

Geobacillus stearothermophilus Mini Self-Contained Biological Indicator (SCBI) Product Comparison

This document refers to Mini SCBIs of *Geobacillus stearothermophilus*, ATCC® 7953 NAMSA Product Codes: MSCS-05 and MSCS-06 in comparison to Crosstex’s equivalent replacement Product Codes: SCS-100 and SCS-106.

Product Code Reference and Shelf Life

Product Description	NAMSA		Crosstex	
	Product Code	Shelf Life	Product Code	Shelf Life
<i>Geobacillus stearothermophilus</i>				
10 ⁵ SCBI	MSCS-05	24 Months	SCS-100	24 months
10 ⁶ SCBI	MSCS-06	24 Months	SCS-106	24 months

Product Lot Comparison: NAMSA MSCS-06 versus Crosstex SCS-106

Product Characteristic	NAMSA			Crosstex		
	Lot Number			Lot Number		
	S91501	S96703	S98503	7000	7010	7020
Population per strip	2.5x10 ⁶	1.7x10 ⁶	1.8x10 ⁶	1.5x10 ⁶	1.5x10 ⁶	1.3x10 ⁶
Steam <i>D</i> value at 121°C In Minutes	2.6	2.2	2.1	2.2	2.4	2.5
Steam Survival Time at 121°C In Minutes	11.5	9.4	9.0	9.2	10.1	10.3
Steam Kill Time at 121°C In Minutes	27.0	22.5	21.5	22.3	24.4	25.2
Steam <i>D</i> value at 124°C In Minutes	Not Certified	Not Certified	Not Certified	1.4	1.5	1.5
Steam Survival Time at 124°C In Minutes				5.9	6.3	6.2
Steam Kill Time at 124°C In Minutes				14.2	15.2	15.1

Product Characteristic	NAMSA			Crosstex		
	Lot Number			Lot Number		
	S91501	S96703	S98503	7000	7010	7020
Steam <i>D</i> value at 132°C In Minutes	0.5	0.18	0.2	0.66	0.71	0.78
Steam Survival Time at 132°C In Minutes	2.2	0.8	0.9	2.8	3.0	3.3
Steam Kill Time at 132°C In Minutes	5.1	1.8	2.0	6.7	7.2	7.8
Steam <i>D</i> value at 134°C In Minutes	0.4	0.11	0.13	0.57	0.61	0.7
Steam Survival Time at 134°C In Minutes	1.8	0.5	0.6	2.4	2.6	2.9
Steam Kill Time at 134°C In Minutes	4.1	1.1	1.3	5.8	6.2	7.0
Steam <i>D</i> value at 135°C In Minutes	Not Certified	Not Certified	Not Certified	0.51	0.55	0.63
Steam Survival Time at 135°C In Minutes				2.2	2.3	2.6
Steam Kill Time at 135°C In Minutes				5.1	5.5	6.3
Steam <i>z</i> value	Determined based on <i>D</i> values at 119°C, 121°C and 130°C			Determined based on <i>D</i> values at 121°C, 124°C and 132°C		
	15°C	9°C	11°C	22.0°C	21.8°C	23.2°C

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

- For Steam sterilization, SporView®10 is available. The SCBIs offer a validated reduced incubation time of 10 hours. The SCBI is utilizing a conventional spore growth readout for rapid and reliable monitoring of steam sterilization processes without the use of enzyme based technology or specific and specialized incubators or monitoring devices.
- Vial labels have an enhanced substrate and adhesive which allows the labels to be peeled off more easily post sterilization.

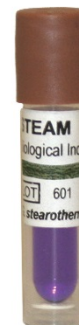
	NAMSA	Crosstex
Cell Line Number	7953	7953
Population	$\geq 1.0 \times 10^x$	1.0 to 5.0 x 10 ^x
Vial Dimensions	9 mm x 50 mm	8.4 mm x 45.5 mm
Incubation Time	24 hours	24 hours
Media Transition (Positive)	Purple to Yellow	Purple to Yellow
Packaging	100/box	100/box
Shelf Life	24 months	24 months
Cap Color	Purple	Brown
Chemical Indicator	Yellow to Dark	Blue to Dark
Compliance	USP, ISO 11138-1, ISO 11138-3	USP, ISO 11138-1, ISO 11138-3

**Chemical Indicator Location and Color Transition on Crosstex
Product Codes: SCS-100 and SCS-106**

Blue CI Before Exposure to Steam



Dark CI After Exposure to Steam



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

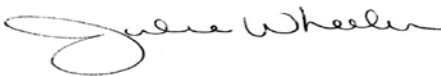
Ordering Information	
Telephone	1 (800) 860-1888
Fax	1 (419) 666-1715
Email	productorders@crosstex.com

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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