Title: Vinylite
Case Ref.) Plasticizers +
Stabilizers

Mr. J. J. Morris
Carbide and Carbon Chemicals Company
First Floor
11 East 41st Street

January 15, 1954

Vinylite
U. S. Catheter & Instrument Corp.

Dear Mr. Morris:

Based upon what information is available to us, as far as vinylite itself is concerned, it is quite physiologically inert. To our knowledge, whenever there have been adverse physiological effects, they have been traceable to either plasticizers or stabilizers utilized in the composition. Most materials when placed within the body for a considerable length of time, such as semipermanent indwelling tubes, etc., could cause abscess or fibrosis from mechanical trauma to the tissues, or a tissue reaction known as a foreign body reaction. I would imagine that such effects have been noted from the use of rubber tubing, which has been so utilized for years.

The stabilizers and plasticizers utilized with vinylite for such applications should be those which are neither known irritants nor sensitizers. They should also possess a low order of toxicity. This would exclude the organic tin stabilizers, and because of reputation alone, the lead stabilizers.

Reviewing the plasticizers listed in the correspondence regarding the formulation, the following are brief notes on the toxicity of those plasticizers which we have studied.

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| DC-55 | Low order of acute oral toxicity. Not an irritant or a sensitizer. |
| A-26 | Moderate acute oral toxicity, but considered safe for proposed use. Not irritating, but was not tested via human patch tests. |
| TOF | Low order of acute oral toxicity. Mildly irritating to the skin. Probably a sensitizer. |
| 480 | Low order of acute oral toxicity. Tested upon thirty human subjects--no sensitization but 3 per cent primary irritation. |

It is my impression that if the customer wishes to be assured of the suitability of his formulation, it would be wise to have pieces of the finished product implanted in animals to see whether it produces injury or irritation to adjacent tissues.

Wish we could give you a more accurate opinion regarding this application and usage.

Sincerely yours,

MEDICAL DIRECTOR
INDUSTRIAL MEDICAL AND TOXICOLOGY DEPARTMENT

Thos. W. Hale, M. D.
jl

UCC

Mr. J. J. Morris
C & C C C
New York City

January 11, 1954

Albany, New York

Dr. T. W. Hale, Industrial
Toxicology Dept.
Mr. V. H. Boden
Mr. D. J. Kelly

U. S. Catheter & Instrument Corp.
Glens Falls, New York

Dear Mr. Morris:

You will recall the writer's previous conversations with the subject regarding the manufacture of catheters from vinyl plastisols.

In the writer's discussions with Mr. Norman C. Jeckel, president, it was brought out by the subject that vinyls have a very bad name in the medical field because of toxicity. Additional information was requested by the writer and Mr. Jeckel has kindly forwarded a letter from C. R. Bard, Inc., Summit, New Jersey, giving their opinion of vinyls. A copy of this letter is attached for your information. Any comment which Dr. Hale or yourself would care to make would help in the writer's relationship with the subject.

Very truly yours,

John R. Hulten/gle
Enc: