CERTIFICATE OF QUALITY / CERTIFICAT DE QUALITÉ / CERTIFICADO DE CALIDAD

Product Name: Sanicult™ Sterile Diluent Solution

Nom du produit: Solution diluante stérile Sanicult[MC]

Nombre del producto: Solución diluente esterilizada Sanicult[MF]

ProductCode / Code du produit / Código del producto:

B30U-S/B30U-S5 /B30U-S1

Lot Number / Lot numéro / Número de lote:

Representative samples were tested according to Starplex Scientific Inc. Quality Control specifications and were found to meet the following criteria for this product:

QUALITY CONTROL:

Appearance:	Clear, yellowish liquid, no precipitate
pH @ 25°C:	7.1 +/- 0.3
Sterility:	This product has been terminally sterilized by irradiation exposure and validated to achieve Sterility Assurance Level of 10^{-6}.
Performance:	Microbial growth observed after 48 hours refrigerated storage for Escherichia coli (ATCC 11229) and Staphylococcus aureus (ATCC 6538).

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Des échantillons représentatifs ont été évalués selon les spécifications de contrôle de la qualité de Starplex Scientific Inc. et se sont avérés conformes aux critères de ce produit qui sont comme suit:

CONTRÔLE DE LA QUALITÉ :

Apparence:	Liquide clair jaunâtre, sans précipité
pH @ 25°C:	7,1 +/- 0,3
Stérilité:	Ce produit a été stérilisé après conditionnement par irradiation, et validé pour atteindre un niveau garanti de sterilisation de 10^{-6}.
Rendement:	prolifération microbienne d'Escherichia coli (ATCC 11229) et de Staphylococcus aureus (ATCC 6538) observée après 48 h d'entreposage frigorifique.

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Las muestras representativas se sometieron a pruebas según las especificaciones de control de calidad de Starplex Scientific Inc., y se determinó que cumplen los siguientes criterios establecidos para este producto:

CONTROL DE CALIDAD:

Apariencia:	Líquido transparente, ligeramente amarillo, sin precipitados
pH a 25°C:	7.1 +/- 0.3
Esterilidad:	Este producto ha sido esterilizado una vez envasado mediante exposición a la radiación y ha sido probado para lograr el nivel garantizado de esterilidad de 10^{-6}.
Desempeño:	Se observó crecimiento microbiano de Escherichia coli (ATCC 11229) y de Staphylococcus aureus (ATCC 6538) tras un almacenaje a baja temperatura por 48 horas.

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Certificate results were obtained at time of release. End users are encouraged to assure product meets internal standards at time of use.

Les résultats qui figurent sur ce certificat sont obtenus au moment de l'évaluation. Nous recommandons aux consommateurs de s'assurer que le produit répond aux normes internes avant de l'utiliser.

Los resultados del certificado se obtuvieron al momento de la emisión. Se recomienda que, al momento de usar el producto, los usuarios finales verifiquen que este cumpla con las normas internas

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Starplex Scientific Inc. Quality Control Department

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Item No. 2176 Rev.09/2011

SANICULT™

INTENDED USE

Sanicult™ is a gamma sterilized, ready to use buffered solution for sampling a variety of environmental surfaces, viscous liquids, semi-solids and powders.

SUMMARY AND EXPLANATION

Environmental surface samples are taken to obtain a microbiological profile. A program to control microorganism levels is essential to minimize the bioburden and to evaluate the effectiveness of cleaning and disinfectant procedures. Many governing bodies have established guidelines for environmental and personnel surface monitoring.

Sanicult™ is ideal for sampling hard-to-reach surfaces, viscous liquids, semisolids, and powders. Each test kit is gamma sterilized and individually wrapped. The kit features a screw cap sampling vial containing sterile diluent and a swab affixed to the cap. Two sterile formats containing approximately 5ml or 10ml of buffered solution are available. Sanicult™ may be used for qualitative or quantitative procedures.

SANICULT™

REF	Description	Unit/Case
B30U-S1	Sanicult™ 1 ml	100
B30U-S5	Sanicult™ 5 ml	100
B30U-S	Sanicult™ 10 ml	100

PRINCIPLES OF THE PROCEDURE

The polypropylene tube is filled with sterile buffer solution, with a polyester swab affixed to the cap. The presence of sterile peptone water provides minimal nutritional value to recover injured microorganisms. Lecithin inactivates the germicidal effect of quaternary ammonium compounds.[1] Polysorbate 80 neutralizes the effect of phenolic disinfectants.[2] Each tube is individually wrapped and gamma sterilized which provides a Sterility Assurance Level of 10^{-6}.

The collected sample can be tested according to standard microbiological procedures including, but not limited to direct plate methods, membrane filtration, or rapid testing protocols.

MEDIUM FORMULATION

The approximate formulation is as follows:

Buffered Peptone Water	= 20.0 g/L
Lecithin	= 0.7 g/L
Polysorbate 80	= 5.0 g/L

PRECAUTIONS

1. Sterility of unit assured only in unopened, intact, sealed pouches.
2. Check expiration date before use.
3. Autoclave all collection materials before discarding.
4. Not intended for in vitro diagnostic use.

STORAGE

Optimum storage temperature range is 4°C to 25°C (40°F to 77°F).

SPECIMEN COLLECTION AND PROCEDURE

Swabbing methods and procedures may vary by laboratory. The following procedure is one example. Each individual laboratory may follow their own established and validated sampling and testing procedures. Technicians should be trained in laboratory safety and aseptic techniques.

1. Open pouch and remove tube.
2. Remove cap/swab assembly using aseptic technique.
3. Excess liquid should be squeezed off the swab tip by carefully pressing against the interior wall of the tube.
4. Holding the swab handle, rub the swab slowly and thoroughly over the surface. A pre-established template may be used for quantitative procedures.
5. Insert swab into buffered solution, tighten cap and mix well.
6. Transport to laboratory for testing.

SPECIMEN TRANSPORTATION

Transport sample to laboratory as soon as possible. Avoid extreme temperature during transportation. If sample cannot be processed within 2-4 hours, the sample should be stored at refrigerated temperatures of (2°-8°C). Sample may be shipped or transported on ice for up to 24 hours.

QUALITY CONTROL

Performance	Result
Escherichia coli ATCC® 11229	Viable
Staphylococcus aureus ATCC® 6538	Viable

Sterility Processing

This product has been terminally sterilized by irradiation exposure and validated to achieve Sterility Assurance Level of 10^{-6}.

LIMITATIONS

Sanicult is intended for collection and transportation of samples obtained from a variety of environmental surfaces. Use of Sanicult for other purposes must be verified. Organism recovery may be affected by transportation time, temperature, microbial type, and bioburden.

REFERENCES

1. Quisno, R., I. W. Gibby, and M. J. Foster. 1946. A neutralizing medium for evaluating the germicidal potency of the quaternary ammonium salts. Am. J. Pharm. 118:320.
2. Erlandson, A. L., Jr., and C.A. Lawrence. 1953. Inactivating medium for hexachlorophene (G-11) types of compounds and some substituted phenolic disinfectants. Science. 118:274-276.
3. USP<116>, Microbiological Evaluation of Clean Rooms and Other Controlled Environments. United States Pharmacopoeia, 2003. United States Pharmacopoeia Convention Inc., Rockville, MD.
4. Starplex Scientific Inc. Internal Evaluation