

<b>-Technical Data Sheet</b>																	
<b>Use in</b>	<ul style="list-style-type: none"> <li>• Pharmaceutical Industry</li> <li>• For industrial, laboratory &amp; research applications only</li> <li>• Basic medium according to EP 2.6.13 and USP &lt;62&gt;</li> </ul>																
<b>Use for</b>	<ul style="list-style-type: none"> <li>• Detection of aerobic and anaerobic micro-organisms</li> <li>• Basic medium composition according EP and USP</li> <li>• Contact sampling, personnel monitoring, as well as active air monitoring</li> <li>• Isolation and growth of fastidious bacteria, yeasts and moulds</li> <li>• Recommended for clean room classes C and D</li> </ul>																
<b>Typical composition per liter</b>	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Casein peptone</td> <td style="width: 16.5%;">15 g</td> <td style="width: 33%;">Lecithin (L)</td> <td style="width: 16.5%;">0,7 g</td> </tr> <tr> <td>Soy peptone</td> <td>5 g</td> <td>Polysorbate 80 (T)</td> <td>5,0 g</td> </tr> <tr> <td>NaCl</td> <td>5 g</td> <td>Histidine</td> <td>0,5 g</td> </tr> <tr> <td>Agar</td> <td>15 g</td> <td></td> <td></td> </tr> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p>	Casein peptone	15 g	Lecithin (L)	0,7 g	Soy peptone	5 g	Polysorbate 80 (T)	5,0 g	NaCl	5 g	Histidine	0,5 g	Agar	15 g		
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<b>Irradiation</b>	<ul style="list-style-type: none"> <li>• Not irradiated</li> </ul>																
<b>Filling volume</b>	<ul style="list-style-type: none"> <li>• 16-19 mL</li> </ul>																
<b>Packaging</b>	<ul style="list-style-type: none"> <li>• Single bagged, staples of 10 plates</li> <li>• Transparent</li> <li>• High barrier foil against desiccation</li> <li>• 12 staples of 10 plates per packaging unit</li> <li>• Temperature isolated handle-bag in the cardboard-boxes</li> </ul>																
<b>Units per pack</b>	<ul style="list-style-type: none"> <li>• 120 plates</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: 15-25 °C</li> <li>• Should be stored at temperatures as stable as possible</li> <li>• Before use: it is recommended to keep the plates upright with the agar always on the bottom</li> <li>• For incubation: it is recommended to keep the plates upside down for reducing the risk of condensation dropping on the agar surface, thus affecting colonies growing on the surface</li> </ul>																
<b>Label</b>	<ul style="list-style-type: none"> <li>• On the side of the bottom part of the dish</li> </ul>																
<b>Label information</b>	<ul style="list-style-type: none"> <li>• Product name: TSA+LTH</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>-Technical Data Sheet</b>	
<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> <li>• For shipments of larger amounts plastic pallets in Euro-size can be used</li> </ul>
<b>Petri dish</b>	<ul style="list-style-type: none"> <li>• Locking lid plate, made from polystyrene</li> <li>• Incubations in vent and closed position possible</li> <li>• Specific design to improve binding of agar to plate</li> <li>• Easy handling due to increased handling area</li> </ul>
<b>Locking lid</b>	<ul style="list-style-type: none"> <li>• Locking-lid plate, made from polystyrene</li> <li>• Inner diameter: 56.5 mm, thus providing an area of 25 cm<sup>2</sup></li> <li>• Outer diameter: 67.5 mm</li> <li>• Bottom part with 1 cm<sup>2</sup> square grid for facilitated evaluation</li> </ul>
<b>Lid positions</b>	<ul style="list-style-type: none"> <li>• All plates are delivered in the non-locked position</li> <li>• The plate contains two locked positions. If turning the lid clockwise the locked positions are in the following order:               <ol style="list-style-type: none"> <li>1. Vent position</li> <li>2. Closed position</li> </ol> </li> <li>• For long incubation of aerobic microorganisms, the closed position is recommended</li> </ul>
<b>Aerobic incubation (Closed position)</b>	<ul style="list-style-type: none"> <li>• Turn the lid clockwise to the right to the end into the final stop position</li> <li>• The lid locks in the closed position</li> <li>• Ideal incubation condition for aerobic micro-organisms</li> <li>• Limits the dehydration of the agar during incubation</li> </ul>
<b>Anaerobic incubation (Vent Position)</b>	<ul style="list-style-type: none"> <li>• The vent position is ideal for anaerobic incubations, as it allows an easy and effective removal of oxygen under anaerobic incubation conditions</li> <li>• Incubate in anaerobic incubator, anaerobic jar or suitable equipment</li> <li>1. First option:           <ul style="list-style-type: none"> <li>• Turn the lid clockwise to the right to the end into the final stop position</li> <li>• Turn the lid one click counter-clock-wise to the vent position</li> </ul> </li> <li>2. Second option:           <ul style="list-style-type: none"> <li>• Turn the lid clockwise directly into the first locked position</li> </ul> </li> </ul>
<b>Place of production</b>	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

<b>Quality control, Certificates</b>																																																																		
<b>Certificates</b>	<p>Each lot of product can be obtained with a certificate of analysis (CoA):</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th colspan="5" style="text-align: left;"><b>Physico-chemical test parameters:</b></th> </tr> </thead> <tbody> <tr> <td>Appearance</td> <td colspan="4">Slightly turbid, yellowish</td> </tr> <tr> <td>pH value</td> <td colspan="4">7,1 – 7,5</td> </tr> <tr> <td>Filling volume</td> <td colspan="4">16 – 19 mL</td> </tr> <tr> <td colspan="5"> </td> </tr> <tr> <th colspan="5" style="text-align: left;"><b>Growth Promotion test: 10-100 CFU</b></th> </tr> <tr> <td><i>S. aureus</i></td> <td>ATCC 6538</td> <td>30-35 °C</td> <td>1 day</td> <td>50-200%</td> </tr> <tr> <td><i>E. coli</i></td> <td>ATCC 8739</td> <td>30-35 °C</td> <td>1 day</td> <td>50-200%</td> </tr> <tr> <td><i>P. paraeruginosa</i></td> <td>ATCC 9027</td> <td>30-35 °C</td> <td>1 day</td> <td>50-200%</td> </tr> <tr> <td><i>B. spizizenii</i></td> <td>ATCC 6633</td> <td>30-35 °C</td> <td>1 day</td> <td>50-200%</td> </tr> <tr> <td><i>C. albicans</i></td> <td>ATCC 10231</td> <td>20-25 °C</td> <td>3-5 days</td> <td>50-200%</td> </tr> <tr> <td><i>A. brasiliensis</i></td> <td>ATCC 16404</td> <td>20-25 °C</td> <td>3-5 days</td> <td>50-200%</td> </tr> <tr> <td colspan="4"><b>Sterility control</b></td> <td>No growth</td> </tr> </tbody> </table>	<b>Physico-chemical test parameters:</b>					Appearance	Slightly turbid, yellowish				pH value	7,1 – 7,5				Filling volume	16 – 19 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	20-25 °C	3-5 days	50-200%	<i>A. brasiliensis</i>	ATCC 16404	20-25 °C	3-5 days	50-200%	<b>Sterility control</b>				No growth
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<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 rev. 3)</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. 300.0060 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 comprise all regular tests which are part of the normal release test of this article (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>