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TSA U+ CSG Contact Plate

Article N°: 101.0100

	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 • **universal 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 • NaCl 5g • Soy peptone 5g • Agar 15g • Lecithin (L) 0.7g • Polysorbate 80 (T) 5g • Histidine (H) 0,5g • Neutralizer PLUS 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
Shelf-life	• 6 months from date of production

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Storage	• 15-25°C
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 U+ • 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 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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<table>
<tr><th colspan="2">QC-Test / Certificates</th></tr>
<tr><td>Certificates</td><td>
Each lot of product can be obtained with a certificate of analysis (CoA):
<table>
<tr><td colspan="5">Physico-chemical test parameters:</td></tr>
<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 - 19ml</td></tr>
<tr><td>irradiation</td><td colspan="4">9-20 kGy</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Growth Promotion test: 10-100 cfu</td></tr>
<tr><td>S. aureus</td><td>(ATCC 6538)</td><td>30-35°C</td><td>1d</td><td>50-200%</td></tr>
<tr><td>E. coli</td><td>(ATCC 8739)</td><td>30-35°C</td><td>1d</td><td>50-200%</td></tr>
<tr><td>P. aeruginosa</td><td>(ATCC 9027)</td><td>30-35°C</td><td>1d</td><td>50-200%</td></tr>
<tr><td>B. subtilis</td><td>(ATCC 6633)</td><td>30-35°C</td><td>1d</td><td>50-200%</td></tr>
<tr><td>C. albicans</td><td>(ATCC 10231)</td><td>20-25°C</td><td>3 - 5d</td><td>50-200%</td></tr>
<tr><td>A. brasiliensis</td><td>(ATCC 16404)</td><td>20-25°C</td><td>3 - 5d</td><td>50-200%</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">Neutralizer PLUS testing: 10-100 cfu, 20µl Biocide A per plate</td></tr>
<tr><td>B. subtilis</td><td>(ATCC 6633)</td><td>30-35°C</td><td>1d</td><td>50-200%</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="4">Sterility control</td><td>no growth</td></tr>
</table>
</td></tr>
<tr><td>Certificate of Origin</td><td>
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)

</td></tr>
</table>

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Neutralization of residues of disinfectants	The disinfection of surfaces is crucial for maintaining an adequate environment for the production of sterile pharmaceutical drugs. To guarantee the best possible success of the disinfection process many pharmaceutical companies do perform a regular rotation of the disinfectants used. Quite often at least one of the disinfectants used contains quaternary ammonium compounds, benzylalkonium compounds, biguanides or even a combination of these substances. The advantages of such disinfectants are the well proved bactericidal activity against microorganisms even if used in relatively low concentrations. However, the disadvantages are the residues which remain on treated surfaces, if not removed by a suitable cleaning step. The removal or inactivation of residues of disinfectants is critical for the reliable detection of viable and cultivable microorganisms. If highly active residues remain on surfaces, these will be picked up with contact plates or swabs when performing environmental monitoring tests. Then these residues can interfere with the growth of potential contaminants and this could finally result in false negative results. Whereas some residues of disinfectants can be neutralized with the standard neutralizers LTHT (Lecithin, Tween 80, Histidine and Thiosulfate – please see product description of art. 100.0100) especially the residues of quaternary ammonium compounds, benzylalkonium compounds as well as biguanides are not sufficiently inactivated by these neutralizers. To overcome this unsatisfactory inactivation of these residues media manufacturer have tried to develop special neutralizer media. However most of the media offered so far had different drawbacks: turbidity, precipitation, short shelf-life, low recovery rates on Gram positive strains and quite high price - and due to these disadvantages such media have not been really accepted. PMM now offers a newly designed plate without showing these drawbacks. **TSA U+ plates** look-like a regular TSA plate and are free of precipitation throughout the shelf-life of more than 6 months. However, the outstanding inactivation of all typically used disinfectants including even high concentrations of quaternary ammonium compounds, benzylalkonium compounds and biguanides really is the big step forward in obtaining reliable results for the environmental monitoring.

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TSA U+ plates were tested 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).

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: Beside the disinfectants inactivated already by our standard plate (see product description of art. 100.0100) **TSA U+ plates** are as well inactivating quite high concentrations of quaternary ammonium compounds, biguanides and benzylalkoniumchlorides. Disinfectants tested were Amphospray 41 IP, Gigasept AF (4%), Hexanios G+R, Hexaquart forte (2%), Incidin plus (2%), Biocide A, Biocide B, Lysoformin 3000 (2%), Melsept SF (2%), Microbac forte (2%) and Terralin protect (2%).

Results obtained with the above listed disinfectants show recovery rates of more than 70% if 20 or 50µl of the disinfectant was applied directly on TSA U+ plates. Even when applying 100µl most recovery rates were above 70%, only few recovery rates dropped to values between 30 to 50%. In comparison to these results standard TSA plates with neutralizers did not show any or very low recovery rates even if only 20µl of these disinfectants were applied. As a conclusion **TSA U+ plates** can be considered as the universal media for performing environmental monitoring, delivering reliable results independent from the disinfectant used.