

GENERAL DESCRIPTION

A Spordex™ Spore Suspension NA091/NA030 consists of a vial containing a certified population of bacterial spores in an aqueous solution. Spordex Suspensions for steam contain a single spore species (*Geobacillus stearothermophilus*, ATCC 7953). Spordex Suspensions are available in concentrations of E6 and E7 per 0.1 mL. The Spordex spore suspensions for steam are produced to meet suggested performance parameters published in the current U.S. Pharmacopeia (USP).

APPLICATION

The Spordex Suspensions for steam are used to validate and re-qualify steam sterilizers and to monitor the effectiveness of common steam sterilizing processes.

The Spordex Suspensions may be used for the following applications:

- To directly inoculate the product to determine the worst-case location in a device that does not accommodate a spore strip or spore disc.
- To directly inoculate the product in the places least accessible to the sterilization agent.
- To manufacture biological indicators utilizing carriers simulating the product being sterilized.

FEATURES

Single species *Geobacillus stearothermophilus* population available of E6 and E7 per 0.1 mL
Lot number, organism name, and expiration on each vial
Certification card in each package
Kit includes 1.0-mL sterile syringe
Dispensed via inoculation

BENEFITS

Flexibility of use with various sterility verification level requirements
Traceable results and valuable documentation
Certification of product integrity
Convenience of use
Can be used to inoculate small carriers, liquids, and locations which cannot accommodate strips or discs

TECHNICAL PROPERTIES

Species: *Geobacillus stearothermophilus* (ATCC 7953)

Suspension: Bacterial spores in water, 10 mL per vial

Population ranges available: E6 and E7 CFU (colony forming units)/0.1 mL

D-value for saturated steam (D_{121}): 1.5-2.5 minutes

– D_{121} is determined by MPN utilizing a $121 \pm 0.5^\circ\text{C}$ exposure temperature.

* NOTE: The labeled D-value is reproducible only under the exact conditions under which it was determined. The user may not necessarily obtain the same result, especially when a different spore carrier is utilized. If the primary packaging, filter paper substrate, recovery culture media, D-value method, and BIER Vessel specifications are not the same as those used during the factory D-value testing, it is unlikely the user D-value test results will closely correspond to the labeled D-value.

Incubation temperature: 55-60°C (131-140°F)

Shelf life: 18 months from time of manufacture. The expiration date is printed on the vial and certification card that accompanies the Spordex Suspensions.

Quantity: 10 mL per vial

DIRECTIONS FOR USE

Select a sample product (or simulated product) for the test. The inoculation of the sample should be performed in a clean area, preferably a laminar-flow clean bench. Do not inoculate the sample in the same area selected for sterility testing.

Follow the procedure on the instruction card enclosed in the Spordex Suspension box to withdraw 1.0 mL of the suspension from the vial. Using the dispenser with needle contained in the Spordex Suspension box, deposit the suspension (0.1 mL) on 10 product (or simulated product) samples. Return the remaining spore suspension to the refrigerator. Place the inoculated samples in an area at a temperature of 21-24°C (70-75°F), protected from extraneous contamination until the inoculum dries. Sterilize the inoculated product (or simulated product) according to your regularly established procedures. Transfer the test samples to a clean place near the area where sterility testing is performed. Test the inoculated samples for sterility using the appropriate procedures specified in the United States Pharmacopeia. Incubate at 55-60°C (131-140°F) for seven days. Examine the culture media during the incubation period for the evidence of microbiological growth: turbidity, cloudiness, sedimentation, or pellicle formation.

See the instruction card enclosed in the Spordex Suspension box for detailed use directions.

STORAGE CONDITIONS

Store refrigerated between 2-8°C (36-46°F). Do not freeze. Avoid contact with, or storage near, sterilants or chemicals; e.g., any oxidizing or reducing agents such as formaldehyde, bleach, ammonia, etc. Do not use after the expiration date printed on the packaging.

DISPOSAL

Before discarding, treat as appropriate for standard microbiological waste, nonpathogenic species; e.g., steam autoclave at 121°C (250°F) for not less than 30 minutes, incinerate, or use other suitable means.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

ORDERING INFORMATION

Population of <i>Geobacillus stearothermophilus</i>	Quantity Per Vial	Reorder Number
Spordex Suspension E7 per 0.1 mL	10 mL	NA091
Spordex Suspension E6 per 0.1 mL	10 mL	NA030

For further information, please contact:



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