TEST FACILITY:

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SPONSOR:

Henkel Corporation
One Henkel Way
Rocky Hill, CT 06067

Modified Summary Test Certificate Biological Evaluation of Medical Devices

Test Article:

Loctite 4902FL

Identification No.

Batch# L36F00079

Completed Tests

ISO 10993-5:	Tests for Cytotoxicity
ISO 10993-10 / USP <88>:	Tests for Irritation and Sensitization
ISO 10993-11 / USP<88>:	Tests for Systemic Toxicity
ISO 10993-4:	Selection of Tests for Interactions with Blood
ISO 10993-6	Tests for Local Effects after Implantation

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ISO 10993-5: Tests for Cytotoxicity

Cytotoxicity Study by Elution

The test article was prepared at a ratio of 6 cm^2:1 mL, and extracted with agitation in minimal essential medium at 37°C for 24 hours. This test extract was placed onto three separate confluent monolayers of L-929 mouse fibroblast cells propagated in 5% CO_2. All monolayers were incubated at 37°C in the presence of 5% CO_2 for 48 hours. The monolayer in the test, reagent control, negative control and positive control wells was examined microscopically at 48 hours to determine any change in cell morphology. The test article cytotoxicity grade was 0. The requirements of the test were met.

ISO 10993-5: Tests for Irritation and Sensitization ISO 10993-10 / USP <88>

Intracutaneous Reactivity Study

The test article was prepared based on a ratio of 6 cm^2:1 mL, and extracted in 0.9% sodium chloride USP solution (SC), alcohol in saline 1:20 solution (AS), polyethylene glycol 400 (PEG), and sesame oil, NF (SO) at 37°C for 72 hours. A 0.2 ml dose of the appropriate test article extract was injected intracutaneously into five sites on the right side of the back of each rabbit. Similarly, the corresponding reagent control was injected on the left side of the back of each rabbit. The injection sites were observed for erythema and edema after injection and at 24, 48 and 72 hours after injection. There was no to very slight erythema and no edema. The test article met the requirements of the study.

ISO 10993-11 / USP <88>: Tests for Systemic Toxicity

Acute Systemic Toxicity Study

The test article was prepared based on a ratio of 6 cm^2:1 mL, and extracted in SC, AS, PEG and SO at 37°C for 72 hours. A single dose of the appropriate test article extract was injected into each of five mice per extract. The animals were observed immediately and at 4, 24, 48, and 72 hours after systemic injection. The animals were weighed daily throughout the study. No mortality or evidence of significant systemic toxicity was noted. The test article met the requirements of the study.

ISO 10993-4: Selection of Tests for Interactions with Blood

Hemolysis Study by ASTM

The test article was prepared based on a ratio of 6 cm^2:1 mL, extracted in calcium and magnesium-free phosphate buffered saline (CMF-PBS) at 37°C for 72 hours. Blood was obtained from three rabbits, pooled, diluted and added to triplicate tubes of the test article extract and triplicate tubes of the test article in CMF-PBS to be tested as the direct contact. The tubes were then maintained in a stationary position for at least 3 hours at 37°C. Following incubation, the suspensions were centrifuged and the resulting supernatant was added to Drabkin's reagent. The absorbance of the extract was spectrophotometrically measured at a wavelength of 540 nm. The test article extract was considered nonhemolytic. At the sponsor's request, the results of the direct contact portion of the study will not be included in the certificate.

ISO 10993-6: Tests for Local Effects after Implantation

Subcutaneous Implantation Study

Previously sterilized test and control samples were aseptically prepared. Three rabbits were implanted with a minimum of 4 test and 4 control samples each and were then euthanized 2 weeks later. Subcutaneous tissues were excised and the implant sites were examined macroscopically. After histological preparation, a microscopic evaluation of representative implant sites from each rabbit was conducted to further define any tissue response. The macroscopic reaction was not significant as compared to the negative control implant material. Microscopically, the test article was classified as a nonirritant as compared to the negative control article.

Approved by Arizona Eugene Carter Date 02-14-17

Arizona E. Carter, BS, ALAT