

MESA'S *Geobacillus stearothermophilus* Spore Suspensions

This document refers to spore suspensions inoculated with *Geobacillus stearothermophilus*, reference #7953, made by Mesa's Bozeman, Montana Manufacturing Facility in comparison to discontinued *Geobacillus stearothermophilus*, reference #7953, 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-3-X	SSSE/X
Population Range ¹	≥ 1.0x10 ^x	≥ 1.0x10 ^x
Volume	≥ 10ml	≥10ml
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	7953	7953
D-value Range ²	1.5-3.0 minutes	≥ 1.5 minutes
Shelf-Life	12 months	24 months
Storage Conditions	2-8°C	Freezer (-25 to -10°C)
Compliance	USP, ISO 11138-1, ISO 11138-3	USP, ISO 11138-1, ISO 11138-3

1. "X" represents the population log per 0.1ml
2. Determined on paper spore strips in glassine envelopes

Product Lot Comparison:

Product Characteristic	SUS-3-X			SSSE/X		
	Lot Number			Lot Number		
	3062603 log6/0.1ml	3062801 log6/0.1ml	3063251 log6/0.1ml	SSS-725 log6/0.1ml	SSS-719 log7/0.1ml	SSS-716 log7/0.1ml
Population per suspension Per 0.1/ml	3.4x10 ⁶	1.2x10 ⁶	2.9x10 ⁶	2.5x10 ⁶	2.2x10 ⁷	2.5x10 ⁷
Steam D-value In Minutes	1.8	2.2	2.0	1.8	2.3	2.0

Based on a product comparison, the SSSE/X suspensions manufactured by Mesa's Bozeman, Montana facility are substantially equivalent to Mesa's discontinued SUS-3-X suspensions formerly manufactured at Mesa's Omaha, Nebraska facility.