

Dated: July 10, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 92F-0261]

Indirect Food Additives: Adhesives and Components of Coatings

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 3-pentadecenyl phenol mixture (obtained from cashew nutshell liquid) reacted with formaldehyde and ethylenediamine in a ratio of 1:2:2 as an epoxy curing agent in resins and coatings intended for contact with food. This action is in response to a petition filed by Cardolite Corp.

DATES: The regulation is effective August 12, 1997. Submit written objections and requests for a hearing by September 11, 1997.

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: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3089.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of July 21, 1992 (57 FR 32226), FDA announced that a food additive petition (FAP 2B4326) had been filed by Cardolite Corp., c/o 1414 Fenwick Lane, Silver Spring, MD 20910 (now c/o Regulatory Assistance Corp., 17 Clearview Circle, Hopewell Junction, NJ 12533). The petition proposed to amend the food additive regulations in § 175.300 *Resinous and polymeric coatings* (21 CFR 175.300) to provide for the safe use of 3-pentadecenyl phenol mixture (obtained from cashew nutshell liquid) reacted with formaldehyde and ethylenediamine in a ratio of 1:2:2 (CAS Reg. No. 68413-28-5) as an epoxy curing agent in resins and coatings intended for contact with food.

FDA's review of the subject petition indicates that the additive may contain trace amounts of formaldehyde and ethylenediamine as impurities. The potential carcinogenicity of formaldehyde and ethylenediamine 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, concerning the Soffritti study, " * * * that the data 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.

The Committee also evaluated the results of a 2-year study submitted by the petitioner on ethylenediamine dihydrochloride (EDA•2HCl) in Fisher 344 rats (Ref. 4). The committee concluded that data from this study do not demonstrate carcinogenic potential for (EDA•2HCl) in Fisher 344 rats (Ref. 5). Based on the Committee's evaluation, the agency has determined that based upon the available data and information, there is no basis to conclude that ethylenediamine is a carcinogen.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, that the additive will have its intended technical effect, and therefore, that the regulations in § 175.300 should be amended as set forth below.

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 § 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 11, 1997, 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., C. 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.

4. Bushy Run Research Center, "Ethylenediamine Dihydrochloride Two-Year Feeding Study in the Rat; Report 46-27," Mellon Institute-Union Carbide Corp., Export, PA.

5. Memorandum of conference concerning "Ethylenediamine Dihydrochloride (EDA•2HCl);" meeting of the Cancer Assessment Committee, FDA; June 7, 1996.

List of Subjects in 21 CFR Part 175

Adhesives, 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 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 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 175.300 is amended in paragraph (b)(3)(viii)(b) by alphabetically adding a new entry to read as follows:

§ 175.300 Resinous and polymeric coatings.

* * * * *

(b) * * *

(3) * * *

(viii) * * *

(b) * * *

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3-Pentadecenyl phenol mixture (obtained from cashew nutshell liquid) reacted with formaldehyde and ethylenediamine in a ratio of 1:2:2 (CAS Reg. No. 68413-28-5).

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Dated: August 5, 1997.

William K. Hubbard,
Associate Commissioner for Policy
Coordination.

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Parts 227, 228, and 229

RIN 1010-AC25

Delegation of Royalty Management Functions to States

AGENCY: Minerals Management Service, Interior.

ACTION: Final rulemaking.

SUMMARY: The Minerals Management Service (MMS) is adding new rules authorizing the delegation of several Federal royalty management functions to States. These rules implement recently-enacted legislation.

EFFECTIVE DATE: September 11, 1997.

FOR FURTHER INFORMATION CONTACT: David Guzy, Chief, Rules and Publications Staff, Royalty Management Program, Minerals Management Service, telephone (303) 231-3432, Fax (303) 231-3385, e-Mail David_Guzy@mms.gov.

SUPPLEMENTARY INFORMATION: The principal authors of this final rulemaking are Larry Cobb, Harry Corley, Jim Detlefs, Clare Onstad, Robert Prael, Todd McCutcheon, Dave Steiber, Cecelia Williams, and Sam Wilson, MMS; and Peter Schaumberg and Sarah Inderbitzin of the Office of the Solicitor.

I. General

On August 13, 1996, Congress enacted the Federal Oil and Gas Royalty Simplification and Fairness Act of 1996, Pub. L. 104-185, as corrected by Pub. L. 104-200 (RSFA). The RSFA amends portions of the Federal Oil and Gas Royalty Management Act of 1982 (FOGRMA), 30 U.S.C. 1701 *et seq.* Prior to the RSFA enactment, section 205 of FOGRMA, 30 U.S.C. 1735, provided for the delegation of only audits, inspections, and investigations to the States. The RSFA amendments to section 205 now provide that the Minerals Management Service (MMS) may delegate other Federal royalty management functions to requesting States for Federal oil and gas leases onshore.

The royalty management functions MMS may delegate under the RSFA amendments are:

- (1) Conducting audits and investigations;
- (2) Receiving and processing production and royalty reports;
- (3) Correcting erroneous report data;
- (4) Performing automated verification; and
- (5) Issuing demands, subpoenas, orders to perform restructured

accounting, and related tolling agreements and notices to lessees or their designees.

The RSFA amendments to section 205(d) also provide that within 12 months after the date of enactment, after consultation with the States, the Secretary must issue standards and regulations pertaining to delegable functions and other relevant responsibilities, including:

- (1) Audits to be performed;
- (2) Records and accounts to be maintained;
- (3) Reporting procedures to be required by the States under this section;
- (4) Receipt and processing of production and royalty reports;
- (5) Correction of erroneous report data;
- (6) Performance of automated verification;
- (7) Issuance of standards and guidelines in order to avoid duplication of effort;
- (8) Transmission of report data to the Secretary; and
- (9) Issuance of demands, subpoenas, and orders to perform restructured accounting, for royalty accounting purposes.

In response to the section 205 RSFA amendments, MMS formed the 205 Consultation Team, comprised of MMS, interested States, representatives from State associations, and a representative of the Bureau of Land Management to discuss how to implement the delegation provisions of the RSFA.

MMS proposed rules implementing the section 205 RSFA amendments (62 FR 19967 April 24, 1997). As part of that proposed rulemaking, MMS explained that it would develop *MMS Standards for Delegation (Standards)* which would contain further information States would need to perform delegated functions. MMS held several outreach meetings in June of 1997 at various locations to discuss the *MMS Standards for Delegation (Standards)* document with States and industry attendees.

II. Indian Lands

In the proposed rule, MMS proposed to amend 30 CFR parts 228 and 229 to remove references to cooperative agreements and delegations for Federal lands under those parts since delegation for Federal lands are now covered under new part 227. MMS also proposed to amend those parts to conform to the principles of "Plain English." Because MMS is not under a statutory deadline to publish parts 228 and 229 like it is for part 227, MMS is not removing the references to Federal lands in, or making the "Plain English" changes to