



UNION CARBIDE CORPORATION
CHEMICALS AND PLASTICS

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bcc: Dr. A. L. Bayes - NY
Dr. W. F. Gorham - BB
Dr. D. L. Heywood - NY
Mr. J. Morrison - Chic.
Mr. J. V. Murray - NY
Mr. G. C. Shipston - NY
✓ Mr. R. N. Wheeler - SC

July 22, 1977

VC FDA

Mr. Ray Johnson
Mayor Plastics
415 - 17th Avenue North
Hopkins, Minn. 55343

Dear Mr. Johnson:

Mr. Jeff Morrison of our Chicago office has asked me to contact you regarding the prior sanctioned status of Bakelite vinyl resin QSAP-7 in flexible vinyl tubing intended for food contact uses.

As you undoubtedly are aware the Federal Food and Drug Administration on September 3, 1975 published in the Federal Register its long awaited Notice of Proposed Rulemaking for Vinyl Chloride Polymers in contact with food. Although this is only a proposal which is open for comments, it probably will become effective without major change late in 1977. This proposal, which is limited to uses of vinyl chloride resins in contact with foods, supports the continued use of these polymers in certain applications where there is clearly no reasonable expectation of monomer migration to foods and permits on an interim basis the use of vinyl chloride polymers in applications where migration is possible but has never been shown to occur. The use of vinyl chloride polymers in applications where the migration of monomer to foods has been established is now banned.

The FDA has concluded that since PVC tubing is highly plasticized and plasticization is known to reduce residual vinyl chloride monomer content, and since flexible tubing is generally used in applications where food contacts the tubing only briefly, there is no reasonable expectation that any vinyl chloride will migrate into food.

Accordingly, FDA has proposed to amend its existing regulations in Part 121 by adding a new paragraph to Regulation 121.106 which will add vinyl chloride monomer to the list of substances prohibited from use in human food. This new paragraph however specifically permits the continued use of vinyl chloride homopolymers and copolymers in coatings, gaskets, cap liners, flexible tubing and plasticized films and confirms the continued validity of citations for use of these polymers.

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To: Mr. Ray Johnson

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Thus, Bakelite brand vinyl resin QSAP-7 in flexible tubing intended for use in contact with foods under conditions of good manufacturing practice where the food contact article contains undetectable quantities of vinyl chloride may not reasonably be expected to become a component of foods or to cause vinyl chloride monomer to become a component of foods. It follows therefore that such use is in conformance with existing prior sanctions and applicable food additive regulations, both existing and proposed.

Very truly yours,

W B Ackart

W. B. Ackart
Manager, FDA Liaison

WBA/bhm

Note on internal copies:

Even though the proposed use is in plasticized tubing rather than rigid pipe and hence involves less likelihood of monomer migration to foods, we believe the limit of 20 ppm residual vinyl chloride in resin as proposed by the Plastic Pipe Institute provides reasonable assurance against monomer migration. Accordingly a special customer requirement of 20 ppm residual monomer maximum should be established.

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