



INTERNAL CORRESPONDENCE

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R. N. WHEELER, JR.

CHEMICALS AND PLASTICS

RIVER ROAD, BOUND BROOK, NEW JERSEY 08805

To (Name)	Mr. R. M. Arnold	- TC	Date	March 15, 1979
	Dr. L. E. Brydia	- BB/200	Originating Dept.	
	Mr. T. B. Gibb	- BB/200	Answering letter date	
	Dr. R. A. Gregory	- BB/203	Subject	
	Mr. R. E. Gulick	- NY/33		
	Dr. G. T. Kwiatkowski	- BB/200		
	Mr. R. W. Lasher	- NY/33		
	Mr. G. S. Peacock	- BB/95		
	Mr. N. H. Reinking	- BB/98		
	Dr. K. R. Szoc	- BB/203		
	Mr. W. I. Wertz	- BB/98		
	Dr. F. G. Willeboordse	- BB/98		
	Mr. R. N. Wheeler	- SC		
	Dr. M. J. Yousseffi	- BB/200		

Attached herewith is a first draft of a protocol for our solvent vinyl resin residual monomer studies which was prepared by Glenn Peacock and I from Tom Gibb's action plan. Please make any changes directly on your copy and return to me as soon as possible. We would like to submit this to FDA before April 1.

I can anticipate potential problems with the solvent evaporation studies. Also, I am bothered about the September 1 completion date, but I doubt if FDA will accept a longer delay.

W B Ackart
W. B. Ackart
Manager, FDA Liaison

WBA:sdb

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UCC
029819

March 15, 1979

The Hearing Clerk (5 copies)
Food and Drug Administration
Room 4-65
5600 Fishers Lane
Rockville, MD 20852

Docket 75-N-0190

Dear Sir:

We submit herewith a protocol of an experimental program currently in progress at Union Carbide Corporation laboratories. This is designed to demonstrate that continued use of Union Carbide's solution polymerized vinyl copolymers and terpolymers in resinous and polymeric coatings for use as food contact surfaces, as currently regulated under Title 21 CFR 175.300, will not result in vinyl chloride monomer becoming a component of food.

Very truly yours,

W. B. Ackart, Ph.D.
Manager, FDA Liaison

WBA:sdb

Attachments

cc: Dr. Arthur Lipman (3 copies)
Bureau of Foods HFF 334
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

UCC
029820

PROTOCOL TO DEMONSTRATE THE ABSENCE OF VINYL
CHLORIDE MONOMER FROM POLYMERIC COATINGS COMPOSED
OF BAKELITE BRAND SOLUTION POLYMERIZED VINYL RESINS

Objective: This experimental program is intended to demonstrate that the continued use of "Bakelite" brand solution polymerized vinyl copolymers and terpolymers as components of polymeric coatings used in contact with foods will not result in vinyl chloride monomer becoming a component of food at any level. These copolymers and terpolymers are cited by chemical identity in 21 CFR 175.300 and by reference in 176.170 and 177.1210.

The experimental program, which has been in progress for approximately one year, consists of three parts as follows:

Part A: Analytical Methods Development.

Part B: Resin Measurements.

Part C: Solvent evaporation Studies and
Mathematical Modeling.

Details of our findings to date and our proposed program are discussed in the following sections.

A. Analytical Methods Development

Studies in UCC laboratories, previously discussed with Bureau of Foods personnel, showed that the analytical method developed in their laboratories for the determination of vinyl chloride monomer is not completely satisfactory for use with vinyl copolymers and terpolymers. However, a modification of this method, which utilizes an electrolytic conductivity detector, has eliminated problems of massive interferences in the analyses of our products. We propose to carry out the following additional studies to validate the accuracy and sensitivity of this modified procedure.

1. Resolution of FDA/UCC differences in residual vinyl chloride monomer in Bakelite brand vinyl chloride-vinyl acetate copolymer VYHH. To be done by analyzing spiked samples of resin by both methods.

2. Determination of precision of current UCC modification. To be done by obtaining six values for single samples of VYHH and VYDS resins over a two-month period and applying suitable statistical methods.

3. Development of improved methodology applicable to all vinyl resins through participation on ASTM committee D-20.70.03.

B. Solvent Evaporation Studies and Mathematical Modeling

1. Solvent Evaporation Studies

Resin samples will be dissolved in solvents typically used in the manufacture of solution coatings. Residual vinyl chloride monomer will be analyzed immediately, at various stages of evaporation, and, if possible, in the cured coating. A family of curves will be developed by adding monomer at various levels to the original solutions. Certain assumptions must be made and validated in order to simulate the coating process.

2. Mathematical Modeling

a) The most simple model will be based upon the level of monomer in resin at the customer's plant, and will include the assumption that all of this will migrate to contained food. The maximum level of monomer that could be present in food under this assumption would be less than 0.0025 ppb.

b) Theoretical considerations indicate that most, if not all, of the monomer present in coatings solutions will not remain in the finished food contact coatings. We will develop mathematical models from the data obtained from solvent evaporation studies to show that vinyl chloride monomer cannot be present in foods.

Completion date: Target date for completion of this program and the submission of a final report is September 1, 1979.

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