VC custom letter

cc: Dr. W. F. Gorham-BB
Mr. D. A. Harwitz-BOST
Mr. D. L. Heywood-NY-21
Mr. J. V. Murray-NY-46
Mr. G. C. Shipston-NY-28
Mr. R. N. Wheeler-SC

UNION CARBIDE CORPORATION
CHEMICALS AND PLASTICS
RIVER ROAD, BOUND BROOK, N. J. 08805 · TELEPHONE (201) 356-8000

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OCT 18 1977
R. N. WHEELER, JR.

October 11, 1977

Mr. Greg Chenevert
Millipore Corporation
Ashley Road
Bedford, MA 01730

Dear Mr. Chenevert:

Mr. D. A. Harwitz of our Boston office has asked me to contact you regarding the status of Bakelite vinyl resins QSQF and QSQH in articles intended for contact with foods and in medical devices.

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 would be banned.

Accordingly, FDA has proposed to amend its existing regulations by adding a new paragraph to Regulation 189.1 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 in coatings, gaskets, cap liners, flexible tubing, and plasticized films and confirms the continued validity of citations for use of these polymers in Regulations 175.300, 176.170, and 177.1210.

Although QSQF and QSQH comply with the existing regulation 177.1950 for vinyl chloride ethylene copolymers at this time we do not know what additional requirements will be imposed when FDA does issue its vinyl chloride regulations in final form.

With regard to the use of QSQF and QSQH resins as components of medical devices, as you know there is no means by which a resin manufacturer can obtain blanket FDA clearance for his product in all medical applications.

It is the responsibility of the device manufacturer to establish the safety and suitability of his product for its intended use.

We have never tested vinyl resins QSQF and QSQH according to the U.S. Pharmacopeia procedures.

During the course of our work to obtain a food additive regulation for vinyl chloride-ethylene copolymers (which resulted in Regulation 177.1950) we studied extractives from these resins and proposed the following extraction limits which subsequently were incorporated into the regulation:

1. Total nonvolatile extractions in n-heptane at 150°F for 2 hours not to exceed 0.10 weight percent.

2. Total nonvolatile extractions in water at 150°F for 2 hours not to exceed 0.03 weight percent.

3. Total extractions in water at 150°F for 2 hours to contain no more than 0.5 mg of vinyl chloride-ethylene copolymer per 100 g of sample tested.

No measurements were made of the migration of residual vinyl chloride monomer from these resins.

We hope this information is helpful.

Very truly yours,

W B Ackart

W. B. Ackart
Manager, FDA Liaison

WBA:cu