EMswab™ - Saline with 0.07% Soya Lecithin and 0.5% Polysorbate 80 I

Intended Use
Ready to use sterile (Gamma-Irradiated) ICR Cotton swab with Saline with 0.07% Soya Lecithin and 0.5% Polysorbate 80 filled in polystyrene tubes, used as rinse solution for surface, equipment sampling in clean rooms and isolators.

Summary
Environmental and surface monitoring forms a key aspect in controlling the environment of clean rooms and isolators. Generally, for surface monitoring contact plates are used, however when surfaces are uneven and for equipment surface, swabbing is employed.

Principle
Sterile EMswab™ Saline with 0.07% Soya Lecithin and 0.5% Polysorbate 80, constitutes swab made of Cotton with a polypropylene applicator. The rinse solution is an isotonic solution to maintain organism viability whereas neutralizer neutralizes traces of disinfectants if present during swabbing of surface. Triple wrapped product subjected to adequate dose of Gamma irradiation ensures the contents are sterile. Triple wrapped product helps to aseptically transfer the product in cleanroom.

Formula*

Ingredients	g/L
Sodium Chloride	9.0
Lecithin	0.07
Polysorbate 80	0.5

Storage and Stability
Store the product at 15°C-25°C. Use before expiry date on label.

Type of Specimen
Bacterial samples for culture may be used, but the survival of bacteria depends on type of bacteria, concentration and transport time.

Specimen Collection and Handling
Follow appropriate techniques for handling specimens as per established guidelines.

Directions
Materials provided: EMswab™ sterile Saline with 0.07% Soya Lecithin and 0.5% Polysorbate 80 with Cotton swab.
Materials required but not provided are culture media, reagents, quality control organisms and laboratory equipment.
1. Determine the surface/surfaces to be sampled.
2. Follow appropriate aseptic technique and open the outer pouch.
3. Once opened, the outer pouch should be used to maintain sterility of inner pouch and its components.
4. Unscrew and squeeze the tip of the swab against inner surface of the tube to remove excess solution.
5. Holding the cap, ensure that the premoistened swab is placed at an appropriate angle on the surface to be sampled.
6. The swab should be stroked in close parallel sweeps over the defined sample area.
7. After slowly rotating, sampling of the same area should be repeated, stroking the same swab perpendicular to the initial sweep.
8. The swab should then be placed back to the solution.
9. Immediately tighten the cap and vortex the tube to release bacteria from the swab.
10. After sampling the sample site surface should be cleaned to remove any residue.
11. The representative sample should be tested within two hours if stored at 15°C-25°C. If stored, the sample may be refrigerated at 2°C-8°C for 24 hours and then tested.

Quality Control

Appearance: Clear, colourless solution in tubes with Cotton swab.
Cultural Response: Cultural characteristics observed after recovery on Accumix® Soyabean Casein Digest Agar (201190200500), (incubated at 30 °C - 35°C for 18-24 hours) for bacteria and on Accumix® Sabouraud Dextrose Agar (201190030100) (at 20 °C - 25 °C for 48 - 72 hours) for fungal growth.

Organisms (ATCC)	% Survival after 24 hours (Stored at 2°-8°C)
Escherichia coli (8739)	≥100 %
Staphylococcus aureus subsp. *aureus* (6538)	≥100 %
Pseudomonas aeruginosa (9027)	≥100 %
Bacillus spizizenii (6633)	≥100 %
Candida albicans 3147 (10231)	≥100 %
Aspergillus brasiliensis WLRI 034(120) (16404)	≥100 %

Note: Inoculum cfu is 100-1000

Limitations

1. This product is intended only for sampling and transport of specimen collected from surface and equipments.
2. Subculture of specimens on primary isolation medium is required for identification of recovered organisms.

Warranty

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

Reference

1. Cleanrooms and associated controlled environments. Biocontamination control – Part 1: General Principles and Methods, ISO 14698-1:2003(E).
2. WHO, Environmental Monitoring of Clean Rooms in Vaccine manufacturing facility.
3. Evaluation of the Recovery Rate of Different Swabs for Microbial Environmental Monitoring, PDA Journal, Vol.71, No.1, January- February 2017, Pg No. 33-41, Marcel Goverde, Julian Willrodt, Alexandra Staerk.
4. Releasing capacity of pre-sterile cotton swabs for discharging sampled microorganisms, European Journal of Parenteral and Pharmaceutical Sciences 2016, 21 (4): 121-127. Ravi Krishna Satyada and Tim Sandle.
5. Microbiological Culture Media, A Complete Guide for Pharmaceutical and Health Care Manufacturers. Tim Sandle, PDA, DHI Publishing, LLC. River Grove,IL,USA.
6. A Study of a new type of swab for the environmental monitoring of isolators and cleanroom. European Journal of Parenteral and Pharmaceutical Sciences 2011:16 (2): Tim Sandle.
7. United States Pharmacopoeia 38 NF 31 (2015): <71> Sterility Tests; <1116> Microbiological Control and Monitoring of Aseptic Processing Environments.
8. Data on file: Microxpress®, A Division of Tulip Diagnostics (P) Ltd.

Product Presentation:

Cat No.	Product description	Pack Size
203050720050	Ready Prepared Saline with 0.07% Soya Lecithin and 0.5% Polysorbate 80 I	50 Tests (50 x 2 mL)