

Spore Suspensions - Manufacturing Transfer Summary

With the acquisition of NAMSA's Sterilization Monitoring Products Division, all manufacturing processes will be transferred to Crosstex. Spore Suspensions have been manufactured by Crosstex for several years; thus, the validated processes and equipment currently being used to manufacture these products will continue to be utilized once the transition is complete.

Crosstex is a FDA registered facility (registration number 1319130). Based on a product comparison and review of best practices, the Spore Suspensions manufactured by Crosstex are equivalent to those manufactured by NAMSA Products Division and offer the following advantages:

- The same primary packaging consisting of a pharmaceutical grade glass vial with screw cap and septum will be used.
- The diluent will change from Water For Injection (WFI) to WFI and 20% Ethanol as the standard offering. The inclusion of the Ethanol provides antifungal properties over pure WFI. Spore Suspensions with only Water For Injection (WFI) are available upon request.
- All the same cell lines of spores will be available.

Information important to the transfer of the Spore Suspensions manufacturing process is outlined below:

Spore Suspensions for Steam:

NAMSA Product Codes: US52304, US52305, US52306, US52307, US52308, SBS-04, SBS-05, SBS-06, SBS-07 and SBS-08

- Product codes for *Bacillus subtilis* cell lines 5230 and 6633 will remain the same as the NAMSA product codes which have been utilized to order these Spore Suspensions historically.
- The shelf life for these Spore Suspensions will also remain unchanged.

NAMSA Product Codes: SUS-02, SUS-03, SUS-04, SUS-05, SUS-06, SUS-07 and SUS-08

- Spore Suspensions (*Geobacillus stearothermophilus* Cell Line 7953) for Steam sterilization will be available under new Crosstex product codes.

Product Description	NAMSA		Crosstex	
	Product Code	Shelf Life	Product Code	Shelf Life
<i>Geobacillus stearothermophilus</i> Cell Line 7953				
10 ²	SUS-02	24 months	VGS-102	24 months
10 ³	SUS-03	24 months	VGS-103	24 months
10 ⁴	SUS-04	24 months	VGS-104	24 months
10 ⁵	SUS-05	24 months	VGS-105	24 months
10 ⁶	SUS-06	24 months	VGS-106	24 months
10 ⁷	SUS-07	24 months	VGS-107	24 months
10 ⁸	SUS-08	24 months	VGS-108	24 months

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Spore Suspensions for Ethylene Oxide (EO) and Dry Heat:

NAMSA Product Codes: SUN-02, SUN-03, SUN-04, SUN-05, SUN-06, SUN-07 and SUN-08

- Spore Suspensions (*Bacillus atrophaeus* Cell Line 9372) for EO and Dry Heat sterilization will be available under new Crosstex product codes.

Product Description	NAMSA		Crosstex	
	Product Code	Shelf Life	Product Code	Shelf Life
<i>Bacillus atrophaeus</i> Cell Line 9372				
10 ²	SUN-02	24 months	VBA-102	24 months
10 ³	SUN-03	24 months	VBA-103	24 months
10 ⁴	SUN-04	24 months	VBA-104	24 months
10 ⁵	SUN-05	24 months	VBA-105	24 months
10 ⁶	SUN-06	24 months	VBA-106	24 months
10 ⁷	SUN-07	24 months	VBA-107	24 months
10 ⁸	SUN-08	24 months	VBA-108	24 months

Spore Suspensions for Hydrogen Peroxide (VH₂O₂):

NAMSA Product Codes: SUS-06H, SUS-07H and SUS-08H

- Spore Suspensions (*Geobacillus stearothermophilus* Cell Line 7953) for VH₂O₂ sterilization will be available under new Crosstex product codes.

Product Description	NAMSA		Crosstex	
	Product Code	Shelf Life	Product Code	Shelf Life
<i>Geobacillus stearothermophilus</i> Cell Line 7953				
10 ⁶	SUS-06H	24 months	VGS-106H	24 months
10 ⁷	SUS-07H	24 months	VGS-107H	24 months
10 ⁸	SUS-08H	24 months	VGS-108H	24 months

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Spore Suspensions for Irradiation (Gamma and E-Beam):

NAMSA Product Codes: SUP-06, SUP-07 and SUP-08

- Spore Suspensions (*Bacillus pumilus* Cell Line 27142) for Irradiation sterilization will be available under new Crosstex product codes.

Product Description	NAMSA		Crosstex	
	Product Code	Shelf Life	Product Code	Shelf Life
<i>Bacillus pumilus</i> Cell Line 27142				
10 ⁶	SUP-06	24 months	VBP-106	24 months
10 ⁷	SUP-07	24 months	VBP-107	24 months
10 ⁸	SUP-08	24 months	VBP-108	24 months

The ordering information associated with the products, during and post transition, will remain the same and as outlined below.

Ordering Information	
Telephone	1 (800) 860-1888
Fax	1 (419) 666-1715
Email	productorders@crosstex.com

As manufacturing activities begin to transfer to Crosstex, product may be branded under NAMSA or Crosstex and will be shipped from two locations depending on the branding of the product. NAMSA branded product will ship from the existing NAMSA facility (6750 Wales Road, Northwood, OH 43619) and Crosstex branded product will be shipped from the Rush, NY, facility (6789 W Henrietta Road, Rush, NY 14543).

Thank you for being a valued client and we look forward to continuing to serve you.