The Safety of StatSeal Powder

StatSeal®

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The following information is proprietary to Biolife, LLC.

StatSeal Powder is an external, topical wound dressing that is not metabolized by the body and is not biologically derived. StatSeal Powder entered commerce as an OTC topical powder to stop bleeding on minor wounds.

StatSeal Powder is composed of a non-toxic mixture of a hydrophilic polymer and potassium ferrate.

The Toxicology Project Director of STS Duotek, an independent, FDA - registered[1] laboratory that routinely performs Good Laboratory Practice (G.L.P.) studies for the pharmaceutical and medical device industries, has confirmed and attested to the safety of StatSeal Powder.

The following table lists all the studies required by the FDA for mucosal membranes and breached or compromised surfaces with prolonged contact[2], the negative control material used, the positive control test results, and the test result/conclusion.

Required Test	StatSeal Powder (reactivity)	Neg. Control Material[3]	Positive Control Result
Cytotoxicity	Negative, non-toxic	USP HDPE Ref. Std.	Toxic Response
Sensitization	Negative, non-toxic	Freund's Complete Adjuvent / Saline	Toxic Response
Irritation	Negative, non-toxic	Gauze Pad	Toxic Response
Systemic Toxicity	Negative, non-toxic	Mineral oil & topical application	Toxic Response
Sub-chronic toxicity*	Negative, non-toxic	Saline / USP standard plastic	Toxic Response
Implantation*	Negative, non-toxic	Saline / USP standard plastic	Toxic Response

*with histopathology

In each test, the level of toxicity (induced biological reactivity) observed and measured using StatSeal Powder was the same as, and/or statistically equivalent to that caused by the negative control material[4]. In each case, the positive control elicited a toxicologically significant biological response in the subject animals.

1 FDA Registration # 1316257
2 Reference: FDA Blue Book Memorandum #G95-1, Attachment A; FDA. Modified ISO Testing Matrix: Initial Evaluation Tests; Surface Devices-Mucosal Membrane & Breached or Compromised Surfaces, Prolonged Exposure. Genotoxicity evaluation was not performed, FDA regulations only call for that test to be performed for permanently implanted surface devices.
3 STS Duotek used both animals/varieties and control materials as defined in the International Organization for Standardization (ISO), Biological Evaluation of Medical Devices - Part 6 and/or United States Pharmacopoeia, and performed in compliance with FDA Good Laboratory Practice regulations (GLP). Caging and care of animals was in compliance with the Animal Welfare Act USDA (1990 and all subsequent revisions).
4 Data and reports from STS Duotek on file.

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