Ethylene Oxide Chemical Process Indicators

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). EO CPIs are not intended for use as sterility indicators, but rather as throughput process indicators used to monitor exposure to EO sterilization processes.

EO CPIs are labeled with 24 months of shelf life and room temperature storage (23 ± 7°C). 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.

EO CPIs are non-odorous and non-hazardous to use. The printed labels are safe to dispose in general waste receptacles. No MSDS required per CFR 1910.1200.

Process Indicator Configurations

Code	Product Type	Number of Indicators / Roll	Example
CPI-E01	Plain 1/2" (12.7 mm) circles	5,000	
CPI-E02	Meto® gun indicators for hand-held labeling systems	1,500	
CPI-E03	Imprinted 1/2" (12.7 mm) circles. Text reads: "Green is Exposed."	5,000	
SP-E16	Imprinted Meto® gun indicators for hand-held labeling systems Text reads: "Green is Exposed."	1,500	

Product Color Change Performance[1]
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Product CPI-E01

Unexposed		600 mg/L 54° C 60% RH 2 minutes[3]	
0 mg/L 60° C >85% RH 90 minutes[2]		600 mg/L 54° C 60% RH 20 minutes[4]	

1 Samples are representative of performance according to ISO 11140-1, for Class 1 Process Indicators.

2 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.

3 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.

4 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.