NAMSA
Ensuring Medical Device Safety and Compliance™

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Confidential

Steve Dively
Dicronite Dry Lube
1326 Larson Street
Sycamore, IL 06178

Lab No. 98C 15673 00
03T_20032_0
03T_21108_01
Test Facility: NAMSA
6750 Wales Road
Northwood, OH 43619

REISSUED REPORT

SUMMARY CERTIFICATE - BIOLOGICAL EVALUATION OF MEDICAL DEVICES

Test Article: Dicronite Dry Lube DL-5
Dicronite Dry Lube

ID No. 477356797
07061/02/21503
07061/02/21703

The above referenced materials were evaluated based on ISO 10993. The sample met the criteria of the studies listed and summarized below.

ISO 10993-10: Tests for Irritation and Sensitization

Intracutaneous Reactivity Study: The test article was prepared at a ratio of 60 cm^2:20 ml and extracted in each of saline, alcohol in saline, polyethylene glycol 400, and cottonseed oil at 121°C for 1 hour. Three rabbits were prepared per pair of extracts. A 0.2 ml dose of the appropriate test article extract was injected by the intracutaneous route into five separate sites on the right side of the back of the rabbits. Similarly, the corresponding reagent control was injected on the left side of the back of each rabbit. Observations for erythema and edema were conducted at 24, 48, and 72 hours after injection. There was no evidence of significant irritation from the extracts injected intracutaneously into rabbits. The Primary Irritation Index calculated for each extract was negligible.

ISO 10993-11: Tests for Systemic Toxicity

Acute Systemic Toxicity Study: The test article was prepared at a ratio of 60 cm^2:20 ml and extracted in each of saline, alcohol in saline, polyethylene glycol 400, and cottonseed oil at 121°C for 1 hour. A single dose of the appropriate test article extract was injected into each of five mice per extract by either the intravenous or intraperitoneal route. Similarly, five mice were dosed with each corresponding blank vehicle. The test extracts did not produce a significantly greater systemic reaction than the blank extractants. Each test article extract met the test requirements.

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

Hemolysis Study: Based on the ratio of 60 cm^2:20 ml, duplicate preparations of the material in saline were extracted at 121°C for 1 hour. Blood was obtained from three rabbits, pooled, diluted and added to duplicate tubes of the test article extract. Following incubation, the suspensions were centrifuged and the resulting supernatant was spectrophotometrically measured at a wavelength of 540 nm. The mean hemolytic index for the test article extract was 0% and the test article extract was considered non-hemolytic.

ISO 10993-6: Tests for Local Effects after Implantation

Muscle Implantation Study: Implant samples and negative control samples were sterilized steam. Rabbits were implanted and were then euthanized 1 week later. Muscle tissues were excised and the implant sites were examined macroscopically. 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.

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REISSUED REPORT

SUMMARY CERTIFICATE - BIOLOGICAL EVALUATION OF MEDICAL DEVICES (continued)

ISO 10993-5: Tests for Cytotoxicity

Cytotoxicity Study Using the Elution Method: The test article was prepared at a ratio of4 g:20 ml, in minimal essential medium and extracted at 37°C for 24 hours. This test extract was placed onto three separate confluent monolayers of L-929 mouse fibroblast cells. All cell 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 showed no evidence of causing cell lysis or toxicity.

ISO 10993-3- Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity

Bacterial Reverse Mutation Study The test article was prepared at a ratio of 4 g:20 ml, extracted in saline at 70°C for 24 hours. A *Salmonella typhimurium* and *Escherichia coli* reverse mutation standard plate incorporation study was conducted to evaluate whether the extracts would cause mutagenic changes in the average number or revertants for histidine-dependent *Salmonella typhimurium* strains TA98, TA100, TA1535, and TA1537, and in tryptophan-dependent *Escherichia coli* strain WP2*uvrA* in the presence and absence of S9 metabolic activation. The saline extract was found to be noninhibitory to growth of tester strains TA98, TA100, TA1535, TA1537, and WP2*uvrA*. Separate tubes containing 2 ml of molten top agar supplemented with histidine-biotin solution for the *S. typhimurium* strains and with tryptophan for the *E. coli* strain were inoculated with 0.1 ml of culture for each of five tester strains, and 0.1 ml of the saline extract. A 0.5 ml aliquot of sterile Water for Irrigation (SWI) or S9 homogenate, simulating metabolic activation, was added when necessary. The mixture was poured across triplicate Minimal E plates. Parallel testing was also conducted with a negative control and five positive controls. The mean number of revertants of the triplicate test plates was compared to the mean number of revertants of the triplicate negative control plates for each of the five tester strains employed. The means obtained for the positive controls were used as points of reference. The saline test article extract was considered to be nonmutagenic to *Salmonella typhimurium* tester strains TA98, TA100, TA1535, and TA1537, and to *Escherichia coli* strain WP2*uvrA*. The negative and positive controls performed as anticipated.

ISO 10993-10: Tests for Irritation and Sensitization

Maximization Sensitization Study: The test article was prepared at a ratio 4 g:20 ml in saline, then extracted at 70°C for 24 hours. The extract was intradermally injected and occlusively patched to ten test guinea pigs in an attempt to induce sensitization. Following a recovery period, the test and control animals received a challenge patch of the test article extract and the reagent control. All challenge sites were scored at approximately 24, 48 and 72 hours after patch removal. The test article showed no evidence of delayed dermal contact sensitization. The semiannual positive control validation study is on file.

Original Date Completed January 23, 2004 Approved By Jason J Anderson 2-13-04
Jason J. Anderson, MS
Technical Specialist