Multipolymer acrylic alloy for medical devices

PLASTICS IN THE MEDICAL MARKET

by Daniel D. Zimmerman

Medical device designers, specifiers and molders use a number of polymers whose properties are critical to their use. For transparent medical devices utilizing thermoplastics, the key properties to consider include satisfactory mechanical properties, specifically impact resistance, property retention after sterilization, chemical resistance to commonly used chemicals, and moldability to fill thin parts in multicavity molds. Last, but not least, material biocompatibility is important since it will speed up development cycles of new devices.

Acrylics are well-known for their excellent clarity, good processability and relatively low cost. Several grades have been evaluated and found to meet the biocompatibility requirements as shown by USP (United States Pharmacopeia) Class VI testing and the newer, more extensive Tripartite testing and ISO 10993 testing. However, general purpose acrylic can have limitations like sufficient impact resistance and limited chemical resistance to commonly used chemicals in the medical industry. Even high molecular weight PMMA (polymethyl methacrylate) has only very limited resistance to IPA (isopropanol alcohol).

CYRO Industries' new CYROLITE® Med 2 acrylic-based multipolymer compound offers medical device manufacturers a superior new level of alcohol and lipid resistance.

Two types of acrylic

Over the years, two types of impact-modified acrylics have been developed. The first type is based on compositions where acrylic-based multipolymers consisting of predominantly methyl methacrylate, copolymerized with styrene and acrylonitrile, are impact-modified with a compatible rubber modifier so as to increase impact resistance. These materials retain clarity, exhibit excellent processability, and also show improved toughness, impact strength and chemical resistance.

These properties are retained after gamma or EtO (ethylene oxide) sterilization, though there is some color formation on gamma sterilization. However, specially formulated acrylics that utilize a patented stabilization package can practically eliminate color formation.

The second type of impact modified acrylic is based on straight acrylic modified with compatible acrylic rubber. These materials exhibit excellent clarity and improved toughness over straight acrylics, as well as good processability, and their chemical resistance is also improved over straight acrylics. They are generally less resistant to IPA and some other chemicals and less impact resistant than the first type. Their main advantage resides in their excellent outdoor weatherability.

Chemical resistance methodology

Both impact modified acrylics described above, though superior in chemical resistance to straight acrylics, are still inadequate in certain applications requiring increased chemical resistance to IPA and lipids. The methodology used in evaluating chemical resistance involves using tensile specimens subjected to a given strain while in contact with the tested chemical for specified times and temperatures. Thus, a tensile bar is fixed on a curved jig of a given radius, imparting a strain to the specimen. From the known values of the radius and the thickness of the specimen, the strain on the sample can be calculated: strain = specimen thickness/(2 radius + specimen thickness). From the known value of the modulus of the material, the stress can be calculated as well: stress = modulus * strain.

The specimen is left on the jig for a predetermined time period while wetted with the chemical, evaluated and checked periodically for evidence of crazes and breaks. If the specimen survives without breakage, it is tested for tensile properties and compared to a control that has not been exposed to the chemical. The results are averaged for five specimens and presented as percent tensile strength and elongation retention. The latter is the more sensitive criterion.

Third type of acrylic developed for medical applications

A new methacrylate copolymer compound for injection molding, specifically developed for medical applications, exhibits greater resistance to isopropanol alcohol than most other acrylic materials. This compound's chemical resistance to IPA and lipids is superior to a number of other clear materials, including copolyesters, styrene-butadiene and clear ABS.

The methacrylate copolymer under strain (at 1.2 percent strain/24 hrs/30 C) in lipid maintains its tensile properties, while other materials show varying degrees of severe attack. Lipid resistant polycarbonate, however, does show better IPA resistance at more severe testing conditions (exposure at five hours vs. three hours previously, at 0.9 percent strain and at 20 C). At these conditions, the compound fractures after 4.25 hours, while the polycarbonate remains essentially unaffected.

Fourth type of acrylic with improved alcohol and lipid resistance over PC

The limited IPA resistance of this methacrylate copolymer compound at the higher strain rates led to the development of a new grade, an alloy of multipolymer with a compatible polymer which results in dramatically improved IPA resistance, as well as good lipid resistance.

To further determine how this multipolymer compound compares to well known IPA resistant materials such as polycarbonate, we evaluated its property retention at more severe conditions by varying its strain rate while under IPA and lipid. The results are shown in Figures 1 and 2. Thus, while exposed to lipids at a 2.0 percent strain rate, this new multipolymer compound shows excellent property retention, while the lipid resistant PC fails at 1.2 percent strain.

The compound also shows excellent property retention in IPA at a 2.0 percent strain rate, while PC deteriorates rapidly at 1.2 percent strain rate. It demonstrates no deterioration after sterilization at typical gamma or E-beam irradiation levels. Sterilization with ethylene oxide gas is possible without any adverse effects.

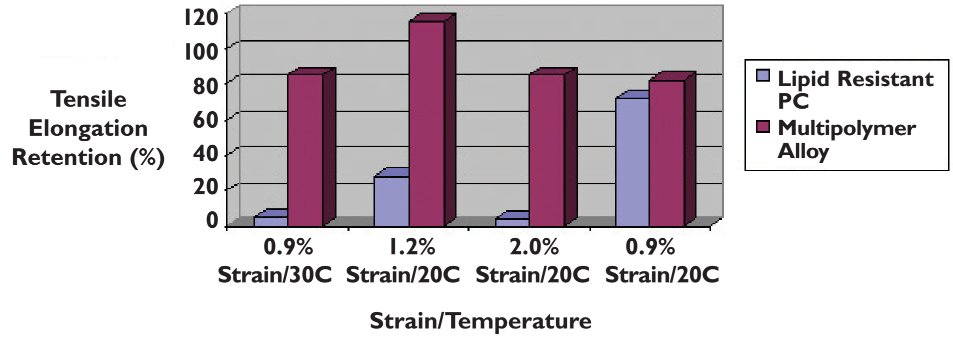

FIGURE 1: LIPID RESISTANCE vs. STRAIN RATE

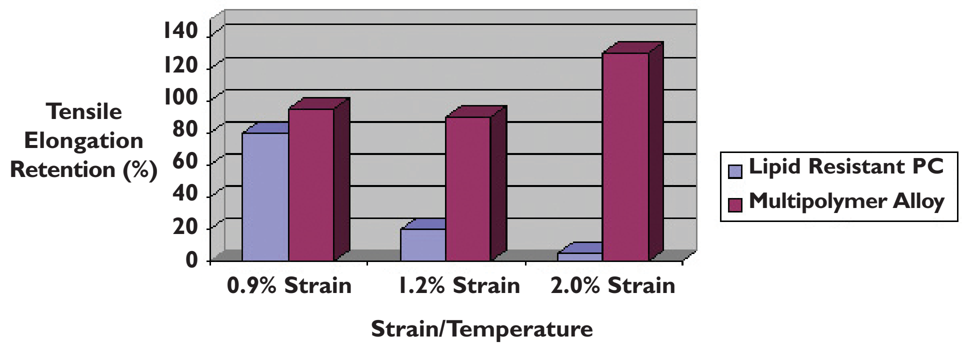

FIGURE 2: IPA RESISTANCE vs. STRAIN RATE

Processability

The compound exhibits excellent processability at low temperatures. One good indicator of processability is flowability, which can be measured under actual injection molding conditions in terms of flow length. Under testing, the compound performed better than other impact modified acrylics. This enables the product to be used for thin-walled applications and difficult-to-mold parts in multicavities. Typical applications can include filter housings, luers, IV connectors and accessories, spikes, cassettes, Y-sites, check valves, pumps, catheter adapters, and caps and funnels for blood filters.

Conclusion

A new medical acrylic-based multipolymer compound offers outstanding lipid and IPA resistance. It retains the good acrylic properties of clarity, processability and impact resistance, even after gamma and EtO sterilization. It has successfully passed testing for biocompatibility as per USP VI, Tripartite testing and ISO 10993 testing. ■

Daniel D. Zimmerman has over 30 years' experience in product and process development, technical service and new product introduction. Currently, his work at CYRO is aimed at developing acrylic-based products for medical applications, electrostatic dissipative products, and applications with demanding thermal and UV requirements. For more information, contact CYRO Industries, 379 Interpace Parkway, Parsippany NJ 07054; 800-631-5384, or visit us on the web at www.cyro.com.