

UNION CARBIDE CORPORATION
Coatings Materials

270 Park Avenue, New York, New York 10017

RECEIVED

FEB 13 1978

R. N. WHEELER, JR.

TO: W. B. Ackert
R. W. Annonio
R. M. Arnold
R. A. Gregory
J. V. Murray
R. N. Wheeler ✓

DATE: February 6, 1978

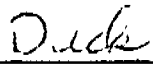
CC: See attached Distribution List

SUBJECT: FDA's Change In Posture Regarding VCM
Regulations For Thin Film Coatings

Attached are the results of our meeting of January 31, 1978, to define solvent vinyls and UCAR 4593X's status in view of statements made by Douglas Kennedy, Commissioner of the FDA, regarding residual vinyl chloride monomer regulations and the extension of the ban on polyvinyl chloride material to previously exempted (safe applications) such as coatings and flexible packaging materials. The attached program and rationale was developed to minimize the impact of those statements and to provide the FDA the necessary data to allow continued use of solvent vinyl resins and UCAR 4593X in food contact application.

It was the opinion of the meeting participants that the program will be successful in convincing the FDA to allow continued use of solvent vinyl resins and UCAR 4593X in thin film food contact applications. However, the long term loss of business caused by the adverse publicity is unknown at this time. Speed in obtaining a favorable ruling is of the utmost importance.

Best regards,



R. W. Lasher

RWL:jc
Attachment

UCC
030043

KEY ISSUES

LOSS OF BUSINESS

Key problems for UCC is the worldwide loss of business which is two-fold.

- . The immediate loss of business by conversions to alternative resins systems due to adverse VCM publicity.
- . The longer term loss of market access due to potential banning by FDA of solvent vinyl resins in food contact applications. At stake is the potential loss of 56MM lbs. which is 48% of the worldwide solvent vinyl resins business. This would have the effect of also banning the water-borne program based on vinyls.

PROVIDE TECHNICAL DATA TO FDA

- . (The technical goal is to demonstrate no detectable quantities of vinyl chloride monomer in the food contact film and further, that there would be no reasonable expectations of having monomer in the film.
- . To work with FDA's technical section by providing the necessary data to support the 1975 proposed regulation which allows use of thin film coatings of polyvinyl chloride in food contact applications.

Heraton 203
Boyer

Rationale For FDA To Allow Continued Use of
Solvent Vinyl Resins and UCAR-4953 in Thin Film
Food Contact Applications

- Demonstrate that residual VCM Monomer exists in fresh solvent vinyl dry resin at levels of 100-200 PPB, 1500 PPB for solution resin on a dry basis and 20,000 PPB for UCAR 4593X on a dry basis.
- Demonstrate that when the resins are formulated into a can coating, applied to the substrate and baked that no detectable VCM can be found by FDA's test method sensitive to 2PPB.
- Further demonstrate by calculation that it is theoretically impossible for any VCM to migrate into food contact.
- State that thin film coatings of solvent vinyl resins and UCAR-4593X are different than the acrylonitrile case for the following reasons:
 - Acrylonitrile was present in the bottles at a 5 PPM level and initially was detected in the food.
 - Acrylonitrile polymer depolymerizes into acrylonitrile monomer, whereas, polyvinyl chloride decomposes into hydrochloric acid which has a safe status for food contact.
 - Provide the FDA technical people with sufficient data to allow them to make permanent their 1975 proposal that thin film applications of solvent vinyl resins and UCAR 4593X are safe for food contact applications.

Background and Problem Definition

The Food and Drug Administration expects to finalize a proposal to ban rigid and semi-rigid polyvinyl chloride materials for food contact use by the spring of this year and to issue a new proposal to ban other uses by the end of 1978, according to a draft memorandum of actions planned by the inter agency regulatory liaison group. Food and Drug Commissioner, Dr. Donald Kennedy, recently revealed that his agency was planning such action in a letter to Ethyl Corporation.

A draft of an FDA staff paper observes that the decision to go beyond its original PVC proposal of 1975 is based largely on the precedent set in the Commissioner's decision on use of acrylonitrile polymers and copolymers in bottles. Although the migration of acrylonitrile monomer cannot be detected, the memo explained, there is every likelihood that residual monomer is present in the polymer and, hence, will migrate to food. Watson Ackert, Union Carbide's FDA liaison, stated it was known that acrylonitrile monomer existed in the bottles and that migration into the food occurred. Monsanto's initial submission to the FDA contained 15,000 PPB of acrylonitrile monomer (ACN) and 2PPB migrated into the food. The latest submission contained 5000 PPB of ACN and non detectable quantities in the food utilizing a test method sensitive to 10 PPB. Theoretical calculations demonstrate the possibility of ACN migration into the food at levels under 10 PPB, therefore, FDA banned the use of acrylonitrile bottles for food contact. Also, the regulatory policy at FDA, is hostile to identified carcinogens.

The FDA has developed a test method to detect VCM to a 2 PPB level. Various PVC samples run by the FDA are given in Table I. It is expected that the method will detect residual VCM in solvent vinyl dry resin at a maximum of 200 PPB level and solution resins at 1500 PPB level on a dry basis. UCAR latex 4593X is expected to have a residual VCM level of approximately 20,000 PPB on a dry basis. The FDA has not formerly proposed the ban at this time but press releases and adverse publicity regarding the issue has created a worldwide problem since most other countries follow the FDA lead in regulating carcinogenic materials.

The key difference between the acrylonitrile logic and the solvent vinyl position is that solvent vinyls are used in coatings applications which are baked and hence result in no detectable residual vinyl chloride in the coating and theoretically, no vinyl chloride monomer can migrate to the food. Polyvinyl chloride does not depolymerize but decomposes into hydrochloric acid which has been ruled safe by the FDA. The FDA proposed a polyvinyl chloride regulation in 1975 to:

- 1) Ban polyvinyl chloride for rigid packaging in food contact use.
- 2) Allow continued use of theoretically safe applications of which the thin filmed coatings of solvent vinyl resins and UCAR 4593X are included.

The 1975 FDA proposed regulation appears to be a viable alternative within the technical section of FDA if Union Carbide establishes data to support this position.

THE PROGRAM

Develop The Necessary Test Data

- 1) Run the residual VCM levels of the resins, VYHD or VYHH, VMCC, VYDS-66 and UCAR 4593X.
- 2) Formulate the above resins into basic can coating formulations. Define these formulations with lab personnel. Determine the VCM level of each formulated coating.
- 3) Bake the coatings, remove from the substrate and analyze for VCM. Hopefully, no detectable VCM will be present utilizing FDA's test method which is sensitive to 2 PPB.
- 4) Check the coating's substrate with the coating in place for residual VCM.
- 5) All tests for residual VCM will be performed by the FDA's test method sensitive to 2 PPB level. Determine the validity of the test method to differentiate VCM from other materials which may be present.

Chromaticgraph testing will be done at Bound Brook with a back up by Texas City. The test work must be completed by mid March. Bob Arnold will select and send resin samples to W. Ackert for analysis.

Presentation To The FDA

A formal presentation to the FDA technical section containing the following main elements will be made by April 1, 1978. The presentation will consist of an explanation of the coatings business and will differentiate the solvent vinyl and latex coatings resins from the general PVC resins. A discussion of the advantages and disadvantages of substitute resins will also be included. A complete description of the solvent vinyl resin process differentiating the VAGH process and demonstrating the number of stripping steps in the process to show why the residual vinyl chloride content of these resins are so low. The presentation will include the test protocol, the test results and the conclusions based on the test results. The differences between solvent vinyl resins and UCAR-4593X coatings and the acrylonitriles will be discussed. The presentation will end with a set of overall conclusions.

Counteract Adverse Publicity Caused By FDA Statements

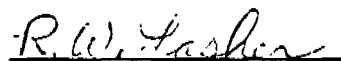
The program to counteract the potential damage and the resulting loss in business caused by FDA's statements suggesting banning heretofor safe applications of polyvinyl chloride films for food contact use consists of the following elements.

- 1) Prepare a position statement that we do not expect to find residual vinyl chloride monomer in applied thin film coatings of solvent vinyl resins and UCAR-4593X. Union Carbide plans to prove to the FDA's satisfaction that residual VCM does not exist in applied coatings and that therotical migration into food is impossible. Distribute the statement to the industry, our customers and the final users.
- 2) Use the position statement in the planned publicity program for solvent vinyl resins. The publicity program can also be used to keep customers and other interested parties informed of our progress.
- 3) Make select calls on large customers and final users to explain Union Carbide's position, program and the expected outcome.
- 4) Speed in obtaining favorable ruling by the FDA or a statement from the FDA permitting the continued use of our products for food contact application is an essential ingredient to minimize adverse publicity and minimize the loss of business.
- 5) A positive ruling can be used to UCC's advantage when other coatings systems come under FDA scrutiny.

CONCLUSION

The meeting participants are optimistic about the program's outcome for two reasons; a reasonable attitude displayed by the FDA's Technical Section and the results of experiments conducted in Denmark. The tests in Denmark consisted of measuring residual VCM in VYHH and typical can coatings formulations using a test method similar to the FDA's. The test results showed no detectable monomer in the resin or the applied coating. The can coating formulations were then spiked with 4000 PPM of VCM, applied to a substrate, baked and measured for contained VCM. No residual VCM was detected in the coating. The results of this work will form the basis of Union Carbide's request to the FDA to withhold a decision on solvent vinyl resins and UCAR-4593X in thin film applications until our program is completed. Union Carbide will also request the FDA to refrain from making further statements concerning the migration of VCM from thin film coatings until the program is completed and factual data exists to substantiate any statements.

The long term loss of business caused by the adverse publicity is unknown at this time. Several large users of vinyl coatings have asked their suppliers to submit samples of non-vinyl coatings. Therefore, it is most urgent that the status of solvent vinyl resins and UCAR-4593X for food contact application in thin films be resolved with the utmost speed.


R. W. Lasher

ACTION NOTES

- 1) Analyze the acrylonitrile petition and decision to determine the differences between solvent vinyls and latex coatings versus acrylonitrile bottles from a legal viewpoint.

Responsibility: W. Ackert, R. A. Gregorgy to be completed by 2/10/78.

- 2) Check with M. Montana on the regulatory status of epichlorohydrin and acrylates.

Responsibility: R. W. Lasher to be completed by 2/7/78.

- 3) Draft an interim statement to explain to customers Union Carbide's position regarding the FDA statements.

Responsibility: W. Ackert, R. N. Wheeler, J. V. Murray to be completed by 2/8/78.

- 4) Set up a meeting with the FDA to present our program and initial data to support our position and ask the FDA for time to complete our program before they make a final ruling.

Responsibility: W. Ackert to be completed by 2/14/78.

TABLE 1. FDA Test Results

Table 1. PVC Sample Summary

Sample No.	Sample Description	VC found ^a (ppb)
1	Rigid calendared food grade sheet	1.2
2	Thin plasticized food film	2.5
3	Thin plasticized food film	2.1
4	Plasticized blood bag	1.2
5	Thin plasticized copolymer food film	2.1
6	Thin plasticized food film	0.6 ^b
7	Plasticized food and milk tubing	0.7 ^b
8	Plasticized beverage tubing	0.7 ^b
9	Rigid vegetable oil bottle	120
10	Rigid French water bottle	913
11	French bottle welding compound	0.6 ^b
12	Thick plasticized canning sheet	0.4 ^b
13	Plasticized blood bag	0.3 ^b
14	Reagent blank	ND ^c

^aQuantitated by tangent skimming VC peak and measuring peak height

^bEstimated value - below method's quantitation limit

^cNone detected

DISTRIBUTION LIST

T. K. Brotherton
J. A. Coe
T. D. Epps
W. F. Gorham
R. E. Gulick
D. L. Heywood
K. J. Hutchinson
J. E. McKeon
A. E. Montagna
E. L. Peterson
F. S. Provenzano
T. Randall
A. G. Ricciardi, Jr.
A. E. Stafford
D. E. Stockman
G. F. Tacquard
D. I. J. Wang
W. B. Watkins
W. I. Wertz
F. G. Willeboordse
Vinyls Team