

**MESA'S *Bacillus pumilus* Spore Suspensions**

This document refers to spore suspensions inoculated with *Bacillus pumilus*, reference #27142, made by Mesa's Bozeman, Montana Manufacturing Facility in comparison to discontinued *Bacillus pumilus*, reference #27142, 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) <sup>1</sup>	SUS-7-X	SSRE/X
Population Range <sup>1</sup>	$\geq 1.0 \times 10^x$	$\geq 1.0 \times 10^x$
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	27142	27142
D-value Range <sup>2</sup>	1.0-3.0 kGry	1.0-4.0 kGry
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 envelops

**Product Lot Comparison:**

Product Characteristic	SUS-7-X			SSRE/X		
	Lot Number			Lot Number		
	7066924 log6/0.1ml	706708 log6/0.1ml	7067021 log6/0.1ml	SSP-225 Log7/0.1ml	SSP-222 log6/0.1ml	SSP-219 Log5/0.1ml
Population per suspension Per 0.1/ml	1.4x10 <sup>6</sup>	1.1x10 <sup>6</sup>	2.2x10 <sup>6</sup>	2.6x10 <sup>7</sup>	2.1x10 <sup>6</sup>	1.6x10 <sup>5</sup>
Steam D-value In kGry	1.9	1.2	1.2	1.2	1.2	1.2

Based on a product comparison, the SSRE/X suspensions manufactured by Mesa's Bozeman, Montana facility are substantially equivalent to Mesa's discontinued SUS-7-X suspensions formerly manufactured at Mesa's Omaha, Nebraska facility.