

Technical Data Sheet									
<b>Use in</b>	<ul style="list-style-type: none"> <li>Pharmaceutical Industry in clean rooms and isolators</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>Isolation and growth of yeasts and molds</li> <li>Contact sampling, personnel monitoring, as well as active air monitoring</li> <li>Inhibits the growth of most bacteria</li> </ul>								
<b>Typical composition per liter</b>	<table> <tbody> <tr> <td>Casein peptone</td> <td>5 g</td> <td>Glucose-D(+)*H<sub>2</sub>O</td> <td>44 g*</td> </tr> <tr> <td>Meat peptone</td> <td>5 g</td> <td>Agar</td> <td>15 g</td> </tr> </tbody> </table> <p>This medium can be adjusted / or supplemented according to the performance criteria required.</p> <p>*Glucose-D(+)+H<sub>2</sub>O = Glucose monohydrate  *44 g Glucose monohydrate = 40 g Glucose = 40 g Dextrose</p>	Casein peptone	5 g	Glucose-D(+)*H <sub>2</sub> O	44 g*	Meat peptone	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>28-32 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>6 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>60 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 before use, agar on the lower part, lid on the upper part to avoid formation of extra condensation</li> <li>After use: it is recommended to keep the plates upside down after use, agar on the upper part, lid on the lower part to reduce the risk of condensation forming during incubation which can affect colony forming</li> </ul>								
<b>Label</b>	<ul style="list-style-type: none"> <li>On the side, at the bottom</li> </ul>								
<b>Label information</b>	<ul style="list-style-type: none"> <li>Product name: SDA</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 are used</li> </ul>
<b>Petri dish (Pink Plates)</b>	<ul style="list-style-type: none"> <li>• Locking lid 90 mm plate, made from polystyrene</li> <li>• Long incubations possible – due to high filling volume</li> <li>• Long expositions possible – due to specific design of plate</li> <li>• Incubations in vent and closed position possible</li> <li>• SDA plates are produced in pink dishes for better differentiation from TSA plates</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 2 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">5,4 – 5,8</td> </tr> <tr> <td>Filling volume</td> <td colspan="4">28 – 32 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>C. albicans</i></td> <td>ATCC 10231</td> <td>20-25 °C</td> <td>2-3 days</td> <td>50-200%</td> </tr> <tr> <td><i>C. albicans</i></td> <td>ATCC 10231</td> <td>30-35 °C</td> <td>1 day</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="5"> </td> </tr> <tr> <th colspan="4" style="text-align: left;"><b>Sterility control</b></th> <td>No growth</td> </tr> </tbody> </table>	<b>Physico-chemical test parameters:</b>					Appearance	Slightly turbid, yellowish				pH value	5,4 – 5,8				Filling volume	28 – 32 mL									<b>Growth Promotion test: 10-100 CFU</b>					<i>C. albicans</i>	ATCC 10231	20-25 °C	2-3 days	50-200%	<i>C. albicans</i>	ATCC 10231	30-35 °C	1 day	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> <p>In compliance with the current 3note 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).</p>																																																							
<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. 426.0060 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 270 days after the production 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>