

## Bacillus atrophaeus Biological Indicator Spore Strip Product Comparison

This document refers to standard spore strips of *Bacillus atrophaeus*, ATCC® 9372 NAMSA Product Codes: STN-02, STN-03, STN-04, STN-05, STN-06, STN-07 and STN-08 in comparison to Crosstex's equivalent replacement Product Codes: BG-102, BG-103, BG-104, BG-105, BG-106, BG-107 and BG-108.

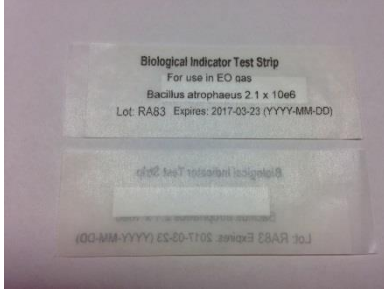
### Product Code Reference and Shelf Life

Product Description	NAMSA		Crosstex	
	Product Code	Shelf Life	Product Code	Shelf Life
<b><i>Bacillus atrophaeus</i></b>				
10 <sup>2</sup> Spore Strip	STN-02	30 months	BG-102	24 months
10 <sup>3</sup> Spore Strip	STN-03	30 months	BG-103	24 months
10 <sup>4</sup> Spore Strip	STN-04	30 months	BG-104	24 months
10 <sup>5</sup> Spore Strip	STN-05	30 months	BG-105	24 months
10 <sup>6</sup> Spore Strip	STN-06	30 months	BG-106	24 months
10 <sup>7</sup> Spore Strip	STN-07	30 months	BG-107	24 months
10 <sup>8</sup> Spore Strip	STN-08	30 months	BG-108	24 months

### Product Lot Comparison: NAMSA STN-06 versus Crosstex BG-106

Product Characteristic	NAMSA			Crosstex		
	Lot Number			Lot Number		
	N35100	N35201	N35300	RA81	RA83	RA92
Population per strip	1.4x10 <sup>6</sup>	1.5x10 <sup>6</sup>	1.2x10 <sup>6</sup>	2.2x10 <sup>6</sup>	2.1x10 <sup>6</sup>	2.2x10 <sup>6</sup>
Ethylene Oxide (EO) <i>D</i> value 600 mg/L, 54°C, 60% RH In Minutes	3.2	3.1	3.2	3.0	2.8	2.8
EO Survival Time In Minutes	13.3	13.0	13.1	13.1	12.2	12.2
EO Kill Time In Minutes	32.4	31.5	32.2	31.0	28.9	28.9

Product Characteristic	NAMSA			Crosstex		
	Lot Number			Lot Number		
	N35100	N35201	N35300	RA81	RA83	RA92
Dry Heat <i>D</i> value at 150°C In Minutes				6.8	5.8	5.4
Dry Heat Survival Time at 150°C In Minutes	Not Certified	Not Certified	Not Certified	29.6	25.1	23.5
Dry Heat Kill Time at 150°C In Minutes				70.3	59.8	55.8
Dry Heat <i>D</i> value at 160°C In Minutes	2.0	2.0	2.1	2.8	2.2	2.3
Dry Heat Survival Time at 160°C In Minutes	8.3	8.4	8.6	12.2	9.6	10.0
Dry Heat Kill Time at 160°C In Minutes	20.2	20.3	21.1	28.9	22.7	23.7
Dry Heat <i>D</i> value at 170°C In Minutes				1.2	0.9	0.9
Dry Heat Survival Time at 170°C In Minutes	Not Certified	Not Certified	Not Certified	5.3	3.9	4.0
Dry Heat Kill Time at 170°C In Minutes				12.4	9.2	9.3
Dry Heat <i>z</i> value	Determined based on <i>D</i> values at 150°C, 160°C and 180°C			Determined based on <i>D</i> values at 150°C, 160°C and 170°C		
	42°C	42°C	43°C	26.5°C	24.7°C	25.7°C



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

- An improved peel area which allows for the Spore Strip to be more easily accessed and removed from the glassine packaging.
- Natural glassine material which does not contain dye.

	<b>NAMSA</b>	<b>Crosstex</b>
<b>Glassine Material</b>	30# Blue	25# White
<p>Worldwide sources for glassine material are limited; thus, the material utilized by NAMSA and Crosstex-SPSmedical are the same with the exception of a blue dye. It is this dye which causes the glassine material NAMSA has utilized to appear blue, whereas Crosstex-SPSmedical utilizes the natural form of the material without the addition of the dye. Crosstex-SPSmedical switched from the dyed material to the natural white version several years ago without any negative impact to the product or its performance.</p>		
<b>Peel Area</b>	Edges of glassine material align with indication to "PEEL HERE".	Edges of glassine material are offset, creating an obvious peel area which requires no indication.
<b>Lot Number</b>	6-7 Digits printed on glassine	4 Digits printed on glassine
<b>Expiration Date</b>	DD-MMM-YYYY	YYYY-MM-DD
<b>Strip Dimension</b>	6 mm x 30 mm	7 mm x 38 mm
<b>Quantity</b>	Boxes of 100	Boxes of 100
<b>Population</b>	1.0 to 6.0 x 10 <sup>x</sup>	1.0 to 5.0 x 10 <sup>x</sup>
<b>EO D value</b>	2.5 to 5.8 minutes	2.5 to 5.8 minutes
<b>Dry Heat D value at 160°C</b>	1.0 to 3.0 minutes	1.0 to 3.0 minutes
<b>Dry Heat z value</b>	≥20°C	≥20°C

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


Ordering Information	
Telephone	1 (800) 860-1888
Fax	1 (419) 666-1715
Email	<a href="mailto:productorders@crosstex.com">productorders@crosstex.com</a>

We understand that our clients have different needs based on your internal quality system requirements or Standard Operating Procedures (SOP's). Because of this, if there is something specific that is required, such as completion of specific forms or documents, samples, etc., please do not hesitate to let us know.

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

If you have any questions, please do not hesitate to contact me.

Sincerely,



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