Art. 116.0100

TSA + LT + β-Lac I/II Contact CSG

	Technical Data Sheet
Use in	• Pharmaceutical industry in clean rooms and isolators • For industrial, laboratory & research applications only • Basic medium according to EP 2.6.12, 2.6.13 and USP <61>, <62>
Use for	• Detection of aerobic and anaerobic micro-organisms • Contact sampling, personnel monitoring, as well as active air monitoring • Isolation 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 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.
Typical composition per liter	Casein peptone 15 g; Soy peptone 5 g; NaCl 5 g; Agar 15 g; Lecithin (L) 0.7 g; Polysorbate 80 (T) 5 g; β-Lac I / Penase*; β-Lactamase II * Penicillinase = Penase = ß-Lactamase I This medium can be adjusted / or supplemented according to the performance criteria required.
Irradiation	• Irradiated at 9-20 kGy
Filling volume	• 16-19 mL
Packaging	• Triple bagged, staples of 10 plates • Transparent • High barrier foil for H_2O_2 as well as for water-vapor • 10 staples of 10 plates per packaging unit • Temperature isolated handle-bag in the cardboard-boxes
Plates per box	• 100 (10 staples with 10 plates each)
Shelf life	• 12 months from production date
Storage conditions	• Recommended storage temperature: 15-25 °C • Should be stored at temperatures as stable as possible • Store protected from light exposure • 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 • 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

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Label	• On the side, at the bottom
Label information	• Product name: TSA+LT+LacI/II • Expiry date: YYYYMMMDD ➔ MMM in letters (e.g.: 2023Nov04) • Lot-number • Individual number • Barcode
Barcode	• 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	• Temperature controlled delivery on request • For shipments of larger amounts plastic pallets in Euro-size are used
Petri dish	• Locking-lid plate, made from polystyrene • Inner diameter: ~ 56.5 mm, thus providing an area of ~25 cm^2 • Outer diameter: ~ 66 mm • Bottom part with 1 cm^2 square grid for facilitated evaluation • Incubations in vent and closed position possible • Specific design to improve binding of agar to plate • Easy handling due to increased handling area
Lid positions	• 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: 1. Vent position 2. Closed position
Aerobic incubation	• The closed position provides ideal incubation conditions for aerobic microorganisms and limits the dehydration of the agar during incubation • For long incubation of aerobic microorganisms, the closed position is recommended • To lock the lid in the closed position turn the lid clockwise into the final stop position
Anaerobic incubation	• 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 1. First option: • Turn the lid clockwise into the final stop position • Turn the lid one click counter-clock-wise to the vent position 2. Second option: • Turn the lid clockwise directly into the first locked position

	Technical Data Sheet
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				
S. aureus	ATCC 6538	30-35 °C	1 day	50-200%
E. coli	ATCC 8739	30-35 °C	1 day	50-200%
P. paraeruginosa	ATCC 9027	30-35 °C	1 day	50-200%
B. subtilis	ATCC 6633	30-35 °C	1 day	50-200%
C. albicans	ATCC 10231	20-25 °C	3-5 days	50-200%
A. brasiliensis	ATCC 16404	20-25 °C	3-5 days	50-200%
Test for β-lactamase Plus activity: 10,000 - 100,000 CFU				
S. aureus	ATCC 6538	30-35 °C	1 day	No inhibition
No inhibition by penicillin (10 IU)				
No inhibition by cefazolin (30 µg)				
Sterility control				No growth

Certificate of origin

All media lots produced by PMM can be obtained with a Certificate of Origin (CoO). All animal derived raw materials are specified as follows:

- Raw material
- Tissue
- Animal source
- Country of origin
- Infectivity category (acc. to TSE guideline: EMA/410/01 current version)

BSE policy

- 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).

	Quality control, Certificates
Temperature stress	• 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).
Penase **Synonyms are:** **Penicillinase or β-lactamase I**	Penase is a commercially available enzyme inactivating Penicillins like benzylpenicillin (penicillin G), ampicillin, amoxycillin, carbenicillin, methicillin, cloxacillin and flucloxacillin. Synonyms for Penase are: Penicillinase or β-lactamase I. Although Penase is sometimes called β -lactamase I it has no activity against β-lactam antibiotics of the class of cephalosporins and/or penems. Penase activity: Enzyme activities are typically specified in international Units (= IU) or international kilo Units (= IkU). 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) Alternative specifications used for Penase used as well: Levy Unit (= LU): 1 LU ~ 0,00167 IU ➔ 1 IU ~ 600 LU Pollock Unit (PU): Pollock Unit: 1 PU ~ 0,0133 IU ➔ 1 IU ~ 75 PU Penase is added aseptically to the PMM medium. 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.

	Quality control, Certificates
β-lactamase II **Synonyms are:** **Cephase** **Lactamator** **Carbamator** **LacBuster**	β-lactamase II is a commercially available enzyme inactivating penicillins, cephalosporins and penems. It was originally extracted from *Bacillus cereus*. β -Lactamases II are available meanwhile from different suppliers under different names, e.g., cephase, lactamator, carbamator etc. This enzyme differs between suppliers in respect to their origin, and their activity against different antibiotics The enzyme activities are typically specified in international Units (= IU) or international kilo Units (= IkU). International Unit (IU): 1 IU hydrolyses 1 µmole of cephalosporin per min. at 25 °C, at pH 7.0 β-Lactamase II is added aseptically to the PMM medium 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.

	Safety Data
Toxic ingredients	• None
Basic composition	• See typical composition
Solvent content	• None
Safety data sheet required	• Not mandatorily required