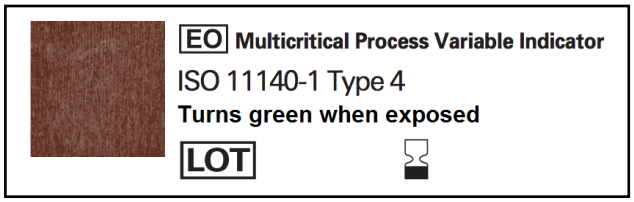
MULTICRITICAL PROCESS VARIABLE INDICATOR STRIP
For Monitoring Ethylene Oxide Processes
(CLASS / TYPE 4)

Excelsior Code: ETO-250E



Product Description

Excelsior Multicritical Process Variable Indicator strips contain no lead or other toxic heavy metals. The Indicator strips are intended for use with individual materials (i.e. packs, containers) to demonstrate that the material has been exposed to an EO process to distinguish between processed and unprocessed items. Multicritical Process Variable Indicators react to all critical process variables (time, temperature, relative humidity and EO gas concentration). The backing of the strip is removable which exposes latex-free adhesive for easy application of the strip to packages during exposure and /or for record keeping purposes after exposure.

Physical Properties

Process	EO
Indicator Strip Dimensions	19 mm x 70 mm (0.75” x 2.75”)
Packaging	250 Strips / Package
Chemical Indicator	Initial Colour: Purple/Brown 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 /Type 1 & 4 Multicritical Process Variable Indicator Stated Values:

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

Instructions for Use

Use a strip or label in each pack, peel pouch or tray intended for EO exposure. Process packages/items as instructed in the steriliser validation or manual.

Upon exposure to EO, the chemical indicator will transition from a purple/brown to green. The transition colour may vary depending on the load configuration, length and conditions of exposure. A colour transition from purple/brown to a shade of green provides indication of exposure to EO. If the signal colour is not achieved this may suggest ideal exposure conditions were not met. Review the exposure conditions and investigate the steriliser malfunction.

The chemical reaction which causes the colour transition is an EO specific reaction and is irreversible under most conditions. Post exposure storage near acidic environments such as reagent or cleaning product fumes may cause involuntary reversion from green back to purple/brown.

Performance Characteristics

Result Availability	Immediately following exposure to EO

Unexposed*	Exposed to 600mg/L at 54°C & 60% RH for 20 mins

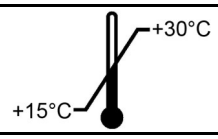
***Colours shown are representations of printed ink initial signal colours but may vary from actual use.**

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 Type 4 Multi-critical Process Variable Indicators, a colour change to green, is an indication that all process variables were achieved during exposure to EO .

Compliance

ISO 11140-1:2014 Sterilization of health care products – Chemical Indicators- Part 1:General Requirements For Type 1 chemical process indicators & Type 4 multicritical process variable 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		Do not reuse
	Keep away from steriliants. Do not use after expiration date. Do not use the product is the indicator has transitioned prior to use.		

Disposal
Discard as general waste.

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

Excelsior Scientific