

Chemical Process Indicators (CPIs) For monitoring Ethylene Oxide Sterilisation Processes (CLASS /TYPE 1)



Excelsior Code: CPI-E01E

Product Description

Excelsior Ethylene Oxide (EO) CPIs contain no lead or other toxic heavy metals. The indicators are manufactured to monitor whether EO conditions were met at the point of application using pressure sensitive adhesive. The indicators are designed for use with individual units (eg. Packs, containers) to indicate that the unit has been directly exposed to an EO process and to distinguish between processed and unprocessed units. The indicators transition from purple to green.

Physical Properties

Process	EO
Dimensions	12.7 mm (1/2") Dot Thickness: 0.10mm (indicator); 0.17mm (indicator and liner)
Packaging	5,000 Indicators/Roll
Chemical Indicator	Initial Colour: Purple Signal Colour: Green Chemical Indicator inks contain no lead or other toxic heavy metals

Indications for Use

The Indicators are for use in all EO sterilisation 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 sterilisation. Place at a location considered most challenging for EO gas to reach. Process the packages/items as instructed in the steriliser validation or manual.

Upon exposure to radiation, the indicator will transition from purple to green. The transition colour may vary depending on the load configuration, length and conditions of exposure. A colour transition from purple to a shade of green provides indication of exposure to radiation. If the signal colour is not achieved, this suggests ideal sterilisation conditions may have not been met. Determine if the load was successfully sterilised by examining a biological indicator, or re-process the load using a new chemical indicator.

The chemical reaction which causes the colour transition is an EO specific reaction and is irreversible under most conditions.

Performance Characteristics

Result Availability	Immediately following exposure to EO Processes
Unexposed*	Exposed to 54°C, 20 mins, 60% RH, 600 mg/L EO gas
	

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

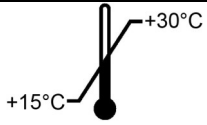
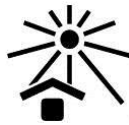





The signal colour achieved from exposure to EO may vary from the example above due to differences in processing parameters (i.e. load content, cycle time, temperature etc.) For a Type 1 Process indicator, a colour change to a shade of green produced during exposure is considered acceptable.

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators- Part 1:General Requirements for Type 1 Chemical Process Indicators.

Storage and Shelf Life

	15°C to 30°C		Keep away from Sunlight
	20% to 80% relative humidity		Keep Dry
Shelf Life	3 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 3 years		
	Keep away from sterilants. Do not use damaged indicators or indicators which have transitioned to green. Do not use after expiration date.		

Disposal

Discard as general waste.

For additional product information:
Please visit us at
www.excelsiorscientific.com
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