

Biological evaluation of Shin-Etsu Silicones

KEG-2000 series

We firmly believe that KEG-2000 series will pass the tests in ISO10993 (cytotoxicity, skin irritation, sensitization, hemolysis, hemostasis activation, pyrogenicity, 12-weeks-implantation) for following reasons.

These ISO10993 tests have been carried out with KEG-2000-20A/B. The KEG-2000-20A/B contains the least amount of filler of KEG-2000 series. This material would be considered the worst case scenario of hazardous material migration because of the low filler content. KEG-2000-20 has passed all the ISO10993 tests referenced in this letter without showing any adverse effects. The change in proportion of filler does not alter the chemical composition and processing of the material in a manner that would affect it meeting the requirements of ISO10993.

KEG-2000 series : KEG-2000-20-A/B, KEG-2000-30-A/B, KEG-2000-40A/B
KEG-2000-50A/B, KEG-2000-60A/B, KEG-2000-70A/B, KEG-2000-75A/B
KEG-2000-80A/B

Your kind consideration and arrangements will be greatly appreciated.



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“ Quality is under his responsibility. “

Please keep all information confidential to any other companies.