

	Technical Data Sheet								
<b>Use in</b>	<ul style="list-style-type: none"> <li>• Pharmaceutical Industry</li> <li>• Cosmetic Industry</li> <li>• For industrial, laboratory &amp; research applications only</li> <li>• Medium according EP 2.6.12 and USP &lt;61&gt;</li> </ul>								
<b>Use for</b>	<ul style="list-style-type: none"> <li>• Test for specified micro-organisms</li> <li>• Preparation of test strains</li> <li>• Identification and growth of aerobic microorganisms</li> </ul>								
<b>Typical composition per liter</b>	<table> <tr> <td>Casein peptone</td><td>15 g</td></tr> <tr> <td>Soy peptone</td><td>5 g</td></tr> <tr> <td>NaCl</td><td>5 g</td></tr> <tr> <td>Agar</td><td>15 g</td></tr> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Casein peptone	15 g	Soy peptone	5 g	NaCl	5 g	Agar	15 g
Casein peptone	15 g								
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<b>Filling volume</b>	<ul style="list-style-type: none"> <li>• 200 mL</li> </ul>								
<b>Bottle format</b>	<ul style="list-style-type: none"> <li>• 220 mL screw cap</li> <li>• Type II glass</li> <li>• Bottle opening about 31 mm</li> <li>• Colour of cap: green</li> <li>• GL40 screw cap with 2 integrated septa</li> </ul>								
<b>Bottles per tray</b>	<ul style="list-style-type: none"> <li>• 12 bottles on a plastic tray wrapped with shrink foil</li> </ul>								
<b>Shelf life</b>	<ul style="list-style-type: none"> <li>• 18 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>• Store protected from light exposure</li> </ul>								
<b>Label</b>	<ul style="list-style-type: none"> <li>• On the side</li> <li>• Contain autoclave indicator</li> </ul>								
<b>Label information</b>	<ul style="list-style-type: none"> <li>• Product name: TSA</li> <li>• Expiry date: YYYYMMDD → MMM in letters (e.g.: 2023Nov04)</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>								

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<b>Delivery</b>	<ul style="list-style-type: none"> <li>• Temperature controlled delivery on request</li> <li>• For shipments of larger amounts plastic pallets in Euro-size can be used</li> </ul>
<b>Bottle information</b>	<ul style="list-style-type: none"> <li>• Label contains autoclaving indicator (brown → green)</li> <li>• Bottles are incubated at 25 – 35 °C for at least 48 hours after autoclaving and then packed</li> <li>• Bottles are not touched any more by hand after autoclaving</li> </ul>
<b>Melting recommendations</b>	<ul style="list-style-type: none"> <li>• Melt the agar (e.g., at 95 °C for 105 min in a water bath)</li> <li>• Transfer the bottle to a water bath at 47 - 50 °C for a maximum time of 4 hours</li> <li>• Pipette your sample into an empty, sterile petri dish</li> <li>• Add 18-25 mL of agar and shake gently</li> <li>• Incubate the plates upside down</li> <li>• <b>Do not</b> use a microwave for melting the agar</li> <li>• <b>Do not</b> melt the agar in an autoclave</li> <li>• <b>Do not</b> reuse melted agar a second time</li> </ul>
<b>Place of production</b>	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Quality control, Certificates	
<b>Certificates</b>	Each lot 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    196 – 206 mL
	<b>Growth Promotion test: 10-100 CFU</b>
	<i>S.aureus</i> ATCC 6538      30-35 °C      1 day          50-200%
	<i>E.coli</i> ATCC 8739      30-35 °C      1 day          50-200%
	<i>P.paraeruginosa</i> ATCC 9027      30-35 °C      1 day          50-200%
	<i>B.spizizenii</i> ATCC 6633      30-35 °C      1 day          50-200%
	<i>C.albicans</i> ATCC 10231     30-35 °C      3-5 days      50-200%
	<i>A.brasiliensis</i> ATCC 16404     30-35 °C      3-5 days      50-200%
	<b>Sterility control</b>
	≥ 7 days at 30-35 °C, no growth

	Quality control, Certificates
<b>Certificate of origin</b>	<p>All media lots produced by PMM can be obtained with a Certificate of Origin (CoO). All animal derived raw materials are specified as follows:</p> <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>
<b>BSE policy</b>	<ul style="list-style-type: none"> <li>• 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).</li> </ul>
<b>Temperature stress</b>	<ul style="list-style-type: none"> <li>• Art. 600.B200 has been exposed to temperature stress conditions (3 days at 2-8 °C as well as 3 days at 30-35 °C) and has passed shelf-life testing at least 30 days after the assigned expiry date. Shelf-life testing comprises all regular tests which are part of the normal release test of this article except for sterility control (see CoA).</li> </ul>

	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>