



This lot of product meets the accepted performance criteria recommended in the USP, ISO 11138-1 and ISO 11138-2.

**PRODUCT NAME:** Spore Suspension

**FOR USE IN MONITORING:** Ethylene Oxide Processes

**ORGANISM:** *Bacillus atrophaeus*, ATCC® 9372

**DILUENT:** Water for Injection (WFI)

**VOLUME:** 10 mL each vial

<b>LOT</b>	A00-1		2021-01-01		2024-01-01
<b>REF</b>	UA-06	POPULATION:		2.0x10 <sup>6</sup> /0.1 mL	
<b>Resistance Characteristics</b>					
<i>D</i> value		Survival		Kill	
Ethylene Oxide, 600 mg/L, 54°C, 60% RH: 2.0 minutes		8.7 minutes		20.6 minutes	
<p>The <i>D</i> value was determined on paper carriers packaged in glassine envelopes per the fraction negative method and are reproducible only when exposed and cultured under the exact conditions used to obtain results reported above. The user would not necessarily obtain the same results, therefore, should determine the suitability for their particular use.</p> <p>Survival-kill times are calculated based on the formulae outlined in USP and ISO 11138-1.</p> <p>Purity: Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the product.</p>					

<b>Storage and Shelf Life</b>			
	Refrigerate at 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat, radioactive sources, & sterilizing agents
<b>Shelf-life</b>	36 Months from the date of manufacture		
	Do not use damaged vials of Spore Suspension. Do not use after expiration date. Spore Suspensions contain live cultures and should be handled with care.		

Dispose: Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

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QUALITY ASSURANCE APPROVAL

January 9, 2022  
DATE