

MESA'S *Bacillus atrophaeus* Spore Suspensions

This document refers to spore suspensions inoculated with *Bacillus atrophaeus*, reference #9372, made by Mesa's Bozeman, Montana Manufacturing Facility in comparison to discontinued *Bacillus atrophaeus*, reference #9372, spore suspensions formerly made by Mesa's Omaha, Nebraska Manufacturing Facility.

General Characteristics:

Specifications	Spore Suspension	Spore Suspension
Manufacturing Location	Omaha, NE	Bozeman, MT
Catalog #(s) ¹	SUS-1-X	SSGE/X
Population Range ¹	$\geq 1.0 \times 10^x$	$\geq 1.0 \times 10^x$
Volume	$\geq 10\text{ml}$	$\geq 10\text{ml}$
Packaging Configuration	DI water containing 40% Ethanol	Distilled water containing 40% Ethanol
Vial Composition	Borosilicate Glass	Borosilicate Glass
Stopper Composition	Gray Chlorobutyl	Red Rubber
Cell Line Number	9372	9372
Oxyfume 2000 D-value Range ²	Not less than 2.5 minutes	Not less than 2.5 minutes
100% EO D-value Range ²	Not less than 2.0 minutes	Not less than 2.0 minutes
Dry Heat D-value Range	1.0-3.0minutes	1.0-3.0minutes
Shelf-Life	12 months	24 months
Storage Conditions	2-8°C	Freezer (-25 to -10°C)
Compliance	USP, ISO 11138-1,	USP, ISO 11138-1,

1. "X" represents the population log per 0.1ml

2. Determined on paper spore strips in glassine envelopes

Product Lot Comparison:

Product Characteristic	SUS-1-X			SSGE/X		
	Lot Number			Lot Number		
	1063218 log6/0.1ml	1063263 log6/0.1ml	1073281 log6/0.1ml	SSG-430 log6/0.1ml	SSG-426 log6/0.1ml	SSG-416 Log8/0.1ml
Population per suspension Per 0.1/ml	4.0x10 ⁶	1.5x10 ⁶	1.6x10 ⁷	2.9x10 ⁶	2.6x10 ⁶	2.6x10 ⁸
Oxyfume 2000 D-value In Minutes	3.6	3.3	4.0	3.9	3.9	3.8
100% EO D-value In Minutes	2.3	2.3	2.4	3.3	3.3	3.3
Dry Heat D-value at 160°C In Minutes	1.1	1.2	1.4	1.6	1.6	1.9

Based on a product comparison, the SSGE/X suspensions manufactured by Mesa's Bozeman, Montana facility are substantially equivalent to Mesa's discontinued SUS-1-X suspensions formerly manufactured at Mesa's Omaha, Nebraska facility.