



Pylon Healthcare
3rd Industrial zone, 6th of October, Giza
Phone +20 122 555 6925
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Quality Assessment data sheet

Pylon Healthcare Egypt for manufacture of
laboratory reagents
&
Disinfectants

- CO2 incubators, laminar flow hoods, glass, plastic, metals, equipment and ultra-sound probes.
- Non - toxic, odourless, colourless and VOC free.
- Rapid action against a wide range of Bacteria, Fungi & Encapsulated viruses
- 4th Generation Quaternary Ammonium Compounds

- صنع خصيصا لحاضنات ثاني أكسيد الكربون حيث يحافظ علي الحساسات الموجودة بها من التاكل و تشمل حاضنات معامل الأجنة و الخلايا و الأنسجة الدقيقة وأماكن التدفق السطحي والزجاج والبلاستيك والمعادن والمعدات و اجهزة السونار.
- غير ضار اوسام للخلايا.
- عديم الرائحة ، عديم اللون وخالي من المركبات العضوية المتطايرة.
- مفعول سريع ضد مجموعة واسعة من البكتيريا والفطريات والفيروسات المغلفة.
- المواد الفعالة مركبات الأمونيوم من الجيل الرابع

فعالية ضد الجراثيم الأتية

1-Bacteria:	2 - Fungi:	3 - Viruses:
<ul style="list-style-type: none">• Staphylococcus aureus.• Pseudomonas aeruginosa• Escherichia coli.• Enterococcus hirae.• Mycobacterium phlei (TbB).• Salmonella typhimurium.<ul style="list-style-type: none">• MRSA - Bacteria (Methicillin resistant Staphylococcus aureus).	<ul style="list-style-type: none">• Aspergillus niger.• Candida albicans.• Trichophyton mentagrophytes.	<p>Hepatitis A, B & C HIV (AIDS-Virus). Rotavirus. Norovirus(calicivirus).</p> <p>Influenza A -virus (H5N1-Bird flu). Influenza A -virus (H1N1-swine flu).</p> <p>SARS, SARS-COV2 (COVID-19) & MERS COV.</p> <p>Adenovirus (DNA-virus group).</p> <p>Polio virus group.</p> <p>Herpes virus group.</p>

Certificate Of Mouse Embryo Assay (MEA)
For B – Safe Disinfectant

Principle:

Measuring the effect of B – Safe disinfectant on mouse embryos regarding viability and blastocyst formation

Assay procedures:

- Test: We cultured randomly fresh collected zygotes of B6CBAF1 mouse (Table 1) in culture media in presence of B – Safe disinfectant in a petri dish (Falcon 3004) at 37 °C in Thermo incubator during full cultivation time (120 hours).
- Control: We cultured the same number of randomly fresh collected zygotes of B6CBAF1 mouse (Table 1) in culture media in absence of B – Safe disinfectant at 37 °C in Thermo incubator.

Results:

Table (1):

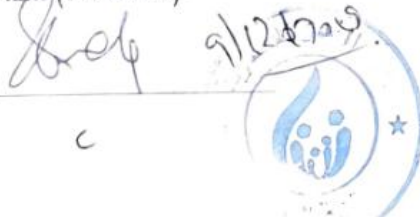
Items	Injected oocytes (D ₃)	Cleaved embryos (D ₃)	Blastocyst (D ₄)	Blastocyst Percentage (%)
Test	11	9	9	≥ 80 %
Control	11	9	9	≥ 80 %

Observation:

- Test: ≥ 80 % of tested mouse embryos cultured in an incubator in presence B – Safe disinfectant were developed to expanded blastocyst stage within 120 hours.
- Control: ≥ 80 % of control mouse embryos were developed to expanded blastocyst stage within 120 hours.

Conclusion: B – Safe disinfectant has no effect on mouse embryo viability and blastocyst formation during full cultivation time (120 hours).

Signature



اختبار أجنة علي أجنة فنان تم بمستشفيات و مراكز الندي – المطهر مر بتطهير حضانات عدة و حقق تغطية فوق 30 الف جنين
بسلامة 100%

Faculty of Medicine
Microbiology Diagnostics &
Infection Control Unit (MDICU)
Medical Microbiology &
Immunology Dept.



DISINFECTION EFFICIENCY REPORT (Bsafe)

Lot No. : not available

Concentration reported by the manufacturer : the same concentration in the bottles (as it is)

Methodology briefing:

Bacterial suspension from different resistant hospital strains were mixed with the given concentration of detergent and left for different contact times (5, 10, 15, 20 minutes) then cultured .

1- CARRIER TEST:

Test strains	Concentration and Duration of exposure	
	10 min	15 min
<i>Staphylococcus aureus</i>	No Growth	No Growth
<i>Pseudomonas aureuginosa</i>	No Growth	No Growth
<i>Klebsiella species</i>	No Growth	No Growth
<i>E. coli</i>	No Growth	No Growth
<i>Candida</i>	No Growth	No Growth

Reference value : Efficient if no growth .

2- SUSPENTION TEST :

Test strains	Microbicidal effect at given concentration and duration of exposure	
	10 min	15 min
<i>Staphylococcus aureus</i>	5	5
<i>Pseudomonas aureuginosa</i>	5	5
<i>Klebsiella species</i>	5	5
<i>E. coli</i>	5	5
<i>Candida</i>	5	5

Test bottle for 10, 15, min is efficient with all reference organisms

- Microbicidal effect ≥ 5 → 99.99% efficiency.
- Microbicidal effect = 2 → 92% efficiency.
- Microbicidal effect = 1 → 90% efficiency.

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CAPACITY TEST:

Test strains	Number of loads without growth at given concentration	
	10 min	15 min
<i>Staphylococcus aureus</i>	5	5
<i>Pseudomonas aureuginosa</i>	5	5
<i>Klebsiella species</i>	5	5
<i>E. coli</i>	5	5
<i>Candida</i>	5	5

Phenol 5 % for (10 min) is efficient with all reference organisms (number of loads = 2-3).

- Efficient if number of loads ≥ 2 .
- Inefficient number of loads = 1.

Recommendations:

The tested disinfectant is efficient against all tested strains at the given concentration, so it is recommended to be used as disinfectant at this concentration.

Director of the unit





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DECLARATION OF CONFORMITY

The company declares in accordance with their own responsibility that

The biocidal product: B-Safe as disinfectant for surface and objects

Meets with the essential requirements of IVD Medical Device Directive 93/42/EEC

Pylon Healthcare certifies that the above mentioned product meets the **EN ISO 13485** requirements.

Ministry of Industry, Trade and Small Industries
(Industrial Development Authority) In Egypt

R\N:2020/500294

Product Reg. No: 3402900000

Swiss Federal Office of Public
Health division for chemical products

does not require to be classified

Active ingredients: Quaternary ammonium compounds 4th generation

Application: Cleaning and Disinfecting laboratory surfaces and incubators.

Product codes: BSINS01PHC-BSINS02PHC-BSINb01PHC-BSINC01PHC-BSHW01PHC

Classification: Classification of the substance or mixture according to EU regulation (EC) No. 1272 / 2008 Not Classified

Metabolites: no known metabolites following the degradation.

Fire Hazard: no fire hazard