STERIS®

SPORDEX® – BACTERIAL SPORE SUSPENSIONS FOR ETHYLENE OXIDE AND DRY HEAT TECHNICAL DATA

GENERAL DESCRIPTION

The Spordex Suspension contains a certified population of bacterial spores suspended in an aqueous solution. For ethylene oxide and dry heat, the suspension contains a single spore species of *Bacillus atrophaeus,* NRRL#B4418. Spordex Suspensions are available in concentrations ranging from E3 to E9 per 0.1 mL. The Spordex spore suspensions for ethylene oxide are tested to meet ISO 11138-1.

APPLICATION

The Spordex Suspensions for ethylene oxide and dry heat are used to validate and re-qualify ethylene oxide gas or dry heat sterilizers and to monitor the effectiveness of common ethylene oxide gas or dry heat 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	BENEFITS
Single specie *Bacillus atrophaeus* populations available ranging from E3 to E9	Flexibility of use with various sterility verification level requirements
Lot number, organism name and expiration on each vial	Traceable results and valuable documentation
Certification card in each package	Certification of product integrity
Kit includes 1-mL sterile syringe	Convenience of use
Dispensed via inoculation	Can be used to inoculate small carriers, liquids, and locations which cannot accommodate strips or disks

TECHNICAL PROPERTIES

Species: *Bacillus atrophaeus,* NRRL#B4418

Suspension: Bacterial spores in water, 10 mL per vial

Population ranges available: E3 cfu per 0.1 mL to E9 cfu per 0.1 mL

D-value for ethylene oxide (D_{EO})*: 2.6-4.5 minutes

D_{EO} is determined with a 600±30 mg/L ethylene oxide concentration, 54±1°C and 50-70% R.H. The spore suspensions are tested at E4, E5 or E6 populations on a filter paper strip and enclosed in a glassine envelope.

D-value for dry heat (D_{DH})*: 1.0-3.0 minutes

D_{DH} is determined utilizing a 160°±2°C exposure temperature. The spore suspensions are tested at E6 population on a filter paper strip and enclosed in a glassine envelope.

* 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: 30-35°C (86-95°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 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. (With ethylene oxide sterilizers aerate the product according to guidelines recommended by the sterilizer manufacturer.) Transfer the test samples to a clean place near the area where you will perform the sterility testing. Test the inoculated samples for sterility using the appropriate procedures specified in the United States Pharmacopeia. Incubate at 30-35°C (86-95°F) for seven days. Examine the culture media during the incubation period for 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 *Bacillus atrophaeus*	**Quantity Per Vial**	**Reorder Number**
Spordex Suspension E9 per 0.1 mL	10 mL	NA028
Spordex Suspension E8 per 0.1 mL	10 mL	NA027
Spordex Suspension E7 per 0.1 mL	10 mL	NA026
Spordex Suspension E6 per 0.1 mL	10 mL	NA002
Spordex Suspension E5 per 0.1 mL	10 mL	NA041
Spordex Suspension E4 per 0.1 mL	10 mL	NA095
Spordex Suspension E3 per 0.1 mL	10 mL	NA051

For further information, please contact:

STERIS®
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-548-4873
www.steris.com