

LAW OFFICES
KELLER AND HECKMAN

1150 17TH STREET, N.W.
SUITE 1000
WASHINGTON, D.C. 20036
—
(202) 956-5600

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES H. REEDMAN
WILLIAM H. BORSHESIAN, JR.
MALCOLM D. MACARTHUR
WAYNE V. BLACK
MARTIN W. BERCOVICI
JOHN S. ELDRED
CAROLE C. HARRIS
MICHAEL F. MORRONE
JOHN B. DUSECK
PETER L. DE LA CRUZ
CHRISTINE A. MEASHER
SHIRLEY S. FUJIMOTO
LAWRENCE P. HALPRIN

EDWARD L. KORNBERG
MARY MARTHA HEMAMARA
MARY FOX EYRE
RALPH A. SIMMONS
C. DOUGLAS JARRETT
PETER A. SUSSER
SHEILA A. MILLAR
RUSSELL H. FOX
KLENE RINGEL HELLER
SUSAN T. CONTI
SUSAN J. BLUM
MARK C. HAYES
SANDRA J.P. DINIIS
E. ADAM LEVENS
S. CRAIG TRAUTMANN

SCIENTIFIC STAFF
DANIEL S. DIXLER
DURWARD F. DOOGEN
CHARLES V. BREDER

TELEX
48 88881

TELECOPIER
(202) 296-7662

CABLE ADDRESS "KELMAN"

WRITER'S DIRECT DIAL NUMBER

DRAFT

(202) 956-5641

June 4, 1986

John B. Miles, Jr., Director
Directorate of Field Operations
Occupational Safety and Health Administration
U.S. Department of Labor
200 Constitution Avenue, N.W.
Washington, D.C. 20210

Re: OSHA Regulation of PVC

Dear Mr. Miles:

Thank you for your letter of April 30, 1986 to Peter Sussner of our firm regarding the regulatory status of polyvinyl chloride (PVC) under the Hazard Communication Standard (HCS), 29 C.F.R. § 1910.1200, and OSHA's vinyl chloride standard, 29 C.F.R. § 1910.1017. Following receipt of your letter, we met with Mr. Gail M. Brinkerhoff in the Office of Health Standards on May 20, 1986. He resolved our question concerning the Registry of Toxic Effects of Chemical Substances (RTECS) and helped us to better frame the remaining issues.

As explained below and based on OSHA's current compliance instructions and prior letters and litigating position, we request an opinion letter confirming that: (1) PVC itself is not a hazardous chemical under the Hazard Communication Standard, and (2) PVC resins and compounds do not trigger the labeling and training provisions of the vinyl chloride standard when no exposure to vinyl chloride monomer (VCM) at or above the action level is anticipated.

While such an opinion letter is plainly consistent with Agency policy, the advent of the HCS has created a real need for the clear articulation of OSHA's current position. We

VEV-151770

KELLER AND HECKMAN

John B. Miles, Jr., Director
June 4, 1986
Page 2

would like the opportunity to meet with you and your staff after you have had an opportunity to consider these materials. We have also taken the liberty of attaching a draft opinion letter of the type we are seeking from your office. We have found the preparation of such draft letters to be helpful in focusing discussion and clearly articulating our request. We will contact your office shortly to schedule a meeting.

A. Current Status of PVC

Polyvinyl chloride (Chemical Abstract Services Registry No. 9002-86-2) is the second most widely used plastic resin in the United States. It is produced from vinyl chloride monomer (CAS No. 75-01-4) by a process called polymerization. PVC resin is fabricated into a wide variety of consumer and industrial products including pipe and conduit, floor tile, curtains, shoes, food packaging, records, medical devices, blood transfusion bags and a myriad of other items. While there is concern about possible adverse health effects relating to VCM exposure, PVC itself is quite inert from a toxicity standpoint. For example, Environmental Protection Agency (EPA) regulations under a variety of statutes minimize the release of VCM into the environment, while PVC itself is not deemed hazardous and is not regulated per se. See, e.g., 40 C.F.R. § 60.61 (VCM regulated as hazardous air pollutant).

The food contact applications for vinyl chloride polymers and copolymers are extensive. While PVC is "prior-sanctioned" for current food contact uses, earlier this year the Food and Drug Administration (FDA) published a long-awaited proposal reaffirming the safety of PVC for all food contact applications. 51 Fed. Reg. 4,173-4,188 (Feb. 3, 1986) (copy enclosed). The key specification in the proposal is a limitation on the amount of residual vinyl chloride monomer (RVCM) permitted in various vinyl chloride polymers.

In the preamble to the proposal, FDA reported on "vastly improved production technology that has made it possible for manufacturers to succeed in reducing the level of residual vinyl chloride monomer in vinyl chloride polymer by a factor of nearly of 1 million." 51 Fed. Reg. at 4173. As the Agency noted, before 1975, residual VCM levels of 1,000 parts per million (ppm) were common. Since then, improved manufacturing procedures have lowered the RVCM level by more than

A

KELLER AND HECKMAN

John B. Miles, Jr., Director
June 4, 1986
Page 3

five orders of magnitude. Id. at 4,178. A review of the FDA proposal indicates that the Agency had no toxicological concerns with PVC polymer itself.

FDA conducted a risk assessment in light of probable exposure to any unwanted vinyl chloride monomer constituent. The Agency concluded that "there is a reasonable certainty of no harm from the exposure to vinyl chloride monomer that may result from the use of vinyl chloride polymers in food packaging complying with the vinyl chloride monomer limitations set forth in" the proposal. Id. at 4,183. As pertinent here, the FDA proposal constitutes a formal finding that PVC is safe for the intimate personal use involved in food contact applications. We also note that PVC is cleared for use in a wide variety of drug and device applications also subject to FDA's jurisdiction. For example, PVC may be used to package pharmaceutical products and is cleared for use in medical devices such as blood bags, in dialysis machine tubing, and in other critical uses.

**B. Status of PVC as a Hazardous Chemical
Under Hazard Communication Standard**

Our review of EPA and FDA regulation as well as the discussion below on OSHA regulation, indicates a uniform position that, apart from the question of RVCM levels, PVC does not present any health concerns. We recognize that OSHA has a legitimate interest in minimizing worker exposure to vinyl chloride monomer. However, it would be very helpful if OSHA provided a clear statement that PVC itself is not a hazardous chemical under the HCS. The question of RVCM and its effect on PVC's status is discussed below. As for PVC itself, however, we do not believe that there is any basis for characterizing it as a hazardous chemical as that term is defined under the HCS.

As discussed more fully in our letter of February 26, 1986 to you (copy enclosed), PVC is not listed as a carcinogen or possible potential carcinogen by the National Toxicology Program (NTP). Similarly, PVC itself is not regulated as a carcinogen by OSHA. No monograph by the International Agency for Research on Cancer (IARC) concludes that PVC is a carcinogen or potential carcinogen. IARC's summary classification of the carcinogenic risk of chemicals does not include PVC under Category 1 or 2. Thus, consistent with OSHA Instruction

A

KELLER AND HECKMAN

John B. Miles, Jr., Director
June 4, 1986
Page 4

CPL 2-2.38A (May 16, 1986), PVC is not considered a carcinogen under the HCS.

Your letter of April 30, 1986 correctly stated that characterizations of IARC studies reported in the Registry of Toxic Effects of Chemical Substances (RTECS) published by the National Institute for Occupational Safety and Health (NIOSH) are the interpretation by the contractor used by NIOSH. Mr. Brinkerhoff further confirmed that interpretations contained in the NIOSH Registry (RTECS) are not necessarily binding. Rather, manufacturers assessing the carcinogenic status of substances should consult the studies themselves to reach a definitive conclusion. In this instance, it is quite clear that the NIOSH contractor erred in characterizing the IARC studies on PVC. Because of the confusion that may be generated by the contractor's interpretation, a letter from your office indicating that PVC itself is not hazardous would help resolve any lingering confusion on this issue.

**C. Status of PVC Resin and Compound Under
the OSHA Vinyl Chloride Standard**

Beginning in January 1974, OSHA worked quickly to publish a final vinyl chloride standard on October 4, 1974. The standard sets a permissible exposure limit (PEL) of 1 part per million (ppm) averaged over any 8-hour period and an action level of 0.5 ppm averaged over an 8-hour work day. Other provisions establish monitoring, medical surveillance, sign and label, and reporting requirements.

The standard applies to the "manufacture, reaction, packaging, repackaging, storage, handling or use of vinyl chloride or polyvinyl chloride, but does not apply to the handling or use of fabricated products made of polyvinyl chloride." 29 C.F.R. § 1910.1017(a)(2). Because "fabricated products" are exempt, their definition has been of particular significance to the regulated community.

Under Section 1910.1710(a)(6), a fabricated product is defined as "a product 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." Slightly restated, PVC is a fabricated product not

KELLER AND HECKMAN

John B. Miles, Jr., Director
June 4, 1986
Page 5

subject to the standard unless it is mass melted and that melting results in the release of vinyl chloride.

Although the concept of mass melting is easily understood, at the time the standard was issued it was unclear what the phrase "resulting in the release of vinyl chloride" meant. In the attached 1975 opinion letters, OSHA stated that "release of vinyl chloride" means the release of an amount of vinyl chloride which would be likely to result in employee exposure at or above the action level without regard to the use of engineering controls. Thus, low residual monomer resins which would not release vinyl chloride in excess of the action level during further processing, such as mass melting, are fabricated products not subject to the Act.

As FDA noted in its February 1986 proposal, residual vinyl chloride levels have been reduced from the 1,000 ppm level found in 1975 by orders of magnitude. Thus, when manufacturers of PVC resin and compound can conclude that exposure at or above the action level is not likely, the training, labeling, and similar provisions of the standard are not applicable.

The continuing validity of the 1975 opinion letters was confirmed in a letter from the Secretary of Labor filed with the Occupational Safety and Health Review Commission (OSHRC). In Secretary of Labor v. Hooker Chemical Company, (OSHRC Docket No. 78-4862) (decision enclosed), an OSHA inspector issued a citation to Hooker Chemical Company for allegedly failing to provide training under the vinyl chloride standard for employees who worked in the calendaring, compounding and warehouse areas of a Hooker facility. Hooker contested the citation on the basis that employees working in these areas were not subject to OSHA's vinyl chloride standard because they were not exposed to vinyl chloride monomer above the action level. Both Hooker and OSHA's monitoring for vinyl chloride in the calendaring and compounding facilities indicated concentrations below the 0.5 ppm action level.

In May 1979, Judge Charles K. Chaplin issued a decision that adopted Hooker's position and vacated the OSHA citation. He held that the training provisions of the standard do not apply to areas where the vinyl chloride level in the ambient air is below the action level. Although not requested to do so by any party, a Commissioner on the Occupational Safety and

A

KELLER AND HECKMAN

John B. Miles, Jr., Director
June 4, 1986
Page 6

Health Review Commission directed that the case be reviewed. In responding to the review proceedings, OSHA changed its position and filed the letter stating that the Judge's decision should be affirmed. Significantly, the Secretary of Labor's letter stated that: "Training requirements are not applicable in this case because respondent's cited compounding and calendering operations simply are not processes which could result in hazardous exposure to vinyl chloride by the nature of the operations themselves." Because OSHA indicated that it did not wish to pursue the case, the Review Commission left the Judge's decision intact.

The training provisions of the vinyl chloride standard provide that "each employee engaged in vinyl chloride or polyvinyl chloride operations shall be provided training in a program relating to the hazards of vinyl chloride and precautions for its safe use." Section 1910.1017(j). Literally interpreted, any "polyvinyl chloride operation" would require training. However, OSHA's consistent position has been that when exposure is below the action level, the standard is largely inapplicable.

A similar conclusion pertains to labeling. For example, PVC is literally required to be labeled with an indication that it contains vinyl chloride, a cancer-suspect agent. However, where exposure to vinyl chloride will not reach or exceed the action level, labeling is not required.

We would appreciate your confirmation that low RVCM resins which are not expected to result in exposure above the action level are not subject to the training and labeling requirements of the standard because such materials would not result in hazardous exposure to vinyl chloride. Again, this is simply a confirmation of the Secretary of Labor's letter and the Hooker case.

D. Conclusion

Based on your letter of April 30, if the mass melting of PVC resin and compound will result in employee exposure at or above the action level of 0.5 ppm, the labeling requirements of both the vinyl chloride standard and the Hazard Communication Standard apply. Alternatively, if PVC resin or compound will not result in exposure to vinyl chloride monomer at or

A

KELLER AND HECKMAN

John B. Miles, Jr., Director
June 4, 1986
Page 7

above the action level, the labeling and training requirements of the vinyl chloride standard do not apply and the provisions of the Hazard Communication Standard do not apply because there would be no hazardous exposure.

As noted at the outset, we have attached a draft letter summarizing the items we wish to confirm. We would like to meet to discuss this matter with you and will contact you in the near future to arrange a mutually convenient meeting time. In the interim, if you should have any immediate comments or questions, please feel free to contact us.

Cordially yours,

DRAFT

Peter L. de la Cruz

Enclosures

cc: Gail M. Brinkerhoff

A

D R A F T

- 1 -

Peter L. de la Cruz, Esquire
Keller and Heckman
1150 17th Street, N.W.
Washington, D.C. 20036

Re: Regulatory Status of PVC

Dear Mr. de la Cruz:

This is in response to your letter of June 2, 1986, and our subsequent meeting on _____, 1986, concerning the regulatory status of polyvinyl chloride (PVC). The first issue you raised was whether PVC itself was a hazardous chemical or carcinogen under the provisions of the Hazard Communications Standard, 29 C.F.R. § 1910.1200. Putting aside for the moment the question of residual vinyl chloride monomer (RVCM) levels, we agree that PVC itself is not a hazardous chemical or a carcinogen under the Hazard Communications Standard.

In determining a substance's carcinogenicity, please note that the Hazard Communication Standard directs employers to consult the National Toxicology Program's (NTP) Annual Report on Carcinogens, International Agency for Research on Cancer (IARC) monographs, and Subpart C of Part 1910 of the Agency's regulations. The Registry of Toxic Effects of Chemical Substances (RTECS) published by the National Institute for Occupational Safety and Health (NIOSH) serves as a handy

D R A F T

- 2 -

reference to NTP and IARC studies. RTECS also includes the interpretation by the contractor used by NIOSH of statements made in NTP and IARC studies. While these characterizations are helpful, they are not necessarily binding and we agree that PVC is not a carcinogen despite the confusion that the NIOSH Registry may create on this point.

Consistent with the Agency's earlier position, we can confirm that PVC resin or compound is not subject to the training or labeling requirements of the standard when the handling, shipping, storage and further processing of the resin or compound are not expected to result in employee exposure to vinyl chloride monomer above the action level of 0.5 ppm. This conclusion is based on the exclusion of fabricated products from the standard and the Agency's earlier interpretation of the term "release of vinyl chloride monomer" as constituting a release at or above the action level.

The interrelationship of the Hazard Communication Standard and the vinyl chloride standard was another issue. When PVC compound or resin is expected to result in exposure to vinyl chloride monomer (VCM) above the action level (0.5 ppm), the training and labeling requirements of the vinyl chloride

D R A F T

- 3 -

standard apply as well as the provisions of the Hazard Communications Standard, subject to the limits on scope and applicability found in the Hazard Communications Standard. If PVC resin or compound are likely to result in VCM exposure below the action level, then the labeling and training provisions of the vinyl chloride standard do not apply and the Hazard Communications Standard would not be triggered. Manufacturers must individually determine whether other adjuvants in PVC compound, apart from PVC and VCM, might independently subject PVC compound to the provisions of the Hazard Communications Standard.

We appreciate the opportunity to address your concerns. Please do not hesitate to contact us again if you have further questions.

Sincerely,

John B. Miles, Jr.

Director

Directorate of Field Operations