

## Bacillus atrophaeus Mini Self-Contained Biological Indicator (SCBI) for Monitoring Ethylene Oxide (EO) Processes - Product Comparison

This document refers to Mini SCBIs of *Bacillus atrophaeus*, Cell Line 9372 NAMSA Product Code MSCE-06 in comparison to Crosstex's equivalent replacement Product Code SCA-100.

### 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>6</sup> SCBI              | MSCE-06      | Earlier expiration date of the two components with individual expiry periods: media ampule and inoculated carrier (spore disc) | SCA-100      | Earlier expiration date of the two components with individual expiry periods: media ampule and inoculated carrier (spore disc) |

### Product Lot Comparison: NAMSA MSCE-06 versus Crosstex SCA-100

| Product Characteristic  | NAMSA               |                     |                     | Crosstex            |                     |                     |
|---|---------------------|---------------------|---------------------|---------------------|---------------------|---------------------|
|   | Lot Number          |                     |                     | Lot Number          |                     |                     |
|   | N31618              | N34104              | N34602              | 4000                | 4010                | 4030                |
| Population per disc   | 1.4x10 <sup>6</sup> | 1.2x10 <sup>6</sup> | 1.1x10 <sup>6</sup> | 2.4x10 <sup>6</sup> | 1.7x10 <sup>6</sup> | 1.8x10 <sup>6</sup> |
| EO D value at 54°C, 600±30 mg/L, 60%±10% Relative Humidity In Minutes | 3.4                 | 2.8                 | 3.2                 | 2.9                 | 2.8                 | 3.2                 |
| EO Survival Time In Minutes   | 14.1                | 11.5                | 13.0                | 12.8                | 11.9                | 13.7                |
| EO Kill Time In Minutes   | 34.4                | 28.2                | 32.1                | 30.1                | 28.6                | 32.8                |

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 NAMSA Products Division.

|                                    | NAMSA  | Crosstex   |
|------------------------------------|--|--|
| <b>Cell Line Number</b>            | 9372   | 9372   |
| <b>Population</b>                  | $\geq 1.0 \times 10^6$   | 1.0 to 5.0 x 10 <sup>6</sup>   |
| <b>Vial Dimensions</b>             | 9 mm x 50 mm   | 8.4 mm x 45.5 mm   |
| <b>Incubation Time</b>             | 48 hours   | 48 hours   |
| <b>Media Transition (Positive)</b> | Green to Yellow  | Green to Yellow  |
| <b>Packaging</b>                   | 100/box  | 100/box  |
| <b>Shelf Life</b>                  | Earlier expiration date of the two components with individual expiry periods: media ampule and inoculated carrier (spore disc) | Earlier expiration date of the two components with individual expiry periods: media ampule and inoculated carrier (spore disc) |
| <b>Cap Color</b>                   | Green  | Green  |
| <b>Chemical Indicator</b>          | Violet to Green  | Cream to Rust (Orange)   |
| <b>Compliance</b>                  | USP, ISO 11138-1,<br>ISO 11138-2   | USP, ISO 11138-1,<br>ISO 11138-2   |

**Chemical Indicator Location and Color Transition on Crosstex  
Product Code: SCA-100**

**CI Before Exposure to EO**



**CI After Exposure to EO**



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

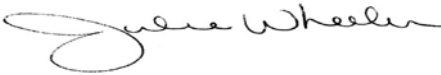
| Ordering Information |                            |
|----------------------|----------------------------|
| Telephone            | 1 (800) 860-1888           |
| Fax                  | 1 (419) 666-1715           |
| Email                | productorders@crosstex.com |

We understand that our clients have different needs based on your internal quality system requirements or Standard Operating Procedures (SOPs). 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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