

Based on this information, the agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, 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 § 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 October 4, 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 revising the entry for "Phosphorous acid, cyclic neopentetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl)ester" under the heading "Substances" and by adding a new entry "2." under the heading "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * *
Phosphorous acid, cyclic neopentetetrayl bis(2,6-di- <i>tert</i> -butyl-4-methylphenyl)ester (CAS Reg. No. 80693-00-1).	For use only: 1. At levels not to exceed 0.25 percent by weight of polypropylene complying with § 177.1520 of this chapter. * * * 2. At levels not to exceed 0.05 percent by weight of polymers complying with § 177.1520(c) of this chapter, item 3.1 or 3.2, and with a maximum thickness of 100 micrometers (0.004 inch) for use with all food types under conditions of use B, C, D, E, F, G, and H described in Table 2 of § 176.170(c) of this chapter.
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Dated: August 20, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-22483 Filed 9-3-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 178

[Docket No. 96F-0027]

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 bis(2,4-di-*tert*-butyl-6-methylphenyl) ethyl phosphite as a

processing stabilizer for olefin polymers intended for use in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective September 4, 1996; written objections and requests for a hearing by October 4, 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 February 9, 1996 (61 FR 5001), FDA announced that a food additive petition (FAP 6B4492) had been filed by Ciba-Geigy Corp., 540 White Plains Rd., Tarrytown, NY 10591-9005, proposing that food additive regulations be amended in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of bis(2,4-di-*tert*-butyl-6-methylphenyl) ethyl phosphite as a processing stabilizer for olefin polymers complying with 21 CFR 177.1520 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 achieve its intended technical effect, and that the regulations in § 178.2010(b) 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 October 4, 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 for bis(2,4-di-*tert*-butyl-6-methylphenyl) ethyl phosphite to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers

(b) * * *

List of Substances				Limitations			
*	*	*	*	*	*	*	*
Bis(2,4-di- <i>tert</i> -butyl-6-methylphenyl) ethyl phosphite (CAS Reg. No. 145650-60-8).				For use only: 1. At levels not to exceed 0.3 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter. The finished polymers may only be used with food of the types identified in § 176.170(c) of this chapter, Table 1, under Categories I, II, IV-B, VI-A, VI-B, VII-B, and VIII, and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.1 percent by weight of propylene polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, 1.3, 3.2b, 3.4, or 3.5, or 3.1a (where the density of this polymer is at least 0.85 gram per cubic centimeter and less than 0.91 gram per cubic centimeter). The finished polymers may only be used in contact with food of the types identified in § 176.170(c) of this chapter, Table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter.			

List of Substances

Limitations

3. At levels not to exceed 0.1 percent by weight of high-density ethylene polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, or 3.6 (where the density of each of these polymers is at least 0.94 gram per cubic centimeter), or 5. The finished polymers may only be used in contact with food of the types identified in § 176.170(c) of this chapter, Table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use C (maximum temperature 70 °C) through G described in Table 2 of § 176.170(c) of this chapter. *Provided*, that the finished food contact articles have a volume of at least 18.9 liters (5 gallons).
4. At levels not to exceed 0.01 percent by weight of low-density ethylene polymers complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.4, 3.5, or 3.6 (where the density of each of these polymers is less than 0.94 gram per cubic centimeter). The finished polymers may only be used in contact with food of the types identified in § 176.170(c) of this chapter, Table 1, under Categories III, IV-A, V, VI-C, VII-A, and IX, and under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter. *Provided*, that the average thickness of such polymers in the form in which they contact food shall not exceed 0.001 inch.

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Dated: August 22, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96-22484 Filed 9-3-96; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 510

New Animal Drugs; Change of Sponsor Name and Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name and address from Roussel-UCLAF to Roussel-UCLAF SA.

EFFECTIVE DATE: September 4, 1996.

FOR FURTHER INFORMATION CONTACT:

Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: Roussel-UCLAF, Division Agro-Vetinaire, 163 Avenue Gambetta, 75020 Paris, France, has informed FDA of a change of sponsor name and address to Roussel-UCLAF SA, Animal Health Division, 102 Route de Noisy, 93235 Romainville Cedex, France. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name and address.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to

the Center for Veterinary Medicine, 21 CFR part 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry "Roussel-UCLAF" and adding in its place a new entry for "Roussel-UCLAF SA" and in the table in paragraph (c)(2) in the entry for "012579" by revising the sponsor name and address to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * *
Roussel-UCLAF SA, Animal Health Division, 102 Route de Noisy, 93235 Romainville Cedex, France	012579
* * *	* * *

(2) * * *