FOR US PRODUCED CA 435 ONLY

TOXIKON
Leaders in Life Science and Technology

Sponsor:
Henkel Corporation
1001 Trout Brook Crossing
Rocky Hill, CT 06067

Date of Test Completion: July 15, 2009
Project Numbers: 09–1572
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ATTN: Colette Kingsbury–Rich

Certificate of Compliance
ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

Test Article: LOCTITE® 435
Bulk Number: IDH# 1250431
Lot/Batch #: L39F007699

INTRACUTANEOUS INJECTION (ISO) – Toxikon Project 09–1572–G1: 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 32, National Formulary 27, 2009; Monograph <88>: Biological Reactivity Tests, *In Vivo*. Based on the criteria set forth by the protocol, the test article is considered a negligible irritant.
Reference: Biological Evaluation of Medical Devices – Part 10: Irritation and Delayed–Type Hypersensitivity, ISO 10993–10, 2002, as amended 2006.

ACUTE SYSTEMIC INJECTION (ISO) – Toxikon Project 09–1572–G2: 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 32, National Formulary 27, 2009; Monograph <88>: Biological Reactivity Tests, *In Vivo.* The test article did not show greater biological reactivity compared to the control material.
Reference: Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity, ISO 10993–11:2006.

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CYTOTOXICITY (ISO) – Toxikon Project 09–1572–G3: The purpose of the MEM Elution is to determine biological reactivity of monolayer cell culture (L929) in response to the test article. The test article is considered non–cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993–5.
Reference: Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity, ISO 10993–5:1999.

HEMOLYSIS (ISO) – Toxikon Project 09–1572–G4: This assay is designed 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: Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, ISO 10993–4, 2002, as amended 2006.

***IN VITRO* HEMOCOMPATIBILITY (ISO) – Toxikon Project 09–1572–G5**: This assay is designed to ensure that the test article extract does not adversely affect the cellular components of blood. The test article was evaluated for its potential to adversely affect selected hematological parameters. The hematological parameters tested included complete blood count, including platelets, hematocrit, erythrocyte indices, and platelet count. The test article extract did not have any adverse effects on any of the hematological parameters tested.
Reference: Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, ISO 10993–4:2002, as amended 2006.

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PHYSICOCHEMICAL TEST (USP) – Toxikon Project 09–1572–G6: This test determines the physical and chemical properties of extracts of the test article. The test article passes the USP Physicochemical Tests for plastics.
Reference: United States Pharmacopeia 31, National Formulary 26, 2008.

IMPLANTATION TEST (ISO) – Toxikon Project 09–1572–G7: The test article was 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: Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation, ISO 10993–6: 2007.

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: July 21, 2009