

file: PVC Labels

RECEIVED

OCT 18 1982

I. F. HARRISON

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEZIAN
WILLIAM H. BORGHESANI, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
PETER THOMAS SMITH
MICHAEL F. MORRONE
LARRY S. SOLOMON

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N.W.
SUITE 1000
WASHINGTON, D.C. 20036

TELEPHONE
202 296-2100
CABLE ADDRESS "KELMAN"

January 9, 1976

No. 12

TO: All Members of VCM/PVC Mailing Lists

Ladies and Gentlemen:

Once again we want to bring you up to date on recent developments regarding PVC. This letter will cover regulatory matters in the Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) areas.

FDA

PVC Pipe

As you know, the FDA proposed regulations included proposals concerning PVC pipe. Preparatory to a formal response to some of the questions raised, a draft "discussion" protocol had been prepared by an action task group representing both PPI and Unibell and was submitted to FDA for its informal review and comments. A meeting had been set for January 6 between FDA personnel and representatives of the action task group to obtain FDA's opinion regarding the draft protocol. Then, at almost the last moment, FDA cancelled the meeting on the grounds that it was "premature." The reasons given by FDA were the following:

1. Until the jurisdictional question between EPA and FDA is settled, comments by either agency may lead to a duplicative waste of effort;
2. Until all the Comments in the PVC docket are reviewed and evaluated and until FDA has decided upon the regulatory approach it will take, any suggestions or recommendations with regard to PVC

25287001

BFG52613

January 9, 1976
Page Three

a final PVC regulation to be published in the Federal Register. To the best of our knowledge, however, this target date has not been administratively programmed. Inasmuch as all the Comments filed have not yet been delivered to the Bureau of Foods and its technical staff has barely started on the review of the scientific data, the April 1 date appears to be a laudable, but perhaps unrealistic, goal. It should be remembered that after the technical review of all the submitted data has been completed, it will then be necessary for Bureau of Foods' personnel to reach a decision as to the proper regulatory stance to take in drafting final regulations that will reflect this position and to prepare a preamble that answers with some specificity every Comment that has been filed.

Cosmetics Packaging

Some of you will recall that Dr. Schaffner of the Food and Drug Administration had earlier indicated that a proposed regulation or policy statement on cosmetics packaging was planned for publication in the Federal Register before the end of December, 1975. No such proposal appeared and we have now learned that the Division of Cosmetics Technology, the division charged with responsibility for drafting such regulations, is waiting to review all the Comments filed in the PVC docket before going forward with any proposed cosmetics position. As we understand it, the Division of Cosmetics Technology is now reasonably assured that present compounds and the products made therefrom pose no significant or urgent safety problems for cosmetics users and feels it can act deliberately, waiting for as much information as can be developed before moving in this area.

OSHA

With regard to the Occupational Safety and Health Administration (OSHA) Standard, you may recall that last spring and summer several companies petitioned OSHA to modify, amend or, at least, explain formally certain portions of the Standard for Occupational Exposure to Vinyl Chloride.

BFG52614

25287002

January 9, 1976
Page Four

We had known for some time and, indeed, had so advised you in these letters that it was highly unlikely that OSHA would ever react publicly to alter the Standard. As a result, during the entire interim, companies had been operating on rather impromptu advice received from counsel or some individual at OSHA in many areas where questions existed. Although OSHA has responded in writing from time to time to requests for advisory opinions concerning a particular plant's problem or condition, now, perhaps for the first time, OSHA has responded to a Petition in a general fashion applicable to the industry at large.

In the attached, self-explanatory letter from OSHA directed to Mr. Raymond Schenck of Air Products and Chemicals, Inc., OSHA has taken a formal position running parallel to that which many in industry have been espousing for some time. Specifically, OSHA has decided that the definition of "fabricated product" must be interpreted, in so far as "release of vinyl chloride" is concerned, to mean a release that is at or above the action level.

The import of this interpretation is that many PVC resins and compounds which contain low residual vinyl chloride monomer will be eligible for classification as "fabricated products." The obvious benefit of this is that these products will be exempt from labeling requirements. Additionally, it should be noted that products which are exempt from labeling requirements are those which should be expected to be exempt from the Standard itself because of the fact that the materials are incapable of releasing vinyl chloride monomer in quantities in excess of the action level. Thus, many of the fabricators, compounders and others handling such PVC materials prior to final fabrication would be effectively exempted from the OSHA Standard providing the rudimentary requirements of initial monitoring and the like are performed and show negative results.

EPA

Until such time as Associate Counsel Ruckelshaus, Beveridge, Fairbanks and Diamond have a reasonable opportunity to comment in writing on the myriad activities in

BFG52615

25287003

U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration
WASHINGTON, D.C. 20210



DEC 17 1975

RECEIVED

DEC 22 1975

APCI CHEM. CO.,
LAW DEPT.

Mr. Raymond H. Schenck
Attorney
Air Products and Chemicals, Inc.
Five Executive Mall
Swedesford Road
Wayne, Pennsylvania 19087

Dear Mr. Schenck:

This is in response to your letter of June 30, 1975 to Assistant Secretary John H. Stender petitioning for the modification of 29 CFR 1910.1017(b)(6), (formerly 29 CFR 1910.93q(b)(6) recodified May 28, 1975), Exposure to Vinyl Chloride, Occupational Safety and Health Standards.

29 CFR 1910.1017(b)(6) defines a fabricated product as being one which is "made wholly or partly from polyvinyl chloride, and which does not require further processing at temperatures, and for times, sufficient to cause mass melting of the polyvinyl chloride resulting in the release of vinyl chloride."

"Release of vinyl chloride" means the release of an amount of vinyl chloride which would likely result in employee exposure at or above the action level without regard to the use of engineering controls. Products which can be classified as fabricated products are exempt from the provisions of the vinyl chloride standard. All other products are subject to the requirements of the standard.

There are no plans presently to formally modify the vinyl chloride standard. Therefore, we hope that the the above clarification of the regulation will satisfy your petition request.

Should you have further questions, please contact me or members of my staff.

Sincerely,

Barry White
Associate Assistant Secretary
For Regional Programs

BFG52616

25287004