Strata Tac
Advanced Coating Technologies
A Duraco Specialty Materials Company

RE: Food and Drug Administration Status of Strata-Tac Performance Polymers' #50614 for use in Primary and Secondary Adhesive Labeling on Blood and Intravenous (IV) Bags

Dear Valued Customer,

The purpose of this letter is to provide you with the information regarding the status, under the laws and regulations of the U.S. Food and Drug Administration (FDA}, of Strata-Tac #50614 for use in primary and secondary adhesive labeling on intravenous (IV} and blood bag applications.

FDA's Guideline for the Uniform Labeling of Blood and Blood Components establishes standards for adhesives and coatings for blood bag labels. In secondary labeling applications, e.g. when the adhesive is applied on a secondary label that will be placed over an original base label for the labeling of blood and blood components, FDA maintains the position that adhesives that comply with Title 21 of the Code of Federal Regulations (C.F.R.) Section 175.105 ("Adhesives") may be safely used in such applications. Section 175.105 requires the adhesives to be behind a functional barrier or used under conditions that prevent the adhesives from migrating into the contents of the IV or blood bags in more than insignificant, or de minimis, amounts. It is the obligation of the customer and/or end user of Strata-Tac #50614 to ensure that a sufficient functional barrier is present when the adhesive is used in a secondary adhesive label on blood or intravenous (IV) bag applications.

For primary applications where labels are applied directly to the blood or IV bags, FDA requires data on the extractability of the adhesive's components, as well as an analysis of potential exposure to such components to blood or other IV injection recipients. These data are relied upon by FDA to support the safety of primary labels when reviewed as a part of a New Drug Application, e.g. a blood collection bag with anticoagulant solution, or as a part of a device submission, e.g. a transfer bag.

In keeping with FDA's Guideline, Strata-Tac's adhesive vendor has performed diffusion modeling to determine the maximum potential extractability of the components present in #50614 when used in primary blood bag labeling applications. The results of the vendor's diffusion modeling also were used to assess the safety of potential recipient exposure. Information on #50614, including its composition, results of diffusion modeling using common blood or IV bag substrates, and recipient exposure levels, has been provided to FDA in a Drug Master File (DMF) for use in evaluations of drug and device submissions.

Please contact Strata-Tac for specific information regarding extraction modeling and its DMF.

Furthermore, the following biological and hemolytic testing has been performed on the #50614 adhesive that may be relevant to support the safety of this adhesive in primary or secondary labels for blood or IV bags:

- United States Pharmacopeia (USP XX.IV) Biological Reactivity Tests, In- Vivo for Systemic Injection. This test determines the intravenous toxicity of the material when injected into mice. This adhesive showed no systemic toxicity under the conditions of this test.
- United States Pharmacopeia (USP XX.IV) Biological Reactivity Tests, In-Vitro for Agar Diffusion. This test determines the biological reactivity of mammalian cell cultures following contact with the test material. This adhesive caused no biological reaction from the exposed cell cultures under the conditions of this test.
- Red Blood Cell Hemolysis in Rabbits. This test determines the dissolution or destruction of red blood cells when exposed to the test material. This adhesive caused no greater dissolution or destruction of the red blood cells that the control material under the conditions of this test.

The information provided in this letter is intended to be, and we believe in good faith should be, helpful to our customers and end-users of our products containing the adhesive referenced above. We believe the analyses described above would be supportive in any safety evaluation carried out by the FDA. This information is subject to revision when additional knowledge/information is gained.

Sincerely,

Strata-Tac, Inc
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