

Mr. R. A. Calsibet
Bakelite Company
Third Floor
9 East 41st Street

November 23, 1954

Dear Mr. Calsibet:

We are returning your file of correspondence from the Surface Engineering Company, Inc. I would not think it would be advisable to identify Bakelite with this use of vinyl. We would not even suggest the utilization of vinyl resins for permanent implants in the human body. To our knowledge, there has been inadequate information on the safety of such application and usage. In fact, there have been published:

"Sarcomas Induced in Rats by Implanting Cellophane," by B. S. Oppenheimer, Enid T. Oppenheimer, and A. P. Stout, PROCEEDINGS OF THE SOCIETY FOR EXPERIMENTAL BIOLOGY AND MEDICINE, Volume 67, pages 33-4, 1948.

"Sarcomas Induced in Rodents by Imbedding Various Plastic Films," by B. S. Oppenheimer, Enid T. Oppenheimer, and A. P. Stout, PROCEEDINGS OF THE SOCIETY FOR EXPERIMENTAL BIOLOGY AND MEDICINE, Volume 79, pages 366-9, 1952.

In this work in which films of various plastics, including vinyl, were implanted in rats, a percentage of the rats developed sarcomas (malignant tumors) at the site of the implant.

Doctor Self's work, as reported in the letter of November 1, 1954 from H. T. Thompson, represents an inadequate piece of work to establish safety in such usage. Animal observations should be for at least one or two years, and dogs are not good subjects to demonstrate adverse effects such as tumors, etc.

Very truly yours,

MEDICAL DIRECTOR
INDUSTRIAL MEDICAL AND TOXICOLOGY DEPARTMENT

Thomas W. Male, M. D.
TS

UCC
063338