

May 2009

Adhesives for Disposable Medical Devices

Adhesive Biocompatibility

To ensure biocompatibility after cure, manufacturers often subject adhesives to various levels of toxicity screening prior to their qualification. To assure manufacturers that the materials they intend to use will be biocompatible when fully cured, DYMAX offers a number of materials that meet ISO 10993 and/or USP Class VI standards. All testing is performed by an independent laboratory certified in biocompatibility testing of medical devices and components.

Testing/Results

Many DYMAX medical-grade adhesives are subject to a standard test regimen which may include, but is not limited to, the following:

- Elution Test for Cytotoxicity
- Systemic Injection
- Intracutaneous Injection
- Non-Permanent Implantation
- Hemocompatibility

Test results are kept on file at DYMAX and summary copies are available to customers upon request.

Adhesive Modifications and Their Effect on Biocompatibility

Manufacturers often request minor modifications to our standard medical products in order to make them more suitable for their unique assembly processes. Some of these modifications only require adjustments to the concentration of existing ingredients within the adhesive. Others may require the addition of ingredients found in other biocompatible DYMAX medical-grade adhesives. Customer feedback and our own testing indicate that these minor adjustments do not affect product biocompatibility. More specifically, DYMAX has identified four commonly performed modifications which have no effect on the biocompatibility of a previously certified DYMAX medical grade adhesive. In any combination, these include:

- Broadening the ability of a UV-curable adhesive to absorb visible light for faster curing and/or curing through a UV-blocked substrate
- Adding a blue- or red-fluorescing indicator for black light inspection
- Customizing product viscosity by adding or reducing concentrations of a bio-inert filler
- Addition of See-Cure technology

Supporting this position are the results of independent testing performed at DYMAX's request on various modified adhesives. For example, the standard DYMAX 136-M was modified to cure with UV and visible light, fluoresce, and possess non-migrating gel viscosities. The new product, identified previously as 1-20430, or 1136-M-GEL, and the control 136-M were subjected to a full series of USP Class VI biocompatibility tests and the ISO 10993 Elution Test for Cytotoxicity. Both the control 136-M and the modified 1136-M-GEL passed all the testing, indicating that these changes had no effect on biocompatibility. This position is supported by device manufacturers who have conducted their own independent testing; and reported back that there were negligible differences in products modified as listed above.

Another recent example was the test and evaluation of the 1187-M control versus the modified version 1201-M-SC, which included the See-Cure technology, whereby the material changes color from blue-to-clear upon reaching a fully cured state. Both versions passed the DYMAX regimen of ISO 10993 biocompatibility testing, indicating, to the best of our knowledge, that the addition of See-Cure technology does not have an impact on biocompatibility of the adhesive.

Please contact DYMAX Applications Engineering at (860) 482-1010 for more information about your specific adhesive or application.

Sincerely,



Kyle Rhodes
Medical Market Manager

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