CHEMICAL PROCESS INDICATORS (CPIs)  
For Monitoring Ethylene Oxide Sterilization Processes  
(CLASS/TYPE 1)  

Crosstex Code: CPI-E01

Product Description

Crosstex Ethylene Oxide (EO) CPIs are manufactured to monitor whether EO exposure conditions were met at the point of application using pressure sensitive adhesive. CPI-E01 are intended for use with individual units (e.g. packs, containers) to indicate that the unit has been directly exposed to EO process and to distinguish between processed and unprocessed units. The indicators color transition from purple to green.

Physical Properties

<table>
<thead>
<tr>
<th>Process</th>
<th>EO</th>
</tr>
</thead>
</table>
| Dimensions | 12.7 mm (0.5” diameter circle)  
Thickness: 0.10 mm (indicator); 0.17 mm (indicator and liner) |
| Packaging | 5,000 Indicators/Roll |
| Chemical Indicator | Initial Color: Purple  
Signal Color: Green |

Intended Use

The indicators are for use in all EO sterilization processes.

Class 1/Type 1 Process Indicator Requirements:

- 600 mg/L at 54°C and 60% RH for 20 minutes

Instructions for Use

Use an indicator on each item, pack, peel pouch, or tray intended for EO sterilization. Place at a location considered most challenging for EO gas to reach. Process the packages/items as instructed in the sterilizer validation or manual.

Upon exposure to EO, the indicator will transition from purple to green. The transition color may vary depending on the load configuration, length and conditions of exposure. A color transition from purple to a shade of green provides indication of exposure to EO. If the signal color is not achieved immediately following exposure, allow the indicator to aerate for 20 minutes. If the signal color is still not achieved, this suggests ideal sterilization conditions may not have been met. Determine if the load was successfully sterilized by examining a biological indicator, or re-sterilize the load using a new chemical indicator.
Performance Characteristics

<table>
<thead>
<tr>
<th>Result Availability</th>
<th>Immediately following exposure to EO processes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unexposed*</td>
<td>Exposed to 54°C, 20 minutes, 60% RH, 600 mg/L EO gas*</td>
</tr>
</tbody>
</table>

*Colors shown are representations of printed ink initial and signal colors but may vary from actual use.

The signal color achieved from exposure to EO may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature, etc.). For a Type 1 Process Indicator, any color change produced during exposure to EO which is different from the initial color is considered acceptable.

Compliance


Storage and Shelf Life

<table>
<thead>
<tr>
<th>Temperature</th>
<th>Humidity</th>
<th>Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>+15°C to +30°C</td>
<td>20% to 70% relative humidity</td>
<td>Keep away from sunlight</td>
</tr>
</tbody>
</table>

Shelf life

2 years from the date of manufacture

The date of manufacture is based on the day the indicating ink is applied to the substrate. The remaining shelf life upon receipt will be shorter than 2 years

Disposal

Discard as general waste.

Crosstex International, Inc. | Industrial Markets
6789 W. Henrietta Road, Rush, NY 14543 | T 800.860.1888 | F 419.666.1715 | E productorders@crosstex.com | www.SterilizationProducts.com