

Silver Ion Antimicrobials in Medical Plastics

When LTL Color Compounders expanded its business in the medical device area in 2008 with the introduction of the ColorRx® line of medical grade resins, they recognized the need to include antimicrobial (AM) protection in the product line. This reflected the heightened concern in the medical and government regulatory communities regarding the increasing number of hospital-acquired infections. LTL, who celebrated its 21st anniversary in July, has, for years, participated in the medical market by supplying custom colors and additives in resins specified by the OEM. They built on this experience by creating the ColorRx line based on pre-selected medical grade resins and colorants.

Silver ion AM is a well-tested, very low toxicity approach to controlling the growth of microorganisms on plastic surfaces. This “silver bullet” prevents the replication of the microorganisms so that over a matter of hours the organism count on the surface declines dramatically. LTL has teamed up with a major international supplier of silver ion AM to offer an especially efficient and cost effective additive. Due to the nature of the inorganic matrix used in this AM, the silver ions are more readily available at the surface of the plastic, which translates into using a lower dosage as compared to other silver ion AMs.

According to Phil Dix, LTL’s Medical Marketing and Development Manager, tests conducted on a number of resins and colors indicate that typical microbial count reductions as great as log 3 to 4, or even more, can be achieved with unusually low AM levels. Log reduction refers to powers of 10: A 99% (100-fold) reduction is log 2, 99.9% (1000-fold) is log 3, 99.99% is log 4, etc. For example, sample coupons of natural polypropylene that were inoculated with *E. coli* bacteria showed greater than log 4 reduction in bacteria count after 24 hours. With *Staphylococcus aureus*, the reduction in PP was greater than log 3. In samples of polycarbonate and ABS, the reduction exceeded log 4 for both species. ABS required a slightly higher loading of AM than the other resin grades.

These are typical data intended only to give an indication of the effectiveness of the silver ion AM and will vary depending on compounding conditions, added colorants, and bacteria growth test methods. These data should not be used for regulatory submissions and are not to be construed as making human health claims.

The predicted life of the silver ion AM is excellent. The manufacturer has conducted accelerated testing and predicts little to no loss in efficacy over 5 years. In addition, LTL conducted tests to simulate the use of sanitizing bleach solutions as an adjunct to silver ion AM. Bleach can be used for immediate reduction in bacterial contamination and the silver ion AM then suppresses the replication of any remaining bacteria or new bacterial contamination. After extended exposure to a bleach solution, sample chips still exhibited greater than a log 3 reduction of *E. coli* and *S. aureus* over 24 hours.

The silver ion AM being used by LTL is approved for food contact applications and can be used in FDA regulated medical devices. It should be noted that human health claims for medical devices that go through FDA scrutiny are allowed with adequate supporting data. In the absence of such data and FDA approval, the EPA registration exemption for silver ion AMs allows only claims that the plastic article itself is protected from the effects of microorganisms, such as a development of color, odor, or degradation.

For additional information on products protected with silver ion AM, custom compounded, or ColorRx products, contact Phil Dix at LTL at phil.dix@ltlcolor.com or phone 800-863-4260.