

Biological Indicators

Technical Data Sheet

Spore Suspensions: *Bacillus atrophaeus*

NAMSA Order Code:
SUN-02, SUN-03, SUN-04,
SUN-05, SUN-06, SUN-07, SUN-08

Physical Properties

Organism	<i>Bacillus atrophaeus</i>
Description	Pure suspensions of viable spores with a known population and resistance to Ethylene Oxide (EO) and Dry Heat Sterilization Processes.
Suspension Volume	10 mL suspended Water For Injection. Suspension of WFI and Ethanol mixtures also available upon request.

Guidelines for Use

Application	For direct inoculation onto samples for exposure to Ethylene Oxide (EO) and Dry Heat Sterilization Processes.
Shelf Life	18 months from date of manufacture
Incubation	Incubate at 30-35°C
Storage Conditions	Refrigeration (2-8°C). Protect from sterilizing agents, direct sunlight and high temperatures.
Clean Up/Disposal	Autoclave for not less than 30 minutes at 121°C or per validated disposal cycle prior to discard.

Performance Characteristics

Population	1.0 to 3.0 x 10 ² - 10 ⁸ spores per 0.1 mL
EO D-value (600 mg/L EO 54°C, 60% RH)	2.5 minutes to 5.8 minutes
Dry Heat D-value	1.0 minutes to 3.0 minutes
z-value	≥ 20°C based on d-value determinations on paper strips at 150°C, 160°C, and 180°C
Compliance	ANSI/AAMI/ISO/EN 11138 and USP (where applicable)

NAMSA offers a variety of sterilization monitoring products and the full range of pre-clinical safety testing and consulting services to medical device, pharmaceutical and biotech companies throughout the world.

For additional product information:
Please visit us at www.namsa.com
Email us at productorders@namsa.com
Call us at 800-860-1888 (toll free)

NAMSA

6750 Wales Road
Northwood, Ohio 43619
T 419-662-4345
F 419-666-1715