

## Branded & Generic Prime Comparisons



Branded Prime	Mtegrity <sup>™</sup> Generic Prime
Identifies producer's grade	Mtegrity <sup>™</sup> grade
Single resin grade	Similar grades from different producers
Tight specification range	Slightly broader specification range to accommodate the several approved grades
Lot-to-lot consistency	Within-lot consistency
Producer's technical data sheet	Mtegrity <sup>™</sup> technical data sheet
Full producer certifications	Mtegrity <sup>™</sup> certifications
FDA compliance letters	FDA compliance on MHC letterhead
Full regulatory documentation	No regulatory documentation (UL, NSF, DMF, USP, REACH, etc.)



# **Resin Class Definitions**

#### **Branded Prime**

As an authorized distributor, M. Holland Company sells all branded prime material under the resin nomenclature and specifications of the manufacturer. All regulatory and certification documents accompanying the branded prime resin will be provided on the manufacturer's letterhead. This includes items such as Certification of Analysis, FDA compliance statements and other regulatory declarations.

#### **Generic Prime**

Mtegrity<sup>™</sup> generic prime resin is certified producer prime resin. Generic prime material will be represented under M. Holland Company's nomenclature. All lot-specific documentation is provided on M. Holland Company letterhead. M. Holland Company has the producer prime certifications on file for our reference and traceability. FDA compliance statements are generally available unless otherwise stated on the data sheet, whereas other regulatory declarations such as Drug Master File (DMF), UL, NSF, REACH, CONEG, etc., are not available with generic prime resins.

### Non-Prime Resin (Off-Grade/Wide Specification/ Down-Grade/Near Prime/Pencil Prime)

These products do not fall within the producer's range for prime certifications. Therefore, these materials cannot be sold as prime grades. Generally, producers no longer offer any regulatory statements on these resins, including FDA compliance. These non-prime resins cover the wide range of product quality offered on the secondary market. No Certifications of Analysis can be issued on these resins. M. Holland Company can only provide as a reference the attributes of these non-prime materials as reported to us by the manufacturer. Some variability can and does occur with these non-prime resins. These products are almost solely sold on an "as available" basis.



