

Oneil M. Banks, Ph.D., DABT (1980-2005)

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Cynthia L. Salisbury
Vice President, Regulatory Affairs
Polytek Development
55 Hilton Street
Easton, PA 18042

Re: Evaluation of PlatSil® Gel-OO Part A, PlatSil® Gel-OO Part B, PlatSil® Gel-10 Part A, PlatSil® Gel-10 Part B, PlatSil® Gel-25 Part A, PlatSil® Gel-25 Part B, PlatSil® 71/73 Part R Retarder, PlatSil® 71/73 Part X Accelerator, PlatSil® Deadener LV, PlatSil® Part H Hardener, PlatThix® Thickener, Poly-Sil® Silicone Fluid 50 cP, Smith's Theatrical Prosthetic Deadener and TinThix Thickener for skin contact.

Dear Ms. Salisbury:

In evaluating PlatSil® Gel-OO Part A, PlatSil® Gel-OO Part B, PlatSil® Gel-10 Part A, PlatSil® Gel-10 Part B, PlatSil® Gel-25 Part A, PlatSil® Gel-25 Part B, PlatSil® 71/73 Part R Retarder, PlatSil® 71/73 Part X Accelerator, PlatSil® Deadener LV, PlatSil® Part H Hardener, PlatThix® Thickener, Poly-Sil® Silicone Fluid 50 cP, Smith's Theatrical Prosthetic Deadener and TinThix Thickener, Oneil M. Banks, Ph.D., CIH, DABT (certified by the American Board of Toxicology in General Toxicology 1980-2005) considered current chemical composition of the art material from the formulation supplied by the manufacturer, Safety Data Sheets for each ingredient, acute and chronic toxic effects of each component and of the total formulation, physical and chemical form of the art material, customary or reasonably foreseeable handling and use including possible accident or misuse, and any adverse health effects of decomposition or combustion products. After review of the supplied information, and risk assessment based on exposure potential, acceptable daily intake and appropriate safety factors, Oneil M. Banks, Ph.D., CIH, DABT (certified by the American Board of Toxicology in General Toxicology 1980-2005) finds PlatSil® Gel-OO Part A, PlatSil® Gel-OO Part B, PlatSil® Gel-10 Part A, PlatSil® Gel-10 Part B, PlatSil® Gel-25 Part A, PlatSil® Gel-25 Part B, PlatSil® 71/73 Part R Retarder, PlatSil® 71/73 Part X Accelerator, PlatSil® Deadener LV, PlatSil® Part H Hardener, PlatThix® Thickener, Poly-Sil® Silicone Fluid 50 cP, Smith's Theatrical Prosthetic Deadener and TinThix Thickener are not considered likely to have adverse effects on skin contact or when used for making human body molds. Contact with eyes and mucous membranes should be avoided. Some individuals may be unusually sensitive or allergic to one or more components and patch testing with a small amount before total application would be prudent.

Yours very truly,



Oneil M. Banks