TOXIKON

ISO-9001 Certified

# TEST RESULT CERTIFICATE

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| **Sponsor** | Cyberbond LLC | **Technical Initiation** | 04/26/02 |
| **Address** | 401 N Raddant Rd. | **Technical Completion** | 04/29/02 |
| | Batavia, IL 60510 | **Report Date** | 05/10/02 |
| **Contact** | Kimberly McCall | **Amended Report Date** | 08/05/02 |
| **P.O. Number** | Not Supplied by Sponsor | **Project Number** | 02-2043-N1 |

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| **Test Article** | Apollo Cyanoacrylate Adhesive | **Ratio** | 6 $cm^2$ per 1 mL |
| **Lot # / Part #** | 1603, 2000W, 2008, 2009, 2011, 2028, 2077 | **Vehicles** | 0.9% USP Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) |
| **Study** | Intracutaneous Test/2 Extracts – ISO | **Temp/Time** | 70±2°C for 24 hours |

**REFERENCE:** The test was conducted based upon the International Organization of Standardization (ISO) Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Sensitization; EN/ISO 10993-10, 1996. Extraction procedures were based upon the standards set by EN/ISO 10993-12, 1997.

**GENERAL PROCEDURE:** The Intracutaneous Test is designed to evaluate local responses to the extracts of test articles, following intracutaneous injection into rabbits. The test article was extracted in NaCl and CSO at a ratio of 6 $cm^2$ per 1 mL at 70±2°C for 24 hours. Control extracts were prepared, in a similar manner to the test article, with each extracting medium. Three rabbits were injected intracutaneously, using one side of the animal for the test article extracts and the other side for the control extracts, at 0.2 mL per site. The injected sites were examined at 24, 48, and 72 hours post inoculation for gross evidence of tissue reaction such as erythema, edema, and necrosis. Values were calculated by averaging the scores for each of the test article and control extracts for each of three individual animals. This was performed by adding the scores for each animal for erythema and edema after each exposure. This total was divided by 15. The control score was subtracted from the test article score. Then, this calculated value for each animal was added together for a total of three animals. The total was divided by 3 to obtain the Primary Irritation Index. A Primary Irritation Index of 0.5 or less will be considered a negligible irritant. Test articles with indices greater than 0.5 to less than 2.0 will be slight irritants. Test articles with indices of 2.0 to less than 5.0 will be moderate irritants. Any test articles with an index of 5.0 or more will be considered severe irritants.

**RESULTS:** The test sites injected with the test article extracts did not exhibit any signs of erythema and edema through the seventy-two hour observation point. The Primary Irritation Index for both NaCl and CSO extracts of this test article is 0.0.

**CONCLUSION:** The test article, under requirements of International Organization of Standardization (EN/ISO) Biological Evaluation of Medical Devices - Part 10: for the Intracutaneous Test, is considered a negligible irritant.

**AUTHORIZED PERSONNEL:**

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