

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 176

[Docket No. 95F-0255]

Indirect Food Additives: Paper and Paperboard Components

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 diallyl maleate and 1-ethynyl-1-cyclohexanol as optional polymerization inhibitors and dimethyl (methyl hydrogen) polysiloxane as a cross-linking agent in the manufacture of vinyl-containing siloxanes that are used in coatings for paper and paperboard that contact food; to increase the maximum permitted residual level of platinum, which remains from the catalyst used in the manufacture of vinyl-containing siloxanes, to 200 parts per million (ppm) of these siloxanes; and to expand the safe use of coatings with vinyl-containing siloxanes for contact with additional food types and under additional conditions of use. This action is in response to a petition filed by GE Silicones.

DATES: The regulation is effective December 17, 1998; written objections and requests for a hearing by January 19, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-215), 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 September 25, 1995 (60 FR 49414), FDA announced that a food additive petition (FAP 5B4475) had been filed by GE Silicones, c/o 700 13th St. NW., Washington, DC 20005. The petition proposed to amend the food additive regulations in § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) to provide for the safe use of vinyl-containing siloxanes as a component of coatings for paper and

paperboard in contact with food and to provide for the safe use of 1-ethynyl-1-cyclohexanol as an optional inhibitor for the additive. The petition also proposed that the regulations be amended to increase the level of platinum catalyst used in the manufacture of vinyl-containing siloxanes to 200 ppm. In a notice published in the **Federal Register** of September 5, 1996 (61 FR 46814), FDA amended the September 25, 1995, notice to indicate that upon further review of the petition, the agency noted that the petitioner also proposed approval of the use of diallyl maleate as an optional polymerization inhibitor and dimethyl (methyl hydrogen) polysiloxane as a cross-linking agent in the manufacture of vinyl-containing siloxanes used in coatings on paper and paperboard that contact food. In addition, the agency clarified that the petitioner proposed to expand the safe use of coatings with vinyl-containing siloxanes for contact with additional food types and under additional conditions of use.

In the filing notices, the agency inadvertently stated that the petition proposed to increase the level of platinum catalyst used in the manufacture of vinyl-containing siloxanes. The petition actually proposed to increase the maximum permitted residual level of platinum in the vinyl-containing siloxanes, which is consistent with the existing regulation.

FDA has evaluated the data in the petition and other relevant material. The agency finds that the proposed use of the additives diallyl maleate and 1-ethynyl-1-cyclohexanol as optional polymerization inhibitors and the proposed use of the additive dimethyl (methyl hydrogen) polysiloxane as a cross-linking agent in the manufacture of vinyl-containing siloxanes intended for use as a component of coatings for paper and paperboard in contact with food are safe and achieve their intended technical effects. Finally, the agency concludes that the resulting vinyl-containing siloxanes are safe and will have their intended technical effects. Therefore, the regulations in § 176.170 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.

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before January 19, 1999, 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.

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, 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: 21 U.S.C. 321, 342, 346, 348, 379e.
 2. Section 176.170 is amended in the table in paragraph (b)(2) by revising the first entry for "Siloxanes and silicones" 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.

* * * * *
 (b) * * *
 (2) * * *

List of substances	Limitations
* * * Siloxanes and silicones; platinum-catalyzed reaction product of vinyl-containing dimethyl polysiloxane (CAS Reg. Nos. 68083-19-2 and 68083-18-1) with methyl hydrogen polysiloxane (CAS Reg. No. 63148-57-2) or dimethyl (methyl hydrogen) polysiloxane (CAS Reg. No. 68037-59-2). Diallyl maleate (CAS Reg No. 999-21-3), dimethyl maleate (CAS Reg. No. 624-48-6), 1-ethynyl-1-cyclohexanol (CAS Reg. No. 78-27-3) and vinyl acetate (CAS Reg. No. 108-05-4) may be used as optional polymerization inhibitors. * * *	* * * For use only as a surface coating. Platinum content not to exceed 200 parts per million. * * *

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 Dated: December 4, 1998.

L. Robert Lake,
Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.
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 BILLING CODE 4160-01-F

attributable to publicly traded partnerships.
DATES: Effective Date: These regulations are effective December 17, 1998.
Applicability Dates: See Effective Dates under **SUPPLEMENTARY INFORMATION** of the preamble.

FOR FURTHER INFORMATION CONTACT: Christopher Kelley or Terri Belanger at (202) 622-3080 (not a toll-free number).

SUPPLEMENTARY INFORMATION:
Background

The final regulations add § 1.7704-3 to the Income Tax Regulations (26 CFR part 1) relating to the definition of qualifying income for publicly traded partnerships under section 7704(d) of the Internal Revenue Code (Code). The final regulations also amend § 1.469-10 of the Income Tax Regulations relating to the application of section 469 to publicly traded partnerships.

On December 19, 1997, proposed regulations (REG-105163-97, 1998-8 I.R.B. 31) were published in the **Federal Register** (62 FR 66575). A number of written comments were received on the proposed regulations under section 7704(d). Two speakers provided testimony at a public hearing held on April 28, 1998. After consideration of all the comments, the proposed regulations under section 7704 are adopted, as revised by this Treasury decision.

No comments were received on the proposed regulations under section 469. The proposed regulations under section 469 are adopted without revision by this Treasury decision.

Explanation of Revisions and Summary of Comments

1. Determination of Gross Income for Purposes of Section 7704(c)(2)

a. Capital Losses
 Section 7704(d)(1)(F) provides that, except as otherwise provided, the term *qualifying income* includes any gain from the sale or disposition of a capital asset (or property described in section 1231(b)) held for the production of income described in section 7704(d). Several commentators requested clarification as to how capital losses incurred by the partnership are treated in determining gross income of the partnership for purposes of section 7704(c)(2). The final regulations clarify that, in general, all losses are ignored in the computation of gross income.

b. Straddles
 The proposed regulations requested comments on the appropriate way to compute the gross income for a partnership that makes a mixed straddle account election under § 1.1092(b)-4T. The final regulations provide that, for purposes of applying the general rule that a capital gain on an investment is taken into account but a capital loss is not, certain rules shall apply that generally net capital gains and losses recognized in a taxable year with respect to a straddle. This treatment applies to all straddles, not just mixed straddle accounts, and to other interests in property that produce a substantial diminution of the partnership's risk of loss similar to that of straddles. In addition, the final regulations contain a wash sale rule for gains in certain

DEPARTMENT OF THE TREASURY
Internal Revenue Service
26 CFR Part 1
[TD 8799]
RIN 1545-AV15
Certain Investment Income Under the Qualifying Income Provisions of Section 7704 and the Application of the Passive Activity Loss Rules to Publicly Traded Partnerships

AGENCY: Internal Revenue Service (IRS), Treasury.
ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the treatment of certain investment income under the qualifying income provisions of section 7704 and the application of the passive activity loss rules to publicly traded partnerships. These regulations provide guidance on calculating a publicly traded partnership's qualifying income under section 7704. The regulations will affect the classification of certain partnerships for federal tax purposes and also will affect the passive activity loss limitations with respect to items