E3609-70

ISO 10993-5 and -10 Compliant EPDM Seal Material

Proven Biocompatability:

Parker's 70 durometer EPDM compound E3609-70 has successfully passed ISO 10993-5 and -10 requirements. This material is also compliant to USP Class VI and USP <87>.

ISO 10993-5 evaluates materials for their potential to kill cell cultures. ISO 10993-10 tests materials for sensitivity and biological response. These standards are accepted in both the United States and the European Union for rubber materials used in surgical instruments, drug delivery devices, pharmaceutical and biopharmaceutical manufacturing, and other medical device applications.

Contact Information:

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Benefits:

- Excellent resistance to repeated steam, gamma, ozone, and ethylene oxide sterilization
- Compliant with ISO 10993-10 and USP Class VI biocompatibility standards
- Compliant with ISO 10993-5 and USP <87> cytotoxicity standards
- Low compression set
- Temperature range -65° to +250°F
- Compatible with all water-soluble chemistries

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Score Definition				
ISO 10993-10			ISO 10993-5	
Erthema (ER)	Edema (ED)	Grade	Reactivity	Conditions of all Cultures
No erythema	No edema	0	None	Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth.
Very slight erythema (barely perceptible)	Very slight edema (barely perceptible)	1	Slight	Not more than 20% of the cells are round, loosely attached and without intracytoplasmic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable
Well-defined erythema	Well-defined edema (edges of area well-defined by definite raising)	2	Mild	Not more than 50% of the cells are round, devoid of intracytoplasmic granules; no extensive cell lysis; not more than 50% growth inhibition observable.
Moderate erthema	Moderate edema (raised approximately 1 mm)	3	Moderate	Not more than 70% of the cell layers contain rounded cells or are lysed; cell layers not completely destroyed, but more than 50% growth inhibition observed
Severe erythema (beet redness) to eschar formation preventing grading of erythema	Severe edema (raised more than 1 mm, and extending beyond exposure area)	4	Severe	Nearly complete or complete destruction of the cell layer

The requirements of the test were met if the difference between the test extract overall mean score and corresponding control overall mean score was 1.0 or less.

ISO 10993-5 Cytotoxity Testing					
Well	Percent Rounding	Percent Cells Without Intracytoplasmic Granules	Percent Lysis	Grade	Reactivity
Test (1)	0	0	0	0	None
Test (2)	0	0	0	0	None
Test (3)	0	0	0	0	None

Recommended for:

- Surgical instruments
- Pharmaceutical manufacturing
- Biopharmaceutical processing
- Disposable medical devices
- Repeated device sterilization

ISO 10993-10 Biocompatibility Testing		
	0.9% NaCl in Water	Sesame Oil
Extraction Process Condition	1 hr at 121°C Clear	1 hr at 121°C Clear
Test Group Mean	0.0	0.9
Control Group Mean	0.0	0.8
Allowable Limit	1.0	1.0
Pass/ Fail	Pass	Pass
Overall Mean Difference	0.0	0.1

The test article met the requirements of the test since the difference between each test extract overall mean score and corresponding control overall mean score was 0.0 and 0.1 for the SC and SO test extracts, respectively.

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