Reference: 271114TI **Technical Data Sheet**

Product: **TSA Contact blister TLHTh triple wrap**

Specification

General purpose solid medium containing animal and plant peptone and neutralisers according to Pharmacopoeial Harmonised Method and ISO Standards, for enumeration of total aerobics in surfaces.

Presentation

	Packaging Details	Shelf Life	Storage
24 Contact Plates/Ird. Contact Plates - Triple Wrapping with: 15 ± 2 ml	1 box with 4 blisters (PET laminated and PPBO bag) with 6 contact plates/blister. Every pack exhibits an irradiation indicator (8-14kGy).	7 months	2-25 ºC

Composition

Composition (g/l):

Peptone from casein	15.0
Soya peptone	5.00
Sodium chloride	5.00
Tween 80	5.00
Lecithine	0.70
Histidin	1.00
Sodium thiosulfate	0.50
Agar	15.0

Description /Technique

Description

TSA is a widely used medium containing two peptones which support the growth of a wide variety of organisms, even that of very fastidious ones such as Neisseria, Listeria, Brucella, etc. It is frequently used for routine diagnostic purposes due to its reliability and its easily reproducible results.
Classical media for microbiological examination of non-sterile products according to Pharmacopeial Harmonised Methods.
The addition of he neutralizing agents TLHTh (Tween 80 - Lecithin - Histidine - Sodium Thiosulphate) may inactivate a variety of disinfectants.
* The combination of lecithin, polysorbate 80 and histidine neutralizes aldehydes and phenolic compounds.
* The combination of lecithin and polysorbate 80 neutralizes the quaternary ammonium compounds.
* The polysorbate 80 neutralizes hexachlorophene and mercurial derivates.
* Sodium thiosulphate neutralizers halogen compounds.
* Lecithin neutralizes clorhexidine.
* Histidine neutralizes formaldehyde.

Technique

Contact plates are used in the microbiological control of disinfection and cleaning of surfaces. It acts simultaneously as a sampler and incubation culture medium without the need for any other intermediate steps.
The plates come in a form appropriate for this function and can be used with different culture media depending on the type of microbe that needs to be controlled. On average the plates provide a contact surface of approximately 25 cm2.
To use, remove the cover and gently press the culture medium on the surface to be controlled, ensuring contact between the two surfaces. The Contact plate is removed and covered with the lid to prevent air contamination. It is advisable that the lid is secured with adhesive tape and the bottom labelled with the sampling data (place, date and time).
If the sample surfaces are rough, the contact plates will not make good contact, even when the pressure is increased. In these cases it is advisable to delineate an sample surface area of 25 cm squared and rub this area vigorously with a wet sterile swab and then rub the swab over the Contact plate.
If verifying the effectiveness of a cleaning or disinfection process, contact plates should be used within two hours after the end of the process, ensuring that the sample surface is dry. It is advisable to always include positive controls, sampling the area before disinfection or dirty areas beside the disinfected area.
The technician will determine the frequency of sampling and disinfection according to performance criteria. Apply the agar directly onto surface to be monitored ensuring that the pressure is distributed over the whole plate for 10 seconds. Clean the surface where the sample was collected in order to remove any traces of agar.
The inoculated plates are incubated at 30-35 º C for 24-72 h (bacteria) and 3-5 days for fungi (yeast & molds). Examined daily.

Note: Contact plates are used for monitoring the microbiological contamination of surface and air inside cleanrooms, isolators, RABS, food industries and hospitals. The double/triple irradiated wrapping ensures that the package itself doesn't contaminate the environment as the first wrapper is removed just before entering the clean area.

The plates must be kept in their original packaging (blisters) to guarantee their stability at the end of their expiration date.

Quality control

Physical/Chemical control

Color : Straw-coloured yellow pH: 7.3 ± 0.2 at 25ºC

Microbiological control

Growth Promotion Test 50-100 CFU according to harmonized Pharmacopoeia monographs (EP) and test methods & ISO 11133:2014/A1:2018
Analytical methodology according to ISO 11133:2014/A1:2018; A2:2020.

Aerobiosis. Incubation at 30-35-37 ºC. Read after 18-24 h to 72 h for bacteria and 3-5 days for fungi.

Microorganism	Growth
Escherichia coli ATCC® 8739, WDCM 00012	Good (≥70%)
Staphylococcus aureus ATCC® 6538, WDCM 00032	Good (≥70%)
Bacillus subtilis ATCC® 6633, WDCM 00003	Good (≥70%)
Candida albicans ATCC® 10231, WDCM 00054	Good (≥70%)
Ps. aeruginosa ATCC® 9027, WDCM 00026	Good (≥70%)
Salmonella typhimurium ATCC® 14028, WDCM 00031	Good (≥70%)
Aspergillus brasiliensis ATCC® 16404, WDCM 00053	Good (≥70%)
L. monocytogenes ATCC® 13932, WDCM 00021	Good (≥70%)
Bacillus cereus ATCC® 11778, WDCM 00001	Good (≥70%)
Enterococcus faecalis ATCC® 29212, WDCM 00087	Good (≥70%)
Clostridium perfringens ATCC® 13124, WDCM 00007, NCTC® 8237	Good (≥70%)
Clostridium sporogenes ATCC® 19404, WDCM 00008	Good (≥70%)
Stph. aureus ATCC® 25923, WDCM 00034	Good (≥70%)
Escherichia coli ATCC® 11775, WDCM 00090	Good (≥70%)

Sterility Control

Incubation 48 h at 30-35 ºC and 48 h at 20-25 ºC: NO GROWTH.
Check at 7 days after incubation in same conditions.

Bibliography

· ATLAS, R.M. & L.C. PARKS (1993) Handbook of Microbiological Media. CRC Press, Inc. London.
· COLIPA (1997) Guidelines on Microbial Quality Management (MQM). Brussels.
· DOWNES, F.P. & K. ITO (2001) Compendium of Methods for the Microbiological Examination of Food, 4th ed, ASM, Washington D.C.
· EUROPEAN PHARMACOPOEIA 11.0 (2023) 11th ed. § 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. EDQM. Council of Europe. Strasbourg.
· FDA (Food and Drug Adminstrations) (1998) Bacteriological Analytical Manual. 8th ed. Revision A. AOAC International. Gaithersburg. MD.
· HORWITZ, W. (2000) Official Methods of Analysis of AOAC INTERNATIONAL, 17th ed. Gaithersburg, MD. USA.
. ISO 11133:2014/ Adm 1:2018. Microbiology of food, animal feed and water. Preparation, production, storage and performance testing of culture media.
. ISO 4973:2023. Quality control of culture media and diluents used in cosmetics standards.
· ISO 18415 Standard (2017) Cosmetics - Microbiology - Detection of specified and non-specified microorganisms.
· ISO 21149 Standard (2017) Cosmetics - Microbiology - Enumeration and detection of aerobic mesophilic bacteria.
· ISO 21150 Standard (2015) Cosmetics - Microbiology - Detection of Escherichia coli.
· ISO 22717 Standard (2015) Cosmetics - Microbiology - Detection of Pseudomonas aeuruginosa.
· ISO 22718 Standard (2015) . Cosmetics - Microbiology - Detection of Staphylococcus aureus.
· ISO 22964 (2017) Microbiology of the food chain.- Horizontal method for the detection of *Cronobacter spp*
· PASCUAL ANDERSON, MªRª (1992) Microbiología Alimentaria. Díaz de Santos S.A., Madrid.
· USP 31 - NF 26 (2008) <61> Microbial Limit Tests. US Phamacopoeial Conv. Inc. Rockville. MD. USA
· USP 33 - NF 28 (2011)<62>Microbiological examination of non-sterile products: Test for specified microorganisms. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.
· USP 33 - NF 28 (2011) <71> Sterility Tests. Harmonised Method. USP Corp. Inc. Rockville. MD. USA.