UNION CARBIDE INTERNAL CORRESPONDENCE

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To (Name) See Attached Distribution
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Date April 17, 1978 R. W. LASHER
Originating Dept. R&D
Answering letter date

Copy to Dr. W. F. Gorham-BB/98
Mr. D. E. Heywood-NY/

Subject DRAFT PROTOCOL ON PVC STUDIES FOR SUBMISSION TO FDA

Attached is a first draft of a protocol for our PVC resin studies which is intended for submission to the FDA. We would appreciate any additions, corrections, changes, etc., which you may care to make. Please make changes directly on your copy and return to me.

W B Ackart

W. B. Ackart

WBA:cu

Attachments

UCC
029893

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

1978

Hearing Clerk
Food and Drug Administration
Dept. of Health, Education, and Welfare
Room 4-65
5600 Fishers Lane
Rockville, MD 20852

DOCKET NO. 75N-0190
NOTICE OF PROPOSED RULE MAKING

RE: VINYL CHLORIDE POLYMERS IN CONTACT WITH FOODS

Dear Sir:

Union Carbide believes and is preparing to demonstrate that food contact films and coatings made with its solution polymerized vinyl resins contain no detectable quantities of vinyl chloride monomer. Therefore, we believe there is no reasonable expectation that foods contacting such films or coatings will be contaminated with vinyl chloride monomer. We have instituted analytical programs and mathematical modeling to support this premise.

Union Carbide, a manufacturer of solution polymerized vinyl coatings resins for 45 years, operates a unique process which continuously polymerizes vinyl chloride and comonomers in a solvent and produces a clear solution of resin in a solvent. This solution is then distilled to remove unconverted vinyl chloride monomer. The distilled resin solution is filtered, and residual monomer is further extracted by a second solvent. The resin is then precipitated with water and is recovered by filtration, washed and dried. After drying, the resin typically contains less than 0.2 ppm residual vinyl chloride, which until recently was the limit of sensitivity of our analytical procedure.

In the can coating process, resins are usually applied by airless spray technique from a 20 to 25 percent total solids solution in a mixture of solvents. The coated container is then passed through a high velocity air oven at ∿320°F to remove solvents. For taste considerations it is essential that virtually no solvents remain in the coating. Normal coating weights range from 4 to 7 mg/in^2 with a thickness of about 0.25 mils.

Calculations by us and others indicate that residual vinyl chloride monomer in the cured coating will be nil.

Our experimental program will include the following:

1. Develop the capability of measuring concentrations of vinyl chloride monomer in resins, resin solutions, resin coatings, and cured resin coatings of a sensitivity of a few parts per billion (ppb). We have found that the analytical procedure currently recommended by the Food and Drug Administration specifies operating temperatures at which available sampling syringes do not function properly. Further, the solvent used in sample preparation frequently contains impurities which mask the vinyl chloride response. However, we believe that solutions to these and other problems, can and will be found, thus leading to a more satisfactory analytical procedure.

2. Collect data for production blends of our solution-polymerized vinyl chloride-vinyl acetate copolymers and modified vinyl chloride-vinyl acetate copolymers at the bagging point as shipped to our customers showing residual vinyl chloride monomer at the ppb level.

3. Collect data for cured coatings (on metal substrates) prepared from solution-polymerized vinyl resins. Initial mathematical modeling of coatings systems, taking into account the evaporation and baking cycles, leads us to believe that residual vinyl chloride monomer will be below the detectable (ppb) level. A feasible method of obtaining a sufficiently large resin sample (20 g specified) from thin coatings (∿5 mg/sq in) remains to be developed.

4. Collect data under conditions simulating various steps in the coating operation which will enable the construction of mathematical equations predicting the theoretical concentration of vinyl chloride monomer in the cured coating (the food contact surface). For example, we propose to measure vinyl chloride monomer in solid resin, in a coating solution as prepared, at various stages of evaporation, in a dry but uncured coating, and in a dried cured coating. We believe the theoretical maximum concentration in the food contact surface will be far below the level of sensitivity of the analytical method.

5. Collect data under conditions still to be determined to test the theory which has been proposed--that there is a limit below which residual vinyl chloride monomer cannot be removed from polyvinyl chloride resins, and hence will not reasonably be expected to migrate to foods.

6. Although solution-polymerized vinyl resins are marketed for use in can ~~coatings, several of these~~ these polymers have physical properties that would enable their use in rigid films and sheetings and/or extruded pipe for potable water. As an extension of the present study we propose to determine residual monomer levels in experimental sheet and pipe fabricated from these low monomer resins.

This laboratory program is in progress. Although we have experienced difficulties with the analytical procedure we believe that a reasonable target date for completion of the proposed study is mid-summer of 1978. We will of course report the results of this study to the Food and Drug Administration.

Very truly yours,

[illegible] test method ~~modifications may be required~~ [illegible] method

add theoretical numbers,

W. B. Ackart, PhD
Manager, FDA Liaison

WBA:cu

15a-A-26

cc: Dr. K. J. Felci
Div. of Chemistry & Physics
Bureau of Foods
Food and Drug Administration
200C Street SW
Washington, DC 20204

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