

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 July 12, 1995 (60 FR 35912), FDA announced that a food additive petition (FAP 5B4469) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532-2188. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of 2-[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]-dioxaphosphepin-6-yl]oxy)-N,N-bis[2-[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]ethylethyl)ethanamine as a process stabilizer in high density olefin copolymers intended for use in contact with food.

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 the intended technical effect, and that the regulations in § 178.2010 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 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 February 23, 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.

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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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 178.2010 is amended in the table in paragraph (b) by alphabetically adding a new entry under the headings “Substances” and “Limitations” to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
2-[[2,4,8,10-Tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]-dioxaphosphepin-6-yl]oxy]-N,N-bis[2-[[2,4,8,10-tetrakis(1,1-dimethylethyl)dibenzo[d,f][1,3,2]dioxaphosphepin-6-yl]oxy]ethyl]ethanamine (CAS Reg. No. 80410–33–9).	For use only: 1. At levels not to exceed 0.075 percent by weight of olefin copolymers complying with § 177.1520(c) of this chapter, item 3.1a or 3.2a (where the density of each of these polymers is not less than 0.94 gram per cubic centimeter), and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.

Dated: January 5, 1996.

Fred R. Shank.

Director, Center for Food Safety and Applied Nutrition.

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Nicarbazin and Bacitracin Methylene Disalicylate

AGENCY: Food and Drug Administration,
HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Planalquimica Industrial Ltda. The ANADA provides for use of nicarbazin and bacitracin methylene disalicylate in Type C broiler feed for the prevention of certain forms of coccidiosis and for