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Data Sheet

SYNTHETIC POLYISOPRENE - K-440

K-440 is a synthetically manufactured polyisoprene. The base polymer is the same as natural rubber but is polymerized in a reactor producing an artificial latex. If your medical application demands the properties of natural rubber latex without the allergy concerns, K440 is the best product available today. The data below depicts typical properties.

1. Physical Properties:

• Tensile	2700 PSI min (18.6 MPa)	ASTM D 412
• Ultimate Elongation	750% min	ASTM D 412
• 100% Modulus	140 PSI avg (1.0 MPa)	ASTM D 412
• 300% Modulus	230 PSI avg (1.6 MPa)	ASTM D 412
• Durometer (hardness)	36 Shore A	ASTM D 2240
• Specific Gravity	0.96 Grams/cc	Federal Test Method Standard 601
• Color	Amber	For identification purposes only; no evaluation is made for degree. Lot to lot variation can be expected.

2. Medical Compatibility: This compound has been tested and passes USP XXII biological Class VI Testing.

• Cytotoxicity – Aggrose Diffusion	Non-toxic
• Acute Systemic Toxicity	Passes
• Intracutaneous Toxicity	Passes
• Implantation Test	Passes
• Primary Skin Irritation Study	Passes
• ISO Vaginal Irritation Study	Passes
• ISO Sensitization Study	Passes

3. FDA Food Grade Compliance: K-440 compound is FDA food grade compliant. All materials used in this compound meet recommended safe levels as specified in the United States FDA Code of Federal Regulations, Title 21, Food and Drug Administration.

<u>Material</u>	<u>21 CFR Section</u>
• Polyisoprene	177.2600
• Zinc Oxide	182.5991
• Age Resistor	177.2600
• Vulcanization Accelerator	177.2600

4. Product Testing: USP XXII Plastic Physiochemical Test results:

• Heavy Metals	< 1 ppm
• Extractables (total mg.)	5.4 mg

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