TOXIKON
Leaders in Life Science and Technology

Henkel Corporation
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Rocky Hill, CT 06067

Date of Test Completion: March 20, 2007
Project Number: 07–0144

Certificate of Compliance
ISO 10993 Biological Tests

Test Article: Loctite®
Bulk Number: Bulk 431
Lot Number: L36G005057

INTRACUTANEOUS INJECTION (ISO): 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 tissue 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 29, National Formulary 24, 2006; Monograph <88>: Biological Reactivity Tests, *In Vivo*. Based on the criteria set forth by the protocol, the test article is considered negligible or slight irritant–conforms.
Reference: ISO 10993–10, 2002, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed–Type Hypersensitivity, as amended 2006.

ACUTE SYSTEMIC INJECTION (ISO): 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 systemic reaction than blank extract when injected into mice. Additional extracts (PEG & Alcohol in Saline) were used to cover the requirements of United States Pharmacopeia 29, National Formulary 24, 2006; Monograph <88>: Biological Reactivity Tests, *In Vivo*. The test article did not show greater biological reactivity compared to the control material–conforms.
Reference: ISO 10993–11, 2006, Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity.

CYTOTOXICITY (ISO): 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 at dilutions of 1:2, 1:4, and 1:8 and meets the requirements of the MEM Elution Test, ISO 10993–5.
Reference: ISO 10993–5, 1999, Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity.

HEMOLYSIS (ISO): This assay is designed to evaluate the hemolytic potential of the test article extracts. 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.

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***IN VITRO* HEMOCOMPATIBILITY ASSAY (ISO)**: This assay is designed to ensure that the test material 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 were complete blood count including platelets, hematocrit, and erythrocyte indices. The test article meets the requirements.
Reference: ISO 10993–4, 2002, Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood, as amended 2006.

PHYSICOCHEMICAL TEST (USP): This test determines the physical and chemical properties of extracts of test material. The test article passes the USP Physicochemical Tests for plastics.
Reference: United States Pharmacopeia 29, National Formulary 24, 2006. <661> Containers, Physicochemical Tests–Plastics.

IMPLANTATION TEST (ISO): The macroscopic and histological reaction of the test article, implanted in rabbit muscle for 2 weeks was not significant when compared to negative control sites–conforms.
Reference: ISO 10993–6, 1994, Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation.

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

Biocompatibility Manager

Quality Assurance

Date of Certificate: April 5, 2007