

Technical Data Sheet																	
Use in	<ul style="list-style-type: none"> Pharmaceutical Industry in clean rooms and isolators For industrial, laboratory & research applications only 																
Use for	<ul style="list-style-type: none"> Detection of aerobic and anaerobic micro-organisms Contact sampling, personnel monitoring, as well as active air monitoring Isolate on and growth of fastidious bacteria, yeasts and moulds Especially designed for use in environments with exposure to penicillins and lower concentrations of cephalosporins For environments exposed to high concentrations of cephalosporins and penicillins please refer to art. 114.0100 <p>The medium should be applied with a uniform and steady pressure to the surface for a few seconds. After sampling the surface must be cleaned to remove residues of the medium.</p>																
Typical composition per liter	<table> <tbody> <tr> <td>Casein peptone</td> <td>15 g</td> <td>Lecithin (L)</td> <td>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>β-Lac I / Penase*</td> <td></td> </tr> <tr> <td>Agar</td> <td>15 g</td> <td>β-Lactamase II</td> <td></td> </tr> </tbody> </table> <p>* Penicillinase = Penase = β-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)	5,0 g	NaCl	5 g	β -Lac I / Penase*		Agar	15 g	β -Lactamase II	
Casein peptone	15 g	Lecithin (L)	0,7 g														
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Irradiation	<ul style="list-style-type: none"> Gamma-irradiated at 9-20 kGy 																
Filling volume	<ul style="list-style-type: none"> 16-19 mL 																
Packaging	<ul style="list-style-type: none"> Triple bagged, staples of 10 plates Transparent High barrier foil for H₂O₂ as well as for water-vapor 10 staples of 10 plates per packaging unit Temperature isolated handle-bag in the cardboard-boxes 																
Units per pack	<ul style="list-style-type: none"> 100 plates 																
Shelf life	<ul style="list-style-type: none"> 8 months from production date 																
Storage	<ul style="list-style-type: none"> Recommended storage temperature: 15-25 °C Should be stored at temperatures as stable as possible 																
Label	<ul style="list-style-type: none"> On the side, at the bottom 																

Technical Data Sheet	
Label information	<ul style="list-style-type: none"> • Product name: TSA Lac I/II • Expiry date: YYYYMMDD → MMM in letters (e.g.: 2023Nov04) • Lot-number • Individual number • Barcode
Barcode	<ul style="list-style-type: none"> • 2-dimensional (data matrix), 20 digits: • Digits 1-3: Art.-No. • Digits 4-9: Lot-Number • Digits 10-14: Individual-Number • Digits 15-20: Date (YYMMDD)
Delivery	<ul style="list-style-type: none"> • Temperature controlled delivery on request • For shipments of larger amounts plastic pallets in Euro-size are used
Petri dish	<ul style="list-style-type: none"> • Incubations in vent and closed position possible • Specific design to improve binding of agar to plate • Easy handling due to increased handling area
Locking lid	<ul style="list-style-type: none"> • Locking-lid contact plate • Bottom part with 1 cm² square grid for facilitated evaluation
Lid positions	<ul style="list-style-type: none"> • All plates are delivered in the non-locked position • 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"> 1. Vent position 2. Closed position
Aerobic incubation	<ul style="list-style-type: none"> • Turn the lid clockwise to the right to the end into the final stop position • The lid locks in the closed position • Ideal incubation condition for aerobic micro-organisms • Limits the dehydration of the agar during incubation
Anaerobic incubation	<ul style="list-style-type: none"> • The vent position is ideal for anaerobic incubations, as it allows an easy and effective removal of oxygen under anaerobic incubation conditions • Incubate in anaerobic incubator, anaerobic jar or suitable equipment <ol style="list-style-type: none"> 1. First option: <ul style="list-style-type: none"> • Turn the lid clockwise to the right to the end into the final stop position • Turn the lid one click counter-clock-wise to the vent position 2. Second option: <ul style="list-style-type: none"> • Turn the lid clockwise directly into the first locked position
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1, 69181 Leimen - Germany

Quality control, Certificates		
Certificates	Each lot of product can be obtained with a certificate of analysis (CoA):	
	Physico-chemical test parameters:	
	Appearance	Slightly turbid, yellowish
	pH value	7,1 – 7,5
	Filling volume	16 – 19 mL
	Irradiation	9-20 kGy
	Growth Promotion test: 10-100 CFU	
	<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. aeruginosa</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%
	Test for β-lactamase Plus activity: 10.000-100.000 CFU	
<i>S. aureus</i>	ATCC 6538 30-35 °C 1 day No inhibition	
No inhibition by penicillin (10 IU)		
No inhibition by cefazolin (30 μ g)		
Sterility control		
	No growth	
Certificate of origin	<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"> • Raw material • Tissue • Animal source • Country of origin • Infectivity category (acc. to TSE guideline: EMA/410/01 rev. 3) 	
BSE policy	<ul style="list-style-type: none"> • 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). 	
Temperature stress	<ul style="list-style-type: none"> • 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 comprise all regular tests which are part of the normal release test of this article (see CoA). 	

Quality control, Certificates	
<p>Penase Synonyms are: Penicillinase or β-lactamase I</p>	<p>Penase is a commercially available enzyme inactivating Penicillins like benzylpenicillin (penicillin G), ampicillin, amoxycillin, carbenicillin, methicillin, cloxacillin and flucloxacillin.</p> <p>Synonyms for Penase are: Penicillinase or β-lactamase I.</p> <p>Although Penase is sometimes called β -lactamase I it has no activity against β-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 (=kU).</p> <p>International Unit (IU): 1 IU hydrolyses 1 μmole of benzyl penicillin per min. at 25°C, at pH 7.0 (1 μmole 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 have to be determined by every customer himself, as the production environments differ from customer to customer as well as the antibiotics produced.</p>
<p>β-lactamase II Synonyms are: Cephase Lactamator Carbamator LacBuster</p>	<p>β -lactamase II is a commercially available enzyme inactivating penicillins, cephalosporins and penems. It was originally extracted from <i>Bacillus cereus</i>.</p> <p>β -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 (=kU).</p> <p>International Unit (IU): 1 IU hydrolyses 1 μmole of cephalosporin per min. at 25 °C, at pH 7.0</p> <p>β -Lactamase II is added aseptically to the PMM medium</p> <p>The amount of enzyme required by customers have to be determined by every customer himself, as the production environments differ from customer to customer as well as the antibiotics produced.</p>

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