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Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12762 Filed 5–20–96; 8:45 am]

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21 CFR Part 178

[Docket No. 93F–0385]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of formaldehyde, polymer with 1-naphthylenol, as a release agent, applied on the internal parts of reactors employed in the production of polyvinyl chloride and acrylic copolymers intended for food-contact applications. This action is in response to a petition filed by Compagnia Italiana di Ricerca e Sviluppo, srl (CIRS).

DATES: Effective May 21, 1996; written objections and requests for a hearing by June 20, 1996.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 18, 1993 (58 FR 60859), FDA announced that a food additive petition (FAP 3B4380) had been filed by Compagnia Italiana di Ricerca e Sviluppo, srl (CIRS), c/o AAC Consulting Group, 1730 Rhode Island Ave. NW., Washington, DC 20036. The petition proposed to amend the food additive regulations in part 178 (21 CFR part 178) to provide for the safe use of formaldehyde, polymer with 1-naphthylenol, as an antiscaling agent, applied on the internal parts of reactors employed in the production of polyvinyl chloride and acrylic copolymers intended for food-contact applications. During its review, the agency determined that the use of the additive as an antiscaling agent has essentially the same technical effect as that of a release agent. This final rule reflects this conclusion and therefore FDA is listing the additive in § 178.3860 *Release agents*.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe and that the regulations in § 178.3860 should be amended as set forth below.

FDA's review of the petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the Committee) of FDA's Center for Food Safety and Applied Nutrition. The Committee noted that for many years, formaldehyde has been known to be a carcinogen by the inhalation route, but it concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The Committee's conclusion was based on the fact that the route of administration (inhalation) is not relevant to the safety of formaldehyde residues in food and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). In addition, the agency has received literature reports of two drinking water studies on formaldehyde: (1) A preliminary report of a carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1); and (2) a negative study by Til et al. (1989), conducted in The Netherlands (Ref. 2). The Committee reviewed both studies and concluded that data concerning the Soffritti study reported, ''* * * were unreliable and could not be used in the assessment of the oral carcinogenicity of formaldehyde'' (Ref. 3). This conclusion is based on a lack of critical details in the study, questionable histopathological conclusions, and the use of unusual nomenclature to describe the tumors. Based on the Committee's evaluation, the agency has determined that there is no basis to conclude that formaldehyde is a carcinogen when ingested.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before June 20, 1996, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Soffritti, M., F. Maltoni, and R. Biagi, ''Formaldehyde: An Experimental Multipotential Carcinogen,'' *Toxicology and Industrial Health*, vol. 5, No. 5:699–730, 1989.

2. Til, H. P., R. A. Woutersen, V. J. Feron, V. H. M. Hollanders, H. E. Falke, and J. J. Clary, ''Two-Year Drinking Water Study of Formaldehyde in Rats,'' *Food Chemical Toxicology*, vol. 27, No. 2, pp. 77–87, 1989.

3. Memorandum of conference concerning ''formaldehyde;'' meeting of the Cancer Assessment Committee, FDA; April 24, 1991, and March 4, 1993.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.3860 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings ''List of substances'' and ''Limitations'' to read as follows:

§ 178.3860 Release agents.

* * * * *

(b) * * *

List of substances	Limitations
* * * * * * *	
Formaldehyde, polymer with 1-naphthylenol (CAS Reg. No. 25359–91–5).	For use only as an antiscaling or release agent, applied on the internal parts of reactors employed in the production of polyvinyl chloride and acrylic copolymers, provided that the residual levels of the additive in the polymer do not exceed 4 parts per million.
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Dated: May 15, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–12761 Filed 5–20–96; 8:45 am]

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DEPARTMENT OF THE TREASURY

Departmental Offices

31 CFR Part 12

Sale and Distribution of Tobacco Products

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Final rule.

SUMMARY: Section 636 of the Department of the Treasury's Appropriations Act, Pub. L. 104–52, requires the Secretary of the Treasury to promulgate regulations that restrict the sale of tobacco products in vending machines and the distribution of free samples of tobacco products in any Federal building under the jurisdiction of the Secretary of the Treasury. Section 636 permits the Secretary to designate areas not subject to these prohibitions, if such areas also prohibit the presence of minors.

EFFECTIVE DATE: May 21, 1996.

FOR FURTHER INFORMATION CONTACT: Robert T. Harper, (202) 622–0500.

SUPPLEMENTARY INFORMATION: The Department of the Treasury has determined that this rule is not a significant regulatory action for the purposes of Executive Order 12866. Pursuant to 5 U.S.C. sec. 553(a)(2), this rule is not required to be published for notice and comment. Therefore, the Regulatory Flexibility Act does not apply.

List of Subjects in 31 CFR Part 12

Concessions, Federal buildings and facilities, Vending machines.

For the reasons set forth in the preamble, 31 CFR part 12 is added as follows:

PART 12—RESTRICTION OF SALE AND DISTRIBUTION OF TOBACCO PRODUCTS

Sec.

Authority: Sec. 636, Pub. L. 104–52, 109 Stat. 507.

§ 12.1 Purpose.

This part contains regulations implementing the ''Prohibition of Cigarette Sales to Minors in Federal Buildings Act,'' Public Law 104–52, Section 636, with respect to buildings under the jurisdiction of the Department of the Treasury.

§ 12.2 Definitions.

As used in this part—

(1) the term *Federal building under the jurisdiction of the Secretary of the Treasury* includes the real property on which such building is located;

(2) the term *minor* means an individual under the age of 18 years; and

(3) the term *tobacco product* means cigarettes, cigars, little cigars, pipe tobacco, smokeless tobacco, snuff, and chewing tobacco.

§ 12.3 Sale of tobacco products in vending machines prohibited.

The sale of tobacco products in vending machines located in or around any Federal building under the jurisdiction of the Secretary of the Treasury is prohibited, except in areas designated pursuant to § 12.5 of this part.

§ 12.4 Distribution of free samples of tobacco products prohibited.

The distribution of free samples of tobacco products in or around any Federal building under the jurisdiction of the Secretary of the Treasury is prohibited, except in areas designated pursuant to § 12.5 of this part.

§ 12.5 Prohibitions not applicable in areas designated by the Secretary of the Treasury.

The prohibitions set forth in this part shall not apply in areas designated by the Secretary as exempt from the prohibitions, but all designated areas must prohibit the presence of minors.

George Muñoz,

Assistant Secretary for Management and Chief Financial Officer.

[FR Doc. 96–12273 Filed 5–20–96; 8:45 am]

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