

<b>Technical Data Sheet</b>																	
<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 Ph. Eur. 2.6.12, 2.6.13 and USP &lt;61&gt;, &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>Contact sampling, personnel monitoring, as well as active air monitoring</li> <li>Isolation and growth of fastidious bacteria, yeasts and moulds</li> <li>Especially designed for use in environments with exposure to penicillins and lower concentrations of cephalosporins</li> <li>For environments exposed to high concentrations of cephalosporins and penicillins please refer to art. 114.0100</li> </ul> <p>The medium should be applied with a uniform and steady pressure to the surface for few seconds. After sampling the surface must be cleaned to remove residues of the medium.</p>																
<b>Typical composition per liter</b>	<table style="width: 100%; border-collapse: collapse;"> <tbody> <tr> <td style="width: 33%;">Casein peptone</td> <td style="width: 16.5%; text-align: center;">15 g</td> <td style="width: 33%;">Lecithin (L)</td> <td style="width: 16.5%; text-align: center;">0.7 g</td> </tr> <tr> <td>Soy peptone</td> <td style="text-align: center;">5 g</td> <td>Polysorbate 80 (T)</td> <td style="text-align: center;">5 g</td> </tr> <tr> <td>NaCl</td> <td style="text-align: center;">5 g</td> <td><math>\beta</math>-Lac I / Penase*</td> <td></td> </tr> <tr> <td>Agar</td> <td style="text-align: center;">15 g</td> <td><math>\beta</math>-Lactamase II</td> <td></td> </tr> </tbody> </table> <p>* Penicillinase = Penase = <math>\beta</math>-Lactamase I</p> <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 g	NaCl	5 g	$\beta$ -Lac I / Penase*		Agar	15 g	$\beta$ -Lactamase II	
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<b>Irradiation</b>	<ul style="list-style-type: none"> <li>Irradiated at 9-20 kGy</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>Triple bagged, staples of 10 plates</li> <li>Transparent</li> <li>High barrier foil for H<sub>2</sub>O<sub>2</sub> as well as for water-vapor</li> <li>10 staples of 10 plates per packaging unit</li> <li>Temperature isolated handle-bag in the cardboard-boxes</li> </ul>																
<b>Plates per box</b>	<ul style="list-style-type: none"> <li>100 (10 staples with 10 plates each)</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>Store protected from light exposure</li> <li>Before use: it is recommended to keep the plates upright (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 (agar on the upper part, lid on the lower part) to reduce the risk of accumulation of condensation during incubation which can affect colony formation</li> </ul>																

Technical Data Sheet	
<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: TSA+LT+LacI/II</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> <li>For shipments of larger amounts plastic pallets in Euro-size are used</li> </ul>
<b>Petri dish</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: ~ 66 mm</li> <li>Bottom part with 1 cm<sup>2</sup> square grid for facilitated evaluation</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>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>Vent position</li> <li>Closed position</li> </ol> </li> </ul>
<b>Aerobic incubation</b>	<ul style="list-style-type: none"> <li>The closed position provides ideal incubation conditions for aerobic microorganisms and limits the dehydration of the agar during incubation</li> <li>For long incubation of aerobic microorganisms, the closed position is recommended</li> <li>To lock the lid in the closed position, turn the lid clockwise into the final stop position</li> </ul>
<b>Anaerobic incubation</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> </ul> <ol style="list-style-type: none"> <li>First option:           <ul style="list-style-type: none"> <li>Turn the lid clockwise into the final stop position</li> <li>Turn the lid one click counterclockwise to the vent position</li> </ul> </li> <li>Second option:           <ul style="list-style-type: none"> <li>Turn the lid clockwise directly into the first locked position</li> </ul> </li> </ol>

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<b>Place of production</b>	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany																																																																																					
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<b>Certificates</b>	<p>Each lot of product can be obtained with a certificate of analysis (CoA):</p> <table border="1"> <thead> <tr> <th colspan="5"><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>Irradiation</td> <td colspan="4">9 - 20 kGy</td> </tr> <tr> <td colspan="5"><b>Growth Promotion test: 10 - 100 CFU</b></td> </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. subtilis</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="5"><b>Test for <math>\beta</math>-lactamase Plus activity: 10,000 - 100,000 CFU</b></td> </tr> <tr> <td><i>S. aureus</i></td> <td>ATCC 6538</td> <td>30-35 °C</td> <td>1 day</td> <td>No inhibition</td> </tr> <tr> <td colspan="5">No inhibition by penicillin (10 IU)</td> </tr> <tr> <td colspan="5">No inhibition by cefazolin (30 <math>\mu</math>g)</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				Irradiation	9 - 20 kGy				<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. subtilis</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>Test for <math>\beta</math>-lactamase Plus activity: 10,000 - 100,000 CFU</b>					<i>S. aureus</i>	ATCC 6538	30-35 °C	1 day	No inhibition	No inhibition by penicillin (10 IU)					No inhibition by cefazolin (30 $\mu$ g)					<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 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>Quality control, Certificates</b>	
<b>Temperature stress</b>	<ul style="list-style-type: none"> <li>Art. 116.0100 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>
<b>Penase Synonyms are: Penicillinase or <math>\beta</math>-lactamase I</b>	<p>Penase is a commercially available enzyme inactivating Penicillins like benzylpenicillin (penicillin G), ampicillin, amoxicillin, carbenicillin, methicillin, cloxacillin and flucloxacillin.</p> <p>Synonyms for Penase are Penicillinase and <math>\beta</math>-lactamase I.</p> <p>Although Penase is sometimes called <math>\beta</math>-lactamase I it has no activity against <math>\beta</math>-lactam antibiotics of the class of cephalosporins and/or penems.</p> <p>Penase activity: Enzyme activities are typically specified in international Units (= IU) or international kilo Units (= kIU).</p> <p>International Unit (IU): 1 IU hydrolyses 1 <math>\mu</math>mole of benzyl penicillin per min. at 25 °C, at pH 7.0 (1 <math>\mu</math>mole benzylpenicillin corresponds to about 0,3564 mg)</p> <p>Alternative specifications used for Penase used as well: Levy Unit (= LU): 1 LU ~ 0,00167 IU → 1 IU ~ 600 LU</p> <p>Pollock Unit (PU): Pollock Unit: 1 PU ~ 0,0133 IU → 1 IU ~ 75 PU</p> <p>Penase is added aseptically to the PMM medium.</p> <p>The amount of enzyme required by customers must be determined by every customer himself, as the production environments differ from customer to customer as well as the antibiotics produced.</p>

Quality control, Certificates	
<b><math>\beta</math>-lactamase II</b> <b>Synonyms are:</b> <b>Cephase</b> <b>Lactamator</b> <b>Carbamator</b> <b>LacBuster</b>	<p><math>\beta</math>-lactamase II is a commercially available enzyme inactivating penicillin, cephalosporins and penems. It was originally extracted from <i>Bacillus cereus</i>.</p> <p><math>\beta</math>-Lactamases II are available meanwhile from different suppliers under different names, e.g., cephase, lactamator, carbamator etc.</p> <p>This enzyme differs between suppliers in respect to their origin, and their activity against different antibiotics</p> <p>The enzyme activities are typically specified in international Units (= IU) or international kilo Units (= Iku).</p> <p>International Unit (IU): 1 IU hydrolyses 1 <math>\mu</math>mole of cephalosporin per min. at 25 °C, at pH 7.0</p> <p><math>\beta</math>-Lactamase II is added aseptically to the PMM medium</p> <p>The amount of enzyme required by customers must be determined by every customer himself, as the production environments differ from customer to customer as well as the antibiotics produced.</p>

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>