

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.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Food Safety and Applied Nutrition, 21 CFR part 176 is amended as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

1. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: Secs. 201, 402, 406, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 346, 348 379e).

2. Section 176.170 is amended in the table in paragraph (a)(5) by alphabetically adding a new entry under the headings "List of substances" and "Limitations" to read as follows:

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

* * * * *

(a) * * *

(5) * * *

List of substances	Limitations
*	*
Ammonium zirconium citrate (CAS Reg. No. 149564-62-5), ammonium zirconium lactate-citrate (CAS Reg. No. 149564-64-7), ammonium zirconium lactate (CAS Reg. No. 149564-63-6).	For use as insolubilizers only for clay coatings with protein binders in coatings for paper and paperboard, at a level not to exceed 1.4 percent by weight of coating solids.
*	*

Dated: August 17, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95-21380 Filed 8-28-95; 8:45 am]

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21 CFR Part 178

[Docket No. 90F-0364]

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 *N,N*-bis(2-ethylhexyl)-*alpha*-methyl-1*H*-benzotriazole-1-methanamine as a copper deactivator for lubricants with incidental food contact. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective August 29, 1995; written objections and requests for a hearing by September 28, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., 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 21, 1990 (55 FR 48693), FDA announced that a food additive petition (FAP 1B4233) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532-2188, proposing that § 178.3570 *Lubricants with incidental food contact* (21 CFR 178.3570) be amended to provide for the safe use of *N,N*-bis(2-ethylhexyl)-*alpha*-methyl-1*H*-benzotriazole-1-methanamine as a copper deactivator for lubricants with incidental food contact complying with 21 CFR 178.3570.

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 § 178.3570(a)(3) should be amended as set forth below.

FDA's review of the subject 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 histopathologic 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 September 28, 1995, 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., Maltoni, F., Maffei, and R. Biagi, "Formaldehyde: An Experimental Multipotential Carcinogen," *Toxicology and Industrial Health*, Vol. 5, No. 5, pp. 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 178.3570 is amended in the table in paragraph (a)(3) by alphabetically adding a new entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.3570 Lubricants with incidental food contact.

* * * * *

(a) * * *
(3) * * *

Substances	Limitations
*	For use as a copper deactivator at a level not to exceed 0.1 percent by weight of the lubricant.
N,N-Bis(2-ethylhexyl)- ar-methyl-1H- benzotriazole-1- methanamine (CAS Reg. No. 94270- 86-7). *	*

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Dated: August 15, 1995.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

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SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Excise Tax Procedural Regulations (26 CFR part 40) relating to deposits of excise taxes. Effective January 1, 1995, the Uruguay Round Agreements Act of 1994 (the Act) amended sections 6302(e) and (f) (relating to deposits of excise taxes). As amended, these provisions require an additional deposit of all excise taxes except air transportation taxes in September of each year. Beginning in 1997, the amendments also apply to air transportation taxes. These temporary regulations provide safe harbor rules for that additional deposit of tax.

Under existing rules, deposits of excise taxes for a semimonthly period generally must equal the amount of tax liability incurred (or in the case of collected taxes, the amount of tax collected) during that semimonthly period unless a safe harbor applies. Sections 40.6302(c)-1(c) and 40.6302(c)-2(b) (2) and (3) provide two safe harbor rules for computing the amount of tax required to be deposited; the look-back quarter safe harbor rule and the current liability safe harbor rule.

These temporary regulations modify the safe harbor rules to reflect the amendments made by the Act.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these temporary regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information: The principal author of these regulations is Ruth Hoffman, Office of Assistant Chief Counsel (Passthroughs and Special Industries). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 40

Excise taxes, Reporting and recordkeeping requirements.