

This amendment postpones the effective date of the subject regulation from March 23, 1978, to May 22, 1978, and must be made effective immediately to accomplish its purpose in the public interest. It does not appear that public participation in this rulemaking proceeding would make additional relevant information available to the Department.

Accordingly, under the administrative procedure provisions of 5 U.S.C. 553, it is found upon good cause that further notice and other public procedure with respect to the amendment are impracticable, unnecessary, and contrary to the public interest.

Done at Washington, D.C., this 22th day of March 1978.

NOTE.—The Animal and Plant Health Inspection Service has determined that this document does not contain a major proposal requiring preparation of an Inflation Impact Statement under Executive Order 11821 and OMB Circular A-107.

E. A. SCHILF,
Acting Deputy Administrator,
Veterinary Services.

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[6355-01]

Title 16—Commercial Practices

CHAPTER II—CONSUMER PRODUCT SAFETY COMMISSION

SUBCHAPTER C—FEDERAL HAZARDOUS SUBSTANCES ACT REGULATIONS

PART 1500—HAZARDOUS SUBSTANCES AND ARTICLES; ADMINISTRATION AND ENFORCEMENT REGULATIONS

Self-Pressurized Household Substances Containing Vinyl Chloride Monomer; Classification as Banned Hazardous Substance

AGENCY: Consumer Product Safety Commission.

ACTION: Reissuance of final regulation.

SUMMARY: The Commission reissues a regulation classifying any household substance in a self-pressurized container containing vinyl chloride monomer as a "banned hazardous substance" under the Federal Hazardous Substances Act. The Commission believes that there is ample scientific evidence to establish the carcinogenicity of vinyl chloride monomer by inhalation and to demonstrate that human exposure to vinyl chloride monomer can result in a rare form of liver cancer. The Commission is reissuing this regulation on a prospective basis, as of the date of the original ban (October 7,

1974), because that original retroactive ban was set aside for failure to hold a hearing on objections to the retroactive effect of the regulation and because retroactive application of the regulation is no longer necessary.

DATES: The effective date of the rule is June 22, 1978. The rule is applicable to products which are manufactured or imported on or after October 7, 1974. Any written objections must be received by April 24, 1978.

FOR FURTHER INFORMATION CONTACT:

Charles M. Jacobson, Consumer Product Safety Commission, Directorate for Compliance and Enforcement, Division of Regulatory Management, Washington, D.C. 20207, 301-492-6400.

SUPPLEMENTARY INFORMATION:

BACKGROUND

On August 21, 1974 the Commission published in the FEDERAL REGISTER, 39 FR 30112, a final regulation pursuant to section 2(q)(1)(B) of the Federal Hazardous Substances Act (FHSA), 15 U.S.C. 1261 (q)(1)(B), declaring any self-pressurized products intended or suitable for household use that contain vinyl chloride monomer as an ingredient or in the propellant to be "banned hazardous substances" (the proposed regulation was published in the FEDERAL REGISTER on May 23, 1974 (39 FR 18115)). The Commission took that action because of scientific studies linking the death of industrial workers from a rare form of liver cancer to vinyl chloride exposure and because of certain animal studies further indicating the carcinogenicity of vinyl chloride monomer. In that same document the Commission declined to exercise any discretion, which it might have had under the FHSA, to make its banning order prospective only, thus requiring repurchase of products already distributed under the provisions of section 15 of the FHSA (15 U.S.C. 1274). That document also provided, as is required for the issuance of regulations pursuant to section 2(q)(1)(B) of the FHSA, that the procedures for rulemaking under section 701(e) of the Federal Food, Drug and Cosmetic Act would govern and that adversely affected persons could file objections and requests for a public hearing within 30 days of the publication of the Commission's order.

Four statements containing objections and requests for a public hearing were received by the Commission. The objections filed focused primarily on the fact that the ban applied to products already in the hands of consumers and suppliers and required that such products be repurchased by the manufacturer. The Commission's action insofar as it prohibited the

future sale of self-pressurized household products containing vinyl chloride monomer was not objected to.

In a decision published in the FEDERAL REGISTER on October 11, 1974 (39 FR 36576), the Commission found that none of the objections received warranted a stay of the effective date of the order or the holding of a public hearing. The Commission noted that none of the objections contained a reference to or an offer to present factual information which might lead the Commission to a conclusion contrary to that reached by it.

As a result of the Commission's rulings on the objections, a petition for review of the vinyl chloride ban as it pertained to goods introduced into interstate commerce prior to the effective date of the ban was filed in the United States Court of Appeals for the Ninth Circuit on October 2, 1974. (Pactra Industries, Inc. v. Consumer Product Safety Commission, Nos. 74-2902; 74-3168). That court, in an opinion filed on May 2, 1977, set aside the vinyl chloride ban on the basis that a public hearing on the objections should have been held.*

In an effort to determine the appropriate regulatory response to the Pactra decision, the Commission staff undertook a field survey to determine the extent of vinyl chloride-containing aerosols in the marketplace. That survey revealed that no new such products containing vinyl chloride had been manufactured since 1974 and that, with the exception of three relatively small lots being held, virtually no products containing vinyl chloride remained in the marketplace. The Commission contacted the 3 firms holding the products and asked that they voluntarily destroy their existing inventories. The firms subsequently reported that the inventories had either been destroyed or removed from Commission jurisdiction.

Because the information available to the Commission indicates that vinyl chloride-containing aerosols are no longer being manufactured or held and because the Commission continues to believe that such products, if produced, would present a risk of serious

*That Court of Appeals on December 13, 1974 had granted a stay of that portion of the vinyl chloride ban which required repurchase and disposal of all household products in the channels of commerce containing vinyl chloride monomer because the Court found that the Commission has failed to comply with the requirements of the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 et seq. Subsequently, the Commission conducted an extensive environmental review of the ban and concluded that the repurchase requirement would not have a significant adverse effect on the human environment and that an environmental impact statement was not necessary. The Court vacated the stay and the ban remained in effect until May 2, 1977.

illness or injury, the Commission has decided to reissue its banning regulation on a prospective basis only, as of the date of the original ban (October 7, 1974). Such action will insure that no self-presurized household substances containing vinyl chloride monomer are manufactured in the future.

GROUNDWORK FOR THE BAN

Vinyl chloride is a colorless, flammable gas under normal conditions of temperature and pressure, but is generally handled as a liquid under pressure. Among the synonyms and trade names for vinyl chloride are chloroethylene, monochloroethene, ethylene monochloride, vinyl chloride monomer, VC and VCM.

Vinyl chloride monomer is not known to occur in nature. The substance has been produced commercially in the United States since at least 1928. In 1971, at least 97 percent of the vinyl chloride monomer consumed in the U.S. was for the production of vinyl chloride homopolymer and copolymer resins. The remainder was used in a variety of ways, such as the production of methyl chloroform, as an additive to specialty coatings, and as a component of propellant mixtures for certain aerosol products.

Vinyl chloride has been shown to be carcinogenic by inhalation in animal bioassays. In addition, a casual relationship has been demonstrated between exposure through inhalation of workers to vinyl chloride monomer during the polymerization process and the onset of angiosarcoma of the liver, a very rare form of liver cancer. The animal and human data demonstrating the carcinogenicity of vinyl chloride was reference in the Commission's 1974 proposed and final vinyl chloride banning regulations (39 FR 18115; 39 FR 30112) and is summarized and updated below.

1. ANIMAL DATA

In 1974 Professor Cesare Maltoni of the Instituto di Oncologia, Bologna, Italy, reported on a series of experiments on the effect of exposure through inhalation on rats, mice, and hamsters to vinyl chloride monomer at concentrations of 10,000, 6,000, 2,500, 500, 250, and 50 ppm for varying periods of time. Preliminary results of this study included the observation of angiosarcomas of the liver in both rats and mice exposed to vinyl chloride at concentrations as low as 250 parts per million. In addition, malignant tumors were induced at several other sites in both species. (Maltoni, C and G. La femine, "Carcinogenicity bioassays on vinyl chloride. I. Research plan and early results." Environm. Res., 7:387 (1974)).

Preliminary studies have suggested that vinyl chloride monomer causes subcutaneous (occurring beneath the

skin) angiosarcomas in the offspring of rats exposed to vinyl chloride during pregnancy. (IARC Monographs on the Evaluation of Carcinogenic Risk of Chemicals to Man, 7:291 (1974)).

In addition, vinyl chloride monomer animal studies are currently being performed at Edgewood Arsenal for CPSC (1975-1978) under an interagency agreement. The results of those studies are expected in the second quarter of 1978.

2. HUMAN DATA

In early 1974, the B.F. Goodrich Chemical Company reported to the National Institute for Occupational Safety and Health (NIOSH) that since 1971, three of its employees, who had an average exposure of approximately 19 years to vinyl chloride monomer at unknown concentrations, had died from angiosarcoma of the liver.

At about the same time reports of 10 other similar deaths among men employed at various vinyl chloride monomer polymerizations plants appeared in the literature. In two of the reported cases, angiosarcomas were present in tissues other than the liver. (Heath, C.W., Jr., Falk, H. and J.L. Creech, Jr., "Characteristics of cases of angiosarcoma of the liver among vinyl chloride workers in the United States", Ann N.Y. Acad. Sci. (1974)).

At the time of its 1974 ban, previously cited herein, the Commission was aware of 24 confirmed cases of angiosarcoma among the 10,000 to 20,000 persons exposed to vinyl chloride in the course of their employment. As of August 1977, NIOSH reported a total of 63 cases of liver angiosarcoma among workers directly involved in the polymerization of VCM. Twenty-five of the cases developed among workers in the U.S., with the other 38 cases observed in workers from 11 other countries. (Table 1, Reported Cases of Angiosarcoma of the Liver Among Vinyl Chloride Polymerization Workers, submitted by NIOSH (August, 1977)). As angiosarcoma of the liver is extremely rare in the general population, there is agreement among scientists that this observation of 63 cases in vinyl chloride monomer workers is evidence of a casual relationship.

3. ACTIONS BY OTHER AGENCIES

In addition to the animal and human data demonstrating the carcinogenicity of vinyl chloride monomer, the Commission notes that actions taken by other agencies further support this ban. For example, on October 4, 1974, the Occupational Safety and Health Administration published a final standard (an emergency temporary standard and a proposed standard had been published earlier) setting an occupational exposure limit for vinyl chloride of 1 ppm averaged over any 8

hour period and a ceiling of 5 ppm averaged over any period not exceeding 15 minutes (39 FR 35890). On August 26, 1974 the Food and Drug Administration (FDA) published final rules applicable to the use of vinyl chloride monomer as an ingredient of self-presurized drug and cosmetic products. The use of vinyl chloride in self-presurized cosmetic products was banned, and an approved new drug application as a condition to marketing was required for all self-presurized drug products containing the substance (39 FR 30830). On April 26, 1974, the Environmental Protection Agency published an emergency suspension order and a notice to cancel the registration of all pesticide spray products containing vinyl chloride that are used in the home, in food handling establishments, in hospitals, or in enclosed areas (39 FR 14753). This notice stated that under some conditions of use of aerosol products in households, the concentration of propellant in the air could be as high as 400 parts per million immediately after spraying. The registration of a number of pesticides was subsequently cancelled under this order (see 40 FR 3494).

EFFECTIVE DATE AND APPLICABILITY

The banning regulation set forth below applies to all self-presurized household products containing vinyl chloride monomer as an ingredient or in the propellant manufactured or imported on or after October 7, 1974, the effective date of the Commission's original banning order. The regulation will, therefore, permit existing stock manufactured or imported before that date to be sold. Since the information available to the Commission indicates that such products are no longer being manufactured or held, the Commission believes that the primary effect of this regulation will be to insure that vinyl chloride monomer will not be used as an ingredient or as a propellant in household products in the future.

The regulation is effective June 22, 1978, except as to any provision that may be stayed by the filing of proper objections. Any written objections must be filed by April 24, 1978. The Commission will consider all objections prior to the effective date of this ban; and as an alternative to staying the ban as a result of the objections and holding a hearing, the Commission may revise its final order.

ENVIRONMENTAL CONSIDERATIONS

Pursuant to section 1021.5 of the Commission's proposed and interim procedures implementing the National Environmental Policy Act (NEPA) (16 CFR 1021), the Executive Director of the Commission has determined that this ban is not a major action, that its impact on the environment will be

negligible, and that no environmental review is necessary. The Executive Director's determination, a copy of which is on file at the Office of the Secretary, concluded that the ban would have no environmental effect because no product which would be affected by the ban is currently being produced or held in inventory. Therefore, since no vinyl chloride aerosols are currently in the channels of commerce, the environmental issue of disposal of repurchased products which was present at the time of the initial ban is now moot. (At that time the Commission had concluded that disposal of concentrations of vinyl chloride aerosols could be accomplished without significant environmental danger. (40 FR 41170).)

CONCLUSION

Section 2(f)(1)(A) Federal Hazardous Substances Act defines "hazardous substance" as "any substance or mixture of substances which is toxic . . . if such substance or mixture of substances may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." Section 2(g) of the act states that the term "toxic" includes any substance or mixture of substances which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface. Provisions of section 2(q)(1)(B) authorize the Commission to issue regulations to classify a "hazardous substance" which is packaged or suitable for use in households as a "banned hazardous substance" if the Commission determines that notwithstanding any cautionary labeling which may be required under the FHSA, the degree or nature of the hazard involved in the presence or use of the substance in households is such that the public health and safety can be adequately served only by keeping that substance out of the channels of interstate commerce.

After careful consideration of all available information as discussed above, the Commission has decided to affirm its earlier determination (see 39 FR 30112) that self-pressurized household products containing vinyl chloride monomer are toxic hazardous substances within the meaning of sections 2 (f) and (g) of the FHSA because vinyl chloride monomer, when inhaled, has the capacity to produce substantial illness, specifically cancer. The Commission believes that ample evidence in the form of scientific studies and chemical reports is available to establish the carcinogenicity of vinyl chloride monomer by inhalation and to demonstrate that human exposure to the substance can result in angio-

sarcoma of the liver. As indicated above, it has been reported that vinyl chloride monomer may be present in the air in concentrations as great as 400 parts per million after household use of self-pressurized containers with vinyl chloride in the propellant. Tumors have been induced in mice after exposure to VCM in concentrations as low as 250 parts per million.

Because no safe level of human exposure to vinyl chloride monomer has been established, the Commission further has decided to affirm its earlier finding that adequate cautionary labeling cannot be written under the FHSA for self-pressurized household products containing vinyl chloride monomer. The Commission concludes that the degree and nature of the hazard presented by the use of self-pressurized household products containing VCM is such that the public health and safety can be adequately served only by keeping such products out of the channels of interstate commerce. Therefore, on the effective date of the regulation promulgated below, all self-pressurized household products containing VCM manufactured or imported on or after October 7, 1974 become banned hazardous substances.

Accordingly, pursuant to provisions of the Federal Hazardous Substances Act (secs. 2(f)(1), (A), (B), (g), (q)(1)(B), 3(a), 74 Stat. 372, 374, as amended 80 Stat. 130-05, 83 Stat. 187-189, 90 Stat. 503; 15 U.S.C. 1261, 1262) and the Federal Food, Drug and Cosmetic Act (sec. 701 (e), (f), (g), 52 Stat. 1055-56, as amended 70 Stat. 919, 72 Stat. 948; 21 U.S.C. 371 (e), (f), (g)), and under authority vested in the Consumer Product Safety Commission by the Consumer Product Safety Act (sec. 30(a), 86 Stat. 1231; 15 U.S.C. 2079(a)), 16 CFR 1500.17 is amended by deleting the existing paragraph (a)(10) and by adding a new paragraph (a)(10), as follows (unchanged, the introductory text of paragraph (a) is included below for context):

§ 1500.17 Banned hazardous substances.

(a) Under the authority of section 2(q)(1)(B) of the act, the Commission declares as banned hazardous substances the following articles because they possess such a degree or nature of hazard that adequate cautionary labeling cannot be written and the public health and safety can be served only by keeping such articles out of interstate commerce;

(10) Self-pressurized products intended or suitable for household use that contain vinyl chloride monomer as an ingredient or in the propellant manufactured or imported on or after October 7, 1974.

Any person who will be adversely affected by the foregoing order may at any time on or before April 24, 1978, file with the Office of the Secretary, Consumer Product Safety Commission, 1111 18th Street NW., Washington, D.C. 20207, written objections thereto, preferably in five copies. Objections shall show wherein the person filing will be adversely affected by the order and specify with particularity the provisions of the order deemed objectionable and the grounds for the objections. Objections should raise material issues that are not frivolous or inconsequential. If a hearing is requested, the objections must state the issues for the hearing. Objections may be accompanied by a memorandum or brief in support thereof. Received objections may be seen in the above office during working hours Monday through Friday.

Effective date: The regulation promulgated above shall become effective June 22, 1978, except as to any provision that may be stayed by the filing of proper objections. As indicated above, as an alternative to staying the ban as a result of any objections and holding a hearing, the Commission may revise its final order. Notice of the filing of objections or the lack thereof or any amending of the final order will be given by publication in the FEDERAL REGISTER.

(Secs. 2(f)(1), (A), (B), (g), (q)(1)(B), 3(a), 74 Stat. 372, 374, as amended 80 Stat. 130-05, 83 Stat. 187-189, 90 Stat. 503 (15 U.S.C. 1261, 1262); sec. 701 (e), (f), (g), 52 Stat. 1055-56, as amended 70 Stat. 919, 72 Stat. 948 (21 U.S.C. 371 (e), (f), (g)); sec. 30(a), 86 Stat. 1231 (15 U.S.C. 2079(a)).)

Dated: March 17, 1978.

SADYE E. DUNN,
Acting Secretary, Consumer
Product Safety Commission

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[1505-01]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER E—ANIMAL DRUGS, FEEDS, AND RELATED PRODUCTS

[Docket No. 77N-0133]

PART 500—GENERAL

Subpart B—Specific Administrative Rulings and Decisions

Correction

In FR Doc. 78-6051 appearing on page 9802 in the issue of Friday, March 10, 1978, on page 9803, in the