PharmaMedia Dr. Müller GmbH -
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TSA + LTHT CSG Contact Plate

Article N°: 100.0100

	CSG – Click & Safe – gamma
Use in	• Pharmaceutical Industry in clean rooms and isolators
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 molds • neutralization of residues of disinfectants (see pages 4 and 5)
Application	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
Typical composition per litre:	• Casein peptone 15g Lecithin (L) 0,7g • NaCl 5g Polysorbate 80 (T) 5,0g • Soy peptone 5g Histidine (H) 0,5g • Agar 15g Thiosulfate (T) 0,1g This medium can be adjusted / or supplemented according to the performance criteria required.
Irradiation	• gamma-irradiated at 9-20 kGray
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 Packaging unit	• 100 pieces

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Shelf-life	• 9 months from date of production
Storage	• Recommended storage temperature: 15-25°C • Can be stored at temperatures outside of the recommended storage temperature for periods up to 48 hours (e.g. down to 4°C or up to 35°C) without having an impact on growth promotion properties • should be stored at temperatures as stable as possible
Plate	• locking-lid plate, made from polystyrene • inner diameter: 56.5 mm, thus providing an area of 25cm^2 • outer diameter: 67.5 mm • bottom part with 1cm^2 square grid for facilitated evaluation
Filling volume	• 16-19 ml
Label	• on side of bottom
Label information	• Product name: TSA + LTHT • Expiry date: YYYYMMMDD ➔ MMM in letters (e.g.: 2018Apr03) • 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 recommended (on request) • for shipments of larger amounts plastic pallets in Euro-size are used
Remarks	• incubations in vent and closed position possible • specific design to improve binding of agar to plate • easy handling due to increased handling area
Place of production	PharmaMedia Dr. Müller GmbH Gustav-Throm-Str. 1 D-69181 Leimen

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Locking Lid	
Lid positions	• all plates are delivered in the **non-locked** position • the plate contains three locked positions. If turning the lid clockwise the locked positions are in the following order: 1. vent position 1 2. vent position 2 3. closed position • both vent positions are identical in respect to the aeration of the agar – however by having 2 identical positions it is unlikely that the lid can be opened accidentally
Aerobic incubation	• 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	• the vent position is ideal for anaerobic incubations, as it allows an easy and effective removal of oxygen under anaerobic incubation conditions • **First option:** • turn the lid clockwise to the right to the end into the final stop position • turn the lid one or two clicks counter-clock-wise to one of the two vent positions **Second option:** • turn the lid clockwise directly into the first locked position **Vent positions:** • the plate contains three locked positions: both vent positions are identical in respect to the aeration of the agar – however by having 2 identical positions it is unlikely that the lid can be opened accidentally

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QC-Test / 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 - 19ml			
irradiation	9-20 kGy			
Growth Promotion test: 10-100 cfu				
S. aureus	(ATCC 6538)	30-35°C	1d	50-200%
E. coli	(ATCC 8739)	30-35°C	1d	50-200%
P. aeruginosa	(ATCC 9027)	30-35°C	1d	50-200%
B. subtilis	(ATCC 6633)	30-35°C	1d	50-200%
C. albicans	(ATCC 10231)	20-25°C	3 - 5d	50-200%
A. brasiliensis	(ATCC 16404)	20-25°C	3 - 5d	50-200%
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 rev. 3)

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Neutralization of residues of disinfectants	The inactivation of residues of disinfectants is critical for the detection of viable and cultivable microorganisms in pharmaceutical production environments. For this purpose different neutralizer combinations are added to the medium used for environmental monitoring. Most commercially available media contain Lecithin, Tween 80, Histidine and Thiosulfate. However, other neutralizers like Saponin, Cysteine and Glycine may be used as well. The composition as well as the concentration of single components are crucial for an effective inactivation of the residuals of disinfectants and therefore for the effective detection of microorganisms. The addition of different neutralizing components and concentrations to media has to be evaluated thoroughly. Besides the inactivation of residues of disinfectants neutralizers may have an inhibiting effect on the growth of microorganisms if used in higher concentrations thus making the detection of certain microorganisms difficult to impossible. Today most media used for environmental monitoring are using at least Lecithin and Tween in more or less identical concentrations: 1. Lecithin: 0,7 g/L 2. Tween: 5 g/L Furthermore most media manufacturer add two additional neutralizers to the media, however here the concentrations differ: 3. Histidine: 0,5 to 1 g/L 4. Na-Thiosulfate: 0,05 to 0,5 g/L We have tested our plates with respect to the inactivation of disinfectants using the worst case approach by directly inoculating defined amounts of disinfectant on the agar plates. Typically 20µl, 50µl or 100µl of disinfectant was used. 100µl of disinfectant applied to a contact plate of about 25 cm² surface correspond to about 40ml of disinfectant used to disinfect an area of one square meter, a concentration typically used in the pharmaceutical industry. After a period of 15 to 20 min the test organisms were applied to the treated plates. Test organisms typically used were the more sensitive Gram positive microorganisms *B. subtilis* (ATCC 6633), *S. aureus* (ATCC 6538) and *Staph. epidermidis* (ATCC 14990) as well as *E. coli* (ATCC 8739), *P. aeruginosa* (ATCC 9027), *C. albicans* (ATCC10231 and *A. brasiliensis* (ATCC 16404).

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As reference, plates without disinfectant were inoculated with the test strains.

Specifications: for sufficient inactivation of disinfectants the amount of 50µl of a disinfectant applied to a contact plate must be inactivated, resulting in a recovery rate of more than 50%.

Results:
TSA plates w. LTHT (Art.-code 100.0100) were able to inactivate the following groups of disinfectant:

1. Alcohols (ethanol, propanol, iso-propanol)
2. Hydrogenperoxyde (Biocide C)
3. Peracetic acids (Incidin active2%, Perform sterile PAA)
4. Mg-peroxyphtalate (Dismozon 4%)
5. K-peroxymonosulfate (Perfom con. OXY 1%)
6. Aldehydes like Glutaraldehyd, Formaldehyde (Aldasan 4%)
7. Combinations of alcohol, hydrogenperoxyde and per-acetic acid (Actril)
8. Combinations of aldehydes and alocohols (Aerodesin 2000, Bacillol Plus)

However, **TSA plates w. LTHT** were only able to inactivate quite low concentrations of quaternary ammonium compounds, biguanides and benzylalkoniumchloride. As these components are normally used in higher concentrations in disinfectants, they do not degrade by themselves and they are not volatile, it is required to clean such surfaces after disinfection with sterile water or sterile alcohol. Whereas the cleaning/rinsing may work properly on flat surfaces it seems likely that on other surfaces residues may remain or eventually even may be concentrated.

Instead of such cleaning/rinsing step newly developed neutralizing contact plates could be used. This special neutralizing plate **TSA U+** inactivates even high amounts of quaternary ammonium compounds, biguanides and benzylalkoniumchlorides, without interfering with the growth of microorganisms.