TECH TIP 31

EPOXY TECHNOLOGY

Understanding Biocompatibility of Epoxy Adhesives Versus Curing Schedule

WHAT

Biocompatibility is sensitive to the curing process.

WHY

Epoxy users might not be fully aligned with the curing schedule and biocompatibility in the device.

Problem statement:

The data sheet defines a curing schedule, under which the epoxy is proven to be biocompatible, but is it biocompatible in the parts or intended device? Let us take a closer look where the manufacturer and user may not be aligned fully.

What are Epoxy Technology's concerns?

Epoxy Technology guarantees a biocompatible outcome at a single curing schedule, but it does not mean others are not possible. Since ISO 10993 tests are expensive, arranged through 3rd parties with months of lead-time, biocompatibility versus curing schedule is generally unproven.

As the manufacturer, we define properly cured epoxy based on thermodynamics such as exothermic energy and resulting Tg, mechanically speaking based on shear strength and physically speaking based on hardness and a tack-free surface, but not normally based upon biocompatibility. To increase the chances of a biocompatible outcome, we take a conservative approach by using "extra curing" via increased temperature and time when selecting a curing schedule.

What are Epoxy Technology's assumptions?

Epoxy Technology assumes other biocompatible curing processes are possible but not proven. The lowest risk route is to cure or post-cure always at the guaranteed biocompatible listed cure. We also assume that the epoxy was handled in the best-case scenario possible, such as the accuracy of the mix ratio, the mass of the epoxy mixture and the homogenous manner in which it was prepared and deposited onto clean parts. (See Tech Tips #1, 2, 4, 6, 9 and 10)

What are the epoxy user's concerns?

All customers want proof of a biocompatible outcome on their parts. This may not come from the adhesive itself, but a biocompatible device is a mandatory expectation. Since every application is unique, the customers wish to know what happens biocompatibility-wise if changes in the curing schedule, whether temperature, time or both, are required contrary to the epoxy's data sheet due to restrictions relating to other materials or aspects of the device design. There is no question that the most common concern by our customers is that they cannot precisely follow the data sheet's guaranteed biocompatible cure.

What are the epoxy user's assumptions?

Among users of "medical-grade epoxy," there seems to be a general assumption that biocompatibility versus curing process is known. As described above, this topic needs further study. There is also a general assumption that the epoxy is sterilized before the ISO 10993 test as the final medical devices carry this expectation. In short, the biocompatibility versus curing schedule is unknown, as is the case with sterilization and disinfection.

What is the biggest risk?

Epoxy Technology finds that the cure temperature is the most common risk when selecting epoxies for biocompatible applications. The reason is that temperature limitations affect the degree of cure, evidenced by lower temperature cure yielding lower strength, hardness Tg and performance. Similarly, low temperature curing might also imply a lower biocompatibility outcome due to incomplete crosslinking. Medical devices are temperature limited due to the plastics they contain, or be-

cause of other components such as Lithium-ion batteries. For this reason, users look for biocompatible epoxy with curing processes < 65°C. Since epoxy resin curing usually has a temperature & time relationship, customers often attempt to mitigate risk by adding more time into the curing process. There is less flexibility when it comes to employing higher cure temperatures to boost cross-linking performance.

What is the position with regards to UV curing epoxy?

Since oven curing uses temperature and time models, which seldom needs translation or definition, UV curing is not so simple. In this case, UV is rarely a constant and therefore the parameters must be defined in order to make the fullest cross-linking. The efficacy of a UV cure is influenced by the form factor, technology, optical spectra and power. This table shows typical choices when it comes to delivering a UV cure. The result of not using the correct UV parameters is under-cured epoxy with a strong likelihood of failures during ISO 10993-5 cytotoxicity testing. It is important to match the data sheet UV curing parameters, in addition to any post-curing instructions, to ensure a successful outcome.

UV Parameters	Option A	Option B
Form factor	Flood/ cabinet	Fiberoptic "spot cure"
Technology	Hg light source	LED
Spectra	Broad rays (200-600nm)	Narrow range (350-400nm)
Optical power (bond-line)	Low (<100mW/cm²)	High (>200mW/cm²)

What else needs to be considered for ensuring a biocompatible outcome?

The mass of an epoxy resin mixture and cure is one area of concern. Since epoxy cures in an exothermic (and mass sensitive) fashion, a larger mix mass makes for better curing. For this reason, we suggest never mixing <2 grams for a two-component epoxy. Consequently, we recommend that the customer buys the pre-mixed/ frozen version from us, thus eliminating mixing errors on their side and the need to make small mixes.

Depending on the product, occasionally a larger mass must be “staged” for some time in order to expect proper curing at the micro-gram mass level on the parts or device. Staging is essentially building more exothermic fuel, to ensure a fully cross-linked cure, by mixing larger masses than expected, resulting in higher heat generation throughout the early onset of its pot-life. Contact ***techserv@epotek.com*** for staging recommendations. Another area of concern is a phenomenon called amine blush or bloom, which is an unwanted side effect when room-temperature curing in high humidity (>60%). See Tech Tip #28 for more information. In short, improperly cured material, resulting from low mass or amine blush/bloom can lead to biocompatibility failures.

How did Epoxy Technology select its Biocompatible Curing Schedule?

As stated above, we used conservative measures to give “extra curing” by our temperature and time selection for each product. We also based them on historical processes, polymer chemistry and theory, professional hunches and the occasional trial-and-error. Our product lineup guarantees biocompatibility at 45C, 65C, 80C, 150C, UV + oven, and UV only curing schedules. Let us help you select the best products matched to your curing intentions and application.

ISO 10993

All EPO-TEK® Medical Device grade adhesives (“MED”) are ISO 10993 tested for biocompatibility

EPO-TEK® MEDICAL GRADE EPOXY TECHNOLOGY

REACH COMPLIANCE

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