

## Mitt Biocompatibility

The sanitary mitt is a body surface-contacting component with contact time well below 24 hours in duration. It is a custom-made HDPE mitt manufactured by Elkay Plastics. The sanitary mitt material specification is provided on the following page.

Biocompatibility testing for cytotoxicity, skin sensitization, and irritation was performed by Nelson Laboratories, an independent microbiology testing services company in Salt Lake City, Utah. The AVACEN Sanitary Mitt passed all 3 tests.

- Cytotoxicity Results using Agar Overlay test
  - Results: “Pass”
- Irritation Testing Results using Primary Skin Irritation Test
  - Results: “The test article was classified as a negligible irritant under the conditions of this assay.”
- Skin Sensitization Results using a Repeated Patch Dermal Sensitization Test (Buehler Method of Modified for Medical Devices)
  - Results: “The test article did not elicit a sensitization response under the conditions of this assay.”

# PRODUCT SPECIFICATION AND DATA SHEET

## HIGH DENSITY POLYETHYLENE

The major advantage of High Density Polyethylene (HDPE) over LDPE is higher thermal resistance and generally better strength properties.

PROPERTY CONDITIONS	ASTM TEST METHOD	HDPE TYPICAL VALUES
<b>Resin Properties</b>		
Melt Index, g/10 min	D1238	.05
Density, g/cm <sup>3</sup>	D1505	.949
<b>Blown Film Properties</b>		
Elongation at Break, %	D638	>800
Tensile Strength Yield, psi	D638	3266
Tensile Impact Strength, ft-lbs/in <sup>2</sup>	D1822	140
IZOD Impact Strength, ft-lbs/in	D256	>7.35
VICAT Softening Point, °F <sup>Ⓞ</sup>	D1525	250 (121)
Stiffness Modulus, psi	D747	92,300
ESCR, F50, hr.	D1693	>1000
Service Temperature °F		-60 to 250
Heat Seal Temperature °F		290 to 370
Hardness, Shore D	D2240	63
Brittleness Temperature, °C	D746	>-70

**LEGEND**

ASTM AMERICAN SOCIETY OF TESTING MATERIALS

- Complies with the following **FDA Regulations**: 21 CFR 175.320, 21 CFR 177.1010, 21 CFR 177.1520, 21 CFR 177.1350, 21 CFR 178.2010, 21 CFR 178.3295, 21 CFR 178.3570, 21 CFR 179.45
- Contains **no** latex, mercury, sulfur, nitrogen, silicon, heavy metals, BPA (biphenyl A), polyvinyl chlorides, polystyrenes, polycarbonates, phthalates, BHT (butylated hydroxyl toluene), DEHA (diethyl hydroxylamine), DEHP (di (2-ethylhexyl) phthalate), PFOS (perfluorooctane sulfonates), PBDE (poly brominated diphenyl ether) or PBB (poly brominated biphenyl).
- Contains no animal derivative ingredients
- Complies with RoHS (Restrictions of Hazardous Substances)
- Complies with WEEE (Waste Electrical & Electronic Equipment)
- Complies with CMM (China's Management Methods)
- Complies with REACH (Registration, Evaluation, Authorisation and Restriction of Chemical Substances).
- Bag measurements are based on inside dimensions and meet industry standard tolerances.

In addition to the above specifications, Elkay Plastics Co., Inc. or its suppliers use no Ozone Depleting Chemicals in the manufacture of its products. The values shown on the chart above are typical values. Due to the use of various resins, additives and manufacturing processes, ELKAY PLASTICS COMPANY, INC. does not guarantee the same results as shown above. **Each user of the material should make their own tests to determine the specific products suitability for their particular application.**