UNION CARBIDE INTERNAL CORRESPONDENCE

CHEMICALS AND PLASTICS • SOUTH CHARLESTON PLANT P. O. BOX 8004, SOUTH CHARLESTON, W. VA. 25303

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Date May 31, 1973

CONFIDENTIAL

Originating Dept.

Answering letter date

Subject Manufacturing Chemists Association
Vinyl Chloride Research Projects

The Vinyl Chloride Research Coordinators met on May 20, 1973 at 9:00 P.M., followed by the sponsoring industries' Technical Task Group on Vinyl Chloride Research meeting at 10:00 A.M. on May 21, to consider the banning of polyvinyl chloride whiskey bottles by the FDA and the proposed vinyl chloride data presentation to NIOSH.

A copy of the proposed rules for the Federal Register banning polyvinyl chloride resins for use in plastic whiskey bottles is attached. Dr. T. R. Torkelson, in calling the meeting, said the ban was the result of no established human tolerance for vinyl chloride monomer in food, the published work on tumors in rats by Viola, and the announced inhalation study by MCA. Other comments, at the meeting, were that FDA would not ban the bottles under the so-called Delaney Amendment because the published inhalation work by Viola was not considered a suitable test by FDA. Dr. B. M. G. Zwicker of Goodrich insisted that the mode of bottle fabrication or the type of resin had no bearing on the dissolved monomer in the bottle.

Other discussion, at both meetings, centered about the forthcoming presentation of vinyl chloride data to NIOSH. Dr. David Duffield from ICI represented the European vinyl chloride group. Borden, Exxon, Uniroyal, British Petroleum Chemicals, Goodyear, Monsanto, and Olin were not represented as sponsoring companies.

The question as to who approved the plans for the NIOSH presentation was raised, discussed vaguely, and tabled as being out of the group's province. The MCA letter to company executive contacts, dated March 26, 1973, which assumed consent if no reply were made, was cited as authorization. Two replies were received- one favorable and one unfavorable.

The need for the NIOSH presentation was discussed with the following pertinent points noted:

1. The MCA letter to company executive contacts, dated March 26, 1973, could be construed as evidence of an illegal conspiracy by industry if the information were not made public or at least made available to the government.

2. If the interim results of the European annual study were made available, the timing might be appropriate for the presentation to NIOSH.

3. If the interim results of the European annual study were not available, i.e. released by the study sponsors, then the presentation to NIOSH should have been made last year or earlier.

Dr. David Duffield was pressured a great deal by the Chairman, Doctor Torkelson from Dow, to secure permission from the European project sponsors to use the interim data. Doctor Torkelson reluctantly agreed to wait until July 1 for the permission. Doctor Duffield promised to arrange an early meeting of the project sponsors to discuss the granting of the desired permission.

Participants in the proposed presentation, in June, are:

1. Dr. M. Key, Director of NIOSH and others he may suggest.

2. Dr. K. D. Johnson and/or Mr. George E. Best of MCA

3. Mr. V. K. Rowe and Mr. G. J. Williams of Dow

4. Mr. Anton Vittone or Mr. T. B. Nantz of Goodrich

5. Mr. H. Kusnetz of Shell

6. Dr. C. U. Dernehl of Union Carbide.

Doctor Dernehl and Doctor Johnson were the only representatives at the meeting.

The presentation would follow this general outline:

A. A listing of the twenty U.S. companies sponsoring the MCA work.

B. Description of the Industry

1. Monomer Production (U.S. and World)

   a) Volume in pounds

   b) Producers

   c) Number of exposed workers

2. PVC and Copolymer Production

   a) Producers

   b) Uses and volume of each use

   c) Number of exposed workers

C. Toxicity Studies - History

1. Past toxicity studies.

2. Past epidemiological studies - acroosteolysis.

3. Work reported by Viola.

4. Unpublished European Work

   Viola's current study and the European consortium study.

D. Toxicity Studies - Current

1. MCA toxicity study protocol.

2. MCA epidemiological study protocol.

3. European consortium study protocol.

4. Viola's current study protocol.

E. Recommendations for Action

1. Control

a) Industry would adhere to a 200 ppm TLV or TWA limit and would work toward lower levels.

b) Industry would monitor extensively the exposure levels of workers. (Dow and Goodrich insisted the monitoring should be continuous and recommended a Davis combustion conductivity or a Davis halide meter. Other devices mentioned were I.R. absorption with a 10-meter (?) cell or vapor phase chromatography. Dow promised to supply data on these instruments.)

2. Establish working contact at NIOSH.

3. Future research - none pending results of ongoing work.

Possible studies are dose response for carcinogenic action, the effect of VCl on (-SH), and metabolism.

This outline is to be a guide, but the representatives at the meeting will have wide latitude in the items discussed.

Items specifically removed from the proposed presentation or discussed and not used are:

1. Dow epidemiological study— study of a limited group of Dow workers showed a 0.08 probability of cancer with 0.1 considered significant. The control group, however, showed 4.2 cancers and the exposed group had 8.

2. Dow air pollution work showed vinyl chloride had a half life of 4 hours in light, 2.5 times as strong as sunlight.

3. All references to use of vinyl chloride in aerosol propellants were removed, since it is a minor part of the industry and is not a worker-exposure problem except for beauticians and can fillers. (This was removed at the insistence of UCC and Allied, but some effort to reinsert it in the presentation by the industry representatives is believed to be possible.)

4. The recommendation for a 50 ppm TLV or TWA was removed because of the government tendency to reduce such limits by a factor of 10. UCC pointed out that manual cleaning of autoclaves could not meet the 50 ppm TLV, and that no resin plant could operate at a 5 ppm TLV. UCC also pointed out that the TLV for autoclave cleaning, recommended in the acroosteolysis study, was 50 ppm but there was no data in the study to support the recommendation. The group generally agreed that the polymer industry did not presently have the ability to live within the 50 ppm TLV.

Other items of interest picked up at the meeting were:

1. Air Products is planning a new emulsion resin plan in the east, but is currently stymied by environmental considerations.

2. The contract with Tabershaw-Cooper Associates for the industry epidemiological study has not been approved by MCA, yet, despite the emergency subscription drive on April 6. MCA will try to give Tabershaw-Cooper a letter of intent in May, it they can find the proposed contract.

3. Comments were heard that the MCA counsel present at the meeting should participate in the NIOSH presentation, since he seemed to be more knowledgeable than anyone else.

Hazard to UCC's interests exists if vinyl chloride is declared to be a carcinogen or if vinyl chloride monomer is detected by FDA in foods exposed to vinyl chloride polymers as film, coatings, or gasketing. Since no data exists

on the monomer content of solvent or dispersion resins, R&D has been requested to determine the monomer present in the resin. If this content is appreciable, then some investigation of fabricated films or coatings appears warranted. Currently, our answer to inquiries is to say we don't believe there can be any in coatings, etc.

R. N. Wheeler, Jr.

RNWJr/ra

Attachment

bc: Dr. D. H. Glenn, 515
Dr. E. Q. Hull, 514

Copied by MCA
5/18/73

NOT BANNING UNDER DELANEY AMENDMENT BECAUSE INHALATION WAS NOT CONSIDERED A SUITABLE TEST

BATF
Bur. Alc., Tob. & Firearms

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 121]

PRIOR-SANCTIONED POLYVINYL CHLORIDE RESIN

Notice of Proposed Rule Making

Polyvinyl chloride (PVC) is a polymeric resin which was used as a component of food packaging materials prior to the passage of the Food Additives Amendment of 1958 and which has been widely used since that time. Not all polyvinyl chloride formulations can be used in food packaging. Polyvinyl chloride having a maximum volatility of not over 3 percent when heated for 1 hour at 105° C., and having an inherent viscosity of not less than 0.35 when determined by American Society for Testing and Materials (ASTM) standard method D 1243–66, is prior-sanctioned for use as a component of a film for food wraps or as a can enamel.

An ingredient whose use in food or food packaging is subject to a prior-sanction or approval within the meaning of section 201(s)(4) of the Federal Food, Drug, and Cosmetic Act is exempt from classification as a food additive and may be used without pre-clearance by FDA.

The sanction for PVC rests on an article entitled "Food Packaging" by A. J. Lehman, Chief of the Division of Pharmacology, FDA, published in the "Association of Food and Drug Officials of the United States," volume 20, No. 4, October 1956. It is clear in the article that acceptance of the resins named therein was based on their lack of migration when tested for solubility in the listed solvent systems. The publication cited did not refer to polyvinyl chloride bottles and did not name an alcoholic medium as a test system.

In January 1973, the Food and Drug Administration began to receive reports of possible stability problems with PVC bottles used for distilled spirits. These bottles were part of an experimental program first authorized by the Treasury Department, Bureau of Alcohol, Tobacco, and Firearms in November 1968. Industrial users of these bottles had discovered an unpleasant taste in lightly flavored alcoholic beverages which had been kept in storage. Preliminary analytical results indicated that vinyl chloride monomer, a component of PVC, was extracted from the bottle to the liquor during storage. The level of vinyl chloride migrating varied, with some samples in a high range of 10–20 p/m. At that time the results had not been confirmed by mass spectrographic examination.

During April a new series of analytical results, including mass spectrographic examination, was presented to FDA by industry which confirmed the early reports of vinyl chloride monomer in various distilled spirits. These beverage samples had been stored in PVC bottles for up to 1 year. Information was also received which reported that wine packaged in PVC bottles was similarly affected.

FDA has now confirmed migration of the monomer in distilled spirits in its own laboratory. While analytical tests are continuing both at FDA and in industrial laboratories to resolve many unanswered technical questions relative to this problem, it seems certain at this time that vinyl chloride monomer migrates to alcohol from PVC bottles used to package distilled spirits and wine.

Vinyl chloride monomer as such is a poisonous and deleterious substance. FDA knows of no studies which establish a safe level of consumption when this monomer is leached from containers into alcoholic foods. Accordingly, the Commissioner concludes that the use of polyvinyl chloride for packaging alcoholic foods may cause such foods to be adulterated.

There is no indication at this time that polyvinyl chloride resins in contact with nonalcoholic foods will result in migration of monomers, and such use need not be restricted.

Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 402, 409, 701(a), 52 Stat. 1042, 1046–1047 as amended, 1049, 1055; 21 U.S.C. 321(s), 342, 348, 371(a)) and under authority delegated to him (21 CFR 2.120), the Commissioner of Food and Drugs proposes to amend part 121 by adding a new section 121.2009 to read as follows:

§ 121.2009 Polyvinyl chloride resins.

(a) Polyvinyl chloride resins consist of basic resins produced by the polymerization of vinyl chloride.

(b) Polyvinyl chloride basic resins have a maximum volatility of not over 3 percent when heated for 1 hour at 105° C., and an inherent viscosity of not less than 0.35 when determined by ASTM method ary 10, 1973.

(c) Polyvinyl chloride resins meeting the criteria of paragraphs (a) and (b) of this section may be used as a component of food packaging material, other than packaging material for use in contact with alcoholic foods.

Interested persons may, on or before July 16, 1973, file with the Hearing Clerk, Department of Health, Education, and Welfare, room 6–86, 5600 Fishers Lane, Rockville, Md. 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated May 15, 1973.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc.73–9981 Filed 5–16–73;9:42 am]

Office of Education

[45 CFR Part 188]

FINANCIAL ASSISTANCE FOR THE IMPROVEMENT OF EDUCATIONAL OPPORTUNITIES FOR ADULT INDIANS

Pursuant to the authority contained in section 314 of the Adult Education Act, as added by part C of title IV of the Education Amendments of 1972 (Public Law 92–318, 86 Stat. 342, 20 U.S.C. 1211a), the Commissioner of Education, with the approval of the Secretary of Health, Education, and Welfare,

[1] Copies may be obtained from: American Society for Testing and Materials, 1916 Race Street, Philadelphia, Pa. 19103.

UCC
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