

# ETHYLENE OXIDE CHEMICAL PROCESS INDICATOR

- Compliance -** Indicators meet ISO 11140-1, for Class 1 Process Indicators
- User Friendly -** Non-toxic self adhesive, purple to green transition
- Convenient -** Room temperature for storage  
24 month shelf life
- Reliable quality -** Each lot is tested to verify color transition.




NAMSA Ethylene Oxide (EO) Chemical Process Indicators (CPIs) are manufactured to meet performance specifications described in ISO 11140-1 "Sterilization of health care products - Chemical indicators - Part 1: General requirements," for Class 1 Process Indicators. The purple-to-green color transition is sensitive to time, temperature, humidity and presence of EO (see chart to right). NAMSA EO CPIs are not intended for use as dosimeters, but rather as throughput process indicators used to monitor exposure to the ethylene oxide sterilization process.

## PRODUCT SPECIFICATIONS AND APPLICATIONS





NAMSA EO CPIs are labeled with 24 months of shelf life and room temperature storage. The shelf life is based on the date the indicating ink is applied to the substrate. Product may have a shelf life of less than 24 months at the time of purchase. Avoid contact or storage of indicators near substrates which are acidic or basic in nature, such as cleaning solutions and disinfectants.

Exposed indicators are stable and will remain green when stored under labeled conditions. Each roll is individually packaged with a certificate of conformance to ensure the products' quality and consistency.

NAMSA EO CPIs are manufactured using a water-based ink formulation made without the use of any heavy metals. They are nonodorous and nonhazardous to use. The printed labels are safe to dispose in general waste receptacles. No MSDS required per CFR 1910.1200.

Product Type	Number of indicators per roll	Product Code	Example
Plain 1/2" (12.7 mm) circles	5,000	CPI-E01	
Meto® gun indicators for hand-held labeling systems	1,500	CPI-E02	
Imprinted 1/2" (12.7 mm) circles	5,000	CPI-E03	

## Product Color Change Performance<sup>1</sup> NAMSA Ethylene Oxide Chemical Process Indicators

Product CPI-E01	
Unexposed 	600 mg/L 54°C 60% RH 2 minutes <sup>3</sup> 
0 mg/L 60°C >85% RH 90 minutes <sup>2</sup> 	600 mg/L 54°C 60% RH 20 minutes <sup>4</sup> 

<sup>1</sup> Samples are representative of performance according to ISO 11140-1, for Class 1 Process Indicators.  
<sup>2</sup> After exposure to 0 mg/L Ethylene Oxide at 60°C ± 2°C at greater than 85% relative humidity (RH) for not less than 90 minutes, the indicator shall show either no change or a change that is markedly different from the change occurring after exposure to an ethylene oxide sterilization process.  
<sup>3</sup> The endpoint indicating exposure to an ethylene oxide sterilization process will not occur until the indicator has been exposed to 600 ± 30mg/L ethylene oxide and 60 ± 10% RH at 54°C ± 1°C for not less than 2 minutes.  
<sup>4</sup> The endpoint indicating exposure to an ethylene oxide sterilization process shall occur when the indicator has been exposed to 600 ± 30 mg/L ethylene oxide and 60 ± 10% RH at 54°C ± 1°C for a period not exceeding 20 minutes.

*NAMSA offers a variety of sterilization monitoring products and the full range of pre-clinical safety testing and consulting services to medical device, pharmaceutical and biotech companies throughout the world.*

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