |      |     |  |  |
| Use for                                | <ul style="list-style-type: none"><li>Culture medium for Aseptic Process Simulation</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                                 |       |                                 |       |             |     |                                 |       |      |     |  |  |
| Typical composition per liter          | <p>Basic medium according to Ph. Eur. 2.6.1 and USP &lt;71&gt;</p> <table><tr><td>Casein peptone</td><td>17 g</td><td>Glucose-D(+) x H<sub>2</sub>O</td><td>2.5 g</td></tr><tr><td>Soy peptone</td><td>3 g</td><td>K<sub>2</sub>HPO<sub>4</sub></td><td>2.5 g</td></tr><tr><td>NaCl</td><td>5 g</td><td></td><td></td></tr></table> <p>This medium can be adjusted and/ or supplemented according to the performance criteria required.</p>                                                                                                                                                                                                         | Casein peptone                  | 17 g  | Glucose-D(+) x H <sub>2</sub> O | 2.5 g | Soy peptone | 3 g | K <sub>2</sub> HPO <sub>4</sub> | 2.5 g | NaCl | 5 g |  |  |
| Casein peptone                         | 17 g                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Glucose-D(+) x H <sub>2</sub> O | 2.5 g |                                 |       |             |     |                                 |       |      |     |  |  |
| Soy peptone                            | 3 g                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | K <sub>2</sub> HPO <sub>4</sub> | 2.5 g |                                 |       |             |     |                                 |       |      |     |  |  |
| NaCl                                   | 5 g                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                 |       |                                 |       |             |     |                                 |       |      |     |  |  |
| Filling volume                         | <ul style="list-style-type: none"><li>20 L</li></ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |                                 |       |                                 |       |             |     |                                 |       |      |     |  |  |
| Information about the <u>empty bag</u> | <ul style="list-style-type: none"><li>Material: polyethylene-based multilayer film, with middle layer out of EVOH which provides a barrier to gases</li><li>2D bag</li><li>Nominal volume 50 L</li><li>Maximal filling volume 45 L</li><li>Double bagged and irradiated with a minimum dose of 25 kGy</li><li>Manufactured in a certified ISO Class 7 clean room</li><li>Complying with the requirements of USP &lt;88&gt; Class VI for biocompatibility</li><li>Sealable tubes out of TPE (Thermoplastic Elastomer)</li></ul>                                                                                                                      |                                 |       |                                 |       |             |     |                                 |       |      |     |  |  |
| Information about the manifold         | <ul style="list-style-type: none"><li>The empty bags for production are delivered to PMM as a manifold</li><li>The manifold is a closed, single-use assembly containing four 50 L bags, a 0.2 µm sterile filter and smaller bags for quality control</li><li>The manifold is sterilized by irradiation and delivered to PMM as a whole</li><li>At PMM, the medium is prepared and autoclaved and enters the manifold through the 0.2 µm sterile filter</li><li>The four bags are filled subsequently, then separated and packed singularly for delivery</li><li>1 L bags for quality control are filled at the end of the filling process</li></ul> |                                 |       |                                 |       |             |     |                                 |       |      |     |  |  |

|                                              | Technical Data                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Bag design</b></p>                     | <div data-bbox="387 360 984 1115"> <p>Handle</p> <p>Empty 1L bag</p> <p>Clamp</p> <p>Retrival tubing</p> </div> <ul style="list-style-type: none"> <li>• Bag with handle</li> <li>• Three meters long retrieval tube with two types of connectors:                         <ul style="list-style-type: none"> <li>○ MPC connector</li> <li>○ Kleenpak™ Presto sterile connector</li> </ul> </li> <li>• Additional connected empty 1 L bag for customer sampling with following features:                         <ul style="list-style-type: none"> <li>○ 2D bag</li> <li>○ 1x tubing with MPC connector</li> <li>○ 1x tubing with needleless injection site</li> </ul> </li> <li>• Clamp closed at delivery; it can be opened to retrieve medium from the 20 L bag to the empty 1 L bag</li> </ul> |
| <p><b>Extra 1 L bags filled with TSB</b></p> | <div data-bbox="387 1202 676 1881"> </div> <ul style="list-style-type: none"> <li>• Two extra 1 L bags filled with TSB are delivered for each batch (4 x 20 L)</li> <li>• The two extra 1 L bags filled with TSB are packed in one of the containers, together with one of the 20 L bags</li> <li>• Features of 1 L bags:                         <ul style="list-style-type: none"> <li>○ 2D bag</li> <li>○ 1x tubing with MPC connector</li> <li>○ 1x tubing with needleless injection site</li> </ul> </li> <li>• These bags can be used e.g. for incoming good controls and shelf-life testing</li> </ul>                                                                                                                                                                                       |

|                                | Technical Data                                                                                                                                                                                                                                          |
|--------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Packaging and transport</b> | <ul style="list-style-type: none"> <li>• One 20 L bag packed in one reusable plastic container</li> <li>• Minimum order and delivery quantity: four bags (one batch)</li> <li>• Four bags are delivered on one pallet</li> </ul>                        |
| <b>Irradiation</b>             | <ul style="list-style-type: none"> <li>• Not irradiated</li> </ul>                                                                                                                                                                                      |
| <b>Shelf life</b>              | <ul style="list-style-type: none"> <li>• 12 months from production date</li> </ul>                                                                                                                                                                      |
| <b>Storage conditions</b>      | <ul style="list-style-type: none"> <li>• Recommended storage temperature: 2 – 25 °C</li> <li>• Should be stored at temperatures as stable as possible</li> <li>• Avoid prolonged exposure to direct sunlight</li> </ul>                                 |
| <b>Label</b>                   | <ul style="list-style-type: none"> <li>• On the 20 L bag and on the plastic container</li> <li>• The 1 L bags (both empty and filled) are marked with the same label as the 20 L bag</li> </ul>                                                         |
| <b>Label information</b>       | <ul style="list-style-type: none"> <li>• Product name: TSB 20 L</li> <li>• Expiry date: YYYYMMDD → MMM in letters (e.g.: 2026Nov04)</li> <li>• Lot-number</li> <li>• Individual number</li> <li>• Barcode</li> </ul>                                    |
| <b>Barcode</b>                 | <ul style="list-style-type: none"> <li>• 2-dimensional (data matrix), 20 digits:</li> <li>• Digits 1 - 3: Art.-No.</li> <li>• Digits 4 - 9: Lot-Number</li> <li>• Digits 10 - 14: Individual-Number</li> <li>• Digits 15 - 20: Date (YYMMDD)</li> </ul> |
| <b>Delivery</b>                | <ul style="list-style-type: none"> <li>• Temperature controlled delivery on request</li> </ul>                                                                                                                                                          |
| <b>Place of production</b>     | PharmaMedia Dr. Müller GmbH<br>Gustav-Throm-Str. 1, 69181 Leimen - Germany                                                                                                                                                                              |

| Quality control, Certificates |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Certificates                  | Every batch of product can be obtained with a certificate of analysis (CoA):                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                               | <b>Physico-chemical test parameters:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|                               | Appearance      Clear, yellowish                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|                               | pH value          7.1 – 7.5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|                               | Filling volume    20 – 25 L                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|                               | <b>Growth Promotion test: 10 – 100 CFU</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                               | <i>S. aureus</i> ATCC 6538      30 – 35 °C      1 day      Good growth                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|                               | <i>E. coli</i> ATCC 8739      30 – 35 °C      1 day      Good growth                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|                               | <i>P. paraeruginosa</i> ATCC 9027      30 – 35 °C      1 day      Good growth                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                               | <i>B. spizizenii</i> ATCC 6633      30 – 35 °C      1 day      Good growth                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Certificate of origin         | <i>B. spizizenii</i> ATCC 6633      20 – 25 °C      ≤ 3 days    Good growth                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|                               | <i>C. albicans</i> ATCC 10231     20 – 25 °C      3-5 days    Good growth                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                               | <i>A. brasiliensis</i> ATCC 16404     20 – 25 °C      3-5 days    Good growth                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|                               | <b>Sterility control</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|                               | ≥ 7 days at 20 - 25 °C and subsequently ≥ 7 days at 30 - 35 °C, no growth                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|                               | All media batches produced by PMM can be obtained with a Certificate of Origin (CoO).                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|                               | All animal-derived raw materials are specified as follows:                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|                               | <ul style="list-style-type: none"> <li>• Raw material</li> <li>• Tissue</li> <li>• Animal source</li> <li>• Country of origin</li> <li>• Infectivity category (acc. to TSE guideline: EMA/410/01 current version)</li> </ul>                                                                                                                                                                                                                                                                                                      |
|                               | Non-animal-derived raw materials are not listed in the CoO; raw materials listed on the CoA in the typical composition section but not listed on the CoO are of non-animal origin.                                                                                                                                                                                                                                                                                                                                                |
|                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| BSE policy                    | In compliance with the current note for guidance on minimizing the risk of transmitting animal spongiform encephalopathy via human or veterinary medicinal products, we check the CoO of raw material in respect to the specified animal source, the country of origin and the infectivity category. We neither store or process ruminant raw materials obtained from high infectivity tissues (IA) nor ruminant raw materials whose animal source originates from countries or regions with an undetermined risk (cat C/GBR IV). |

|                                   | Safety Data                                                                |
|-----------------------------------|----------------------------------------------------------------------------|
| <b>Toxic ingredients</b>          | <ul style="list-style-type: none"><li>• None</li></ul>                     |
| <b>Basic composition</b>          | <ul style="list-style-type: none"><li>• See typical composition</li></ul>  |
| <b>Solvent content</b>            | <ul style="list-style-type: none"><li>• None</li></ul>                     |
| <b>Safety data sheet required</b> | <ul style="list-style-type: none"><li>• Not mandatorily required</li></ul> |