

Immunological Evaluation of Silicone Gel in Female B6C3F1 Mice

VII. Conclusions

These studies were conducted for McGhan Medical Corporation by _____ to determine the potential of the Silicone Gel Test Article to compromise the immune system. In female B6C3F1 mice implanted with Silicone Gel Test Article for 28 days, no biologically significant effects were observed on standard toxicological parameters including body weight gain, thymus weights, thymus histopathology, or hematological parameters. While a slight increase in spleen weight was observed at the high dose, no adverse effect on the functional integrity of the immune system occurred. Furthermore, studies by Luster *et al.*¹⁴ have demonstrated that changes in lymphoid organ weights alone are not good predictors of immunotoxicity.

Exposure to the Silicone Gel Test Article did not produce significant changes in the functional ability of the immune system. No significant changes were observed in B cell, T cell, or T cell subset populations following exposure to the Silicone Gel. In the three functional assays, the IgM spleen antibody-forming cell response, the mixed leukocyte response, and the natural killer cell assay, no significant decrease in function was observed in the animals exposed to the Silicone Gel Test Article.

The results of this comprehensive immunotoxicological evaluation demonstrate that, under the experimental conditions used, exposure to the Silicone Gel Test Article did not adversely affect the functional ability of the immune system.