

SciLog D/N: 3149

Revision: A

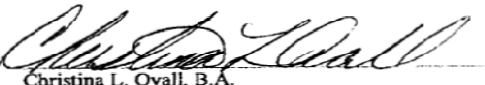
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**Title: USP Biological Reactivity Tests, In Vivo, Material Compliance Statement for SciLog Disposable Sensors**

This document applies to the following part numbers: 080-594PSX-5, 080-595PSX-5, 080-596PSX-5, 080-597PSX-5, 080-599PSX-5, 080-694PSX-5, 080-695PSX-5, 080-696PSX-5, 080-697PSX-5, 080-699PSX-5, 080-794PSX-5, 080-795PSX-5, 080-796PSX-5, 080-797PSX-5, 080-799PSX-5

(Lot Specific Documents are available upon request, preferably at time of order.)

<b>NAMSA</b>	
PEOPLE > SCIENCE > SOLUTIONS	
Confidential TCLAS_VI7	Lab No. 07T_42981_01 P.O. No. 4500331395 Test Facility: NAMSA 6750 Wales Road Northwood, OH 43619
Chris Smith Solvay Advanced Polymers, L.L.C. 17005 State Route 7 P.O. Box 446 Marietta, OH 45750	
<b>CERTIFICATE OF COMPLIANCE</b> <b>USP BIOLOGICAL REACTIVITY TESTS, <i>IN VIVO</i></b>  <b>USP PLASTIC CLASS VI</b>	
Test Article: Udel P-1700 Nt 11MG ID No.	
<p><b>USP Systemic Toxicity Study in the Mouse:</b> The test article was prepared as indicated below and injected into mice. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater systemic reaction than the blank extractants.</p> <p><b>USP Intracutaneous Toxicity Study in the Rabbit:</b> The test article was prepared as indicated below and injected intracutaneously into rabbits. The saline, alcohol in saline, polyethylene glycol 400 and sesame oil extracts did not produce a significantly greater tissue reaction than the blank extractants.</p> <p><b>USP Muscle Implantation Study in the Rabbit:</b> The macroscopic reaction of the test article, implanted in rabbit muscle for 1 week, was not significant when compared to the USP negative control plastic.</p> <p>The test article was prepared at a ratio of 4 g:20 ml and extracted at 121°C for 1 hour. The test article extracts met the requirements of a USP Plastic Class VI.</p>	
mdo Date Completed <u>8-10-07</u>	Approved By  Christina L. Ovali, B.A. Technical Writer
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