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Sponsor:
Henkel Corporation
One Henkel Way
Rocky Hill, CT 06067

Date of Test Completion: January 30, 2014
Project Numbers: 13-04234

ATTN: Colette Rich

Certificate of Compliance
ISO 10993 Biological Tests

Test Article Name: Loctite M-11FL

Bulk Number: Not Supplied by Sponsor (N/S)

Lot/Batch Number: LM3JA12656

HEMOLYSIS (ISO) –
Toxikon Project 13-04234–G1: The purpose of this assay is to evaluate the hemolytic potential of the test article. Hemolytic activity of the test article with rabbit blood indicated that the test article was non–hemolytic (< 5%).
Reference: ISO 10993–4, 2002, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, as amended 2006.

MUSCLE IMPLANTATION TEST (ISO) –
Toxikon Project 13-04234–G2: The purpose of the implant test is to evaluate local toxicity from direct exposure to the test article. The test article is implanted in the paravertebral muscle tissue of New Zealand White rabbits for a period of two weeks. The results indicate that the test article does not demonstrate any remarkable difference as compared to the control implant sites in local tissue responses and the potential to induce local toxic effects.
Reference: ISO 10993–6: 2007 Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation.

***IN VITRO* HEMOCOMPATIBILITY (ISO) –**
Toxikon Project 13-04234–G3:The purpose of the InVitro Hemocompatiblity test is to determine the effect of the test article or its extract to adversely affect selected hematological parameters, including the complete blood count, platelets count, hematocrit, and erythrocytes indices. The test article extract did not have any adverse effects on any of the hematological parameters tested.
Reference: ISO 10993–4:2002, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, as amended 2006.

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INTRACUTANEOUS INJECTION (ISO) –
Toxikon Project 13-04234–G4: The purpose of this test is to evaluate the irritation potential of the test article extracts in rabbits after intracutaneous injection. Test article extract in saline, cottonseed oil, polyethylene glycol 400, and alcohol in saline did not produce a significantly greater biological reaction than blank extract when injected intracutaneously into rabbits. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 36, National Formulary 31, 2013; Monograph <88>: Biological Reactivity Tests, *In Vivo*. The test article is not considered an irritant and passes the criteria set forth by the protocol.
Reference: ISO 10993–10, 2010 Biological Evaluation of Medical Devices – Part 10: Test for Irritation and Skin Sensitization.

L929 MEM ELUTION CYTOTOXICITY (ISO) –
Toxikon Project 13-04234–G5: The purpose of the MEM Elution is to determine biological reactivity of the mammalian cell culture (L929) in response to the test article extract via microscopic observation. The test article is considered non–cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993–5.
Reference: ISO 10993–5, 2009 Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity.

ACUTE SYSTEMIC INJECTION (ISO) –
Toxikon Project 13-04234–G6: The purpose of this assay is to evaluate the test article extracts for potential toxic effects as a result of single dose systemic injection in mice. Test article extracted in saline, cottonseed oil, polyethylene glycol 400, and alcohol in saline did not produce a significantly greater biological reaction than blank extract when injected into mice. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 36, National Formulary 31, 2013; Monograph <88>: Biological Reactivity Tests, *In Vivo*. The test article did not show greater biological reactivity compared to the control material.
Reference: ISO 10993–11:2006 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.

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PHYSICOCHEMICAL TEST (USP) –
Toxikon Project 13-04234–G7: This test determines some physical and chemical properties of extracts of the test article. The test article passes the USP Physicochemical Tests for plastics.
Reference: United States Pharmacopeia 35, National Formulary 31, 2013.

These studies are in conformance to all applicable laws and regulations. Specific regulatory requirements include the current Good Laboratory Practice for Nonclinical Studies (GLP), FDA, 21 CFR, Part 58.

Director of Biocompatibility

Quality Assurance

Date of Certificate: February 28, 2014