Sterilization Compatibility Study

PURPOSE

To support the healthcare packaging industry in its efforts to understand various sterilization modality exposure impact to packaging material performance, Oliver has performed aging studies on common flexible sterile barrier materials across its portfolio.

Tested Alternative Modalities		
Chemical Gas	Chlorine Dioxide (ClO_2) – True gas sterilant operated within a chamber at room temperature and relatively fast cycle times; broad material compatibility and good distribution and penetration.	ClorDiSys
Irradiation	E-beam – Electrons are accelerated to a high energy. The 'beam' of electrons is scanned over the material being irradiated to inactivate microorganisms. Relatively quick process with broad material compatibility, appropriate for low to medium density products. X-ray – Electrons are accelerated to a high energy and directed onto a metal target, which creates X-rays. X-ray has a high capability to penetrate deep into materials to inactivate microorganisms; excellent penetration and broad material compatibility. Appropriate for a wide range of product densities.	Sterigenics. A Sotera Health company

RESULTS & CONCLUSION

The below results are a summary of study findings meant to provide direction and confidence to manufacturers as they consider use of these various sterilization modalities with materials in scope.

Detailed test results are available upon request.

Product	Performance Tests			Material Compatability		
	Non-sterile	Post-sterile	1, 2, 5yr AA	ClO_2	E-beam	X-ray
UT-73 / LF-1250AV	Tensile Strength Puncture Resistance Seal Strength Visual Inspection			✓	✓	✓
ST-7382C / UF-1250AV				✓	✓	✓
UT-73 / LF-2550AV				✓	✓	✓
UT-73 / LF-2550				Use with caution*	✓	✓
LF-2575AV / LF-2575AV				–	✓	✓
LC-1209AWV / LC-1209AWV				–	✓	✓
ST-7382C / PETG	Seal Strength Visual Inspection			✓	✓	✓
XT-73NP34 / PETG				✓	✓	✓
HDPE CleanCut Cards	Visual Inspection			✓	✓	✓

Based on the results in this study, there were no adverse effects to the seal strength or mechanical performance of these products due to exposure to chlorine dioxide (ClO_2), E-beam Irradiation or X-ray Irradiation. **These products are recommended for further analysis in applications using these sterilization modalities.**

*Film delamination is a potential concern for extrusion laminate films exposed to chemical gas modalities (EtO and ClO_2), particularly when using extreme parameters and test conditions

NOTE: Results are for reference only and do not include conclusions related to device compatibility or final sterile barrier system penetration considerations.

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STUDY SCOPE

Sterilization Parameters		
Chlorine Dioxide	**E-beam**	**X-ray**
Conditioning: 70% RH for 60min Gas Concentration: 1 mg/L ClO_2 gas Dosage: 3500 ppm-hours	Min. kGy: 52.8 Max. kGy: 55.2	Min. kGy: 44.7 Max. kGy: 46.7

Test Details	
Tensile Strength	ASTM F882, n=10
Puncture Test	ASTM F1306, n=10
Seal Strength	ASTM F88 Technique A, n=40
Visual Inspection	Color (Tyvek) and delamination or wrinkling (films)

Test Times & Accelerated Aging	Non-sterile	Post-sterile (t=0)	1yr, 2yr, and 5yr AA*

**ASTM F1980: 55°C (using Q10 = 2.0 and TRT = 23°C; every 1 year AA = 40 days chamber time)*

MATERIALS AND CONFIGURATIONS

Product	Material Description	Configuration
UT-73 / LF-1250AV	1073B Tyvek sealed to peelable PET/PE film (adhesive lamination)	Pouch
ST-7382C / UF-1250AV	Coated 1073B Tyvek sealed to PET/PE film (adhesive lamination)	Pouch
UT-73 / LF-2550AV	1073B Tyvek sealed to peelable Nylon/PE film (adhesive lamination)	Pouch
UT-73 / LF-2550	1073B Tyvek sealed to peelable Nylon/PE film (extrusion lamination)	Pouch
LF-2575AV / LF-2575AV	Peelable Nylon/PE film sealed to itself (adhesive lamination)	Pouch
LC-1209AWV / LC-1209AWV	Peelable Foil/PE film sealed to itself (adhesive lamination, white)	Pouch
ST-7382C / PETG	Water-based adhesive coated 1073B Tyvek/PETG strip	1”x2” (2.5cm x 5.1cm) sealed swatch
XT-73NP34 / PETG	Hot melt adhesive coated 1073B Tyvek/PETG strip	1”x2” (2.5cm x 5.1cm) sealed swatch
HDPE CleanCut Cards	28mil HDPE	5”x5” (12.7cm x 12.7cm) sample