sulfobenzyl)ammonium hydroxide inner salt. Additionally, FD&C Blue No. 1 is manufactured by the acid catalyzed condensation of one mole of sodium 2-formylbenzenesulfonate with two moles from a mixture consisting principally of 3-[(ethylphenylamino)methyl] benzenesulfonic acid, and smaller amounts of 4-[(ethylphenylamino)methyl] benzenesulfonic acid and 2-[(ethylphenylamino)methyl] benzenesulfonic acid to form the leuco base. The leuco base is then oxidized with lead dioxide and acid, or with dichromate and acid, or with manganese dioxide and acid to form the dye. The intermediate sodium 2-formylbenzenesulfonate is prepared from 2-chlorobenzaldehyde and sodium sulfite.

* * * * *

Dated: March 18, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 93–7841 Filed 4–2–93; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 178

[Docket No. 92N–0388]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the titles of material incorporated by reference in the regulation that provides for the use of polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids (§ 178.3770 (21 CFR 178.3770)). The titles of the material included in § 178.3770(a)(2), (a)(3), (b)(2), (b)(3), (d)(2), and (d)(3) were inadvertently transposed. Therefore the agency is inserting the correct titles for the incorporated material.

EFFECTIVE DATE: April 5, 1993.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: In reviewing its regulations on food additives, FDA has determined that the titles of certain material incorporated by reference in § 178.3770 are incorrect. In each of the paragraphs listed below the titles of the methods ("Standard Test Method for Saponification Number (Empirical) of Synthetic and Natural Waxes" (Revised 1978) and "Standard Test Method for Acid Number (Empirical) of Synthetic Natural Waxes" (Revised 1978)) are transposed.

Upon review, the agency determined that these errors occurred when it amended the incorporating regulatory text in 21 CFR parts 170 through 189 to make clear that an incorporation by reference was intended as required by 1 CFR part 51 (47 FR 11835, March 19, 1982). These errors appeared in § 178.3770(a)(2), (a)(3), (b)(2), and (b)(3). This error was later extended to § 178.3770(d)(2) and (d)(3), which were added in the **Federal Register** of July 9, 1990 (55 FR 28020).

FDA concludes that notice and comment rulemaking to correct these errors is impracticable, contrary to the public interest, and unnecessary because these corrections rectify mistakes that are clear on their face, and which do not involve any controversial or substantive matters (5 U.S.C. 553(b)(B)).

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Incorporation by reference.

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 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, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.3770 *Polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids* is amended in paragraphs (a)(2), (b)(2), and (d)(2) by removing the words "ASTM method D1386–78 ("Standard Test Method for Saponification" and adding in their place the words "ASTM method D 1386–78 ("Standard Test Method for Acid"; and in paragraphs (a)(3), (b)(3), and (d)(3) by removing the words "ASTM method D1387–78 ("Standard Test Method for Acid" and adding in their place the words "ASTM method D 1387–78 ("Standard Test Method for Saponification"; and in paragraph (d)(2) by removing "20 to 30" and replacing it with "20–30".

Dated: February 12, 1993.

Jerry Burke,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93–7766 Filed 4–2–93; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 178

[Docket No. 91F–0020]

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 phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C_{11-14}-alkylamines as components of surface lubricants that may contact food. This action is in response to a petition filed by the Ciba-Geigy Corp.

DATES: Effective April 5, 1993; written objections and requests for a hearing by May 5, 1993.

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: Richard H. White, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9511.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 5, 1991 (56 FR 4632), FDA announced that a food additive petition (FAP 0B4232) had been filed by the Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532–2188, proposing that § 178.3910 *Surface lubricants used in the manufacture of metallic articles* (21 CFR 178.3910) be amended to provide for the safe use of phosphoric acid, mono- and dihexyl esters reacted with tetramethylnonylamines and C_{11-14}-alkylamines as components of surface lubricants that may contact food. Upon further review, however, the agency has noted that the same additive is currently regulated in 21 CFR 178.3570 as phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C_{11-14}-alkylamines. FDA is therefore adopting the name that is currently used in 21 CFR 178.3570, to avoid confusion over the identity of the additive.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe and that § 178.3910(b)(2) 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 May 5, 1993, 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. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

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 of the 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, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.3910 is amended in the table in paragraph (b)(2) by alphabetically adding a new entry under the headings "List of substances" and "Limitations" to read as follows:

§ 178.3910 Surface lubricants used in the manufacture of metallic articles.

* * * * *

(b) * * *

(2) * * *

List of substances	Limitations
* * * * *	
Phosphoric acid, mono- and dihexyl esters, compounds with tetramethylnonylamines and C_{11-14}-alkylamines (CAS Reg. No. 80939-62-4).	For use only at levels not to exceed 0.5 percent by weight of the finished surface lubricant formulation.
* * * * *	

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Dated: February 24, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93-7767 Filed 4-2-93; 8:45 am]

BILLING CODE 4160-01-F

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21 CFR Part 178

[Docket No. 91F-0464]

Indirect Food Additives; Colorants for Polymers

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 2,2'-[1,2-ethanediylbis(oxy-2,1-phenyleneazo)]bis[N-(2,3-dihydro-2-oxo-1*H*-benzimidazol-5-yl)]-3-oxo-butanamide (C.I. Pigment Yellow 180) as a colorant in polymers that are intended to contact food. This action is in response to a petition filed by Hoechst Celanese Corp.

DATES: Effective April 5, 1993; written objections and requests for a hearing by May 5, 1993.

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: Richard H. White, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9511.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 17, 1992 (57 FR 2106), FDA announced that a food additive petition (FAP 1B4289) had been filed by Hoechst Celanese Corp., 500 Washington St., Coventry, RI 02816, proposing that § 178.3297 *Colorants for polymers* (21 CFR 178.3297) be amended to provide for the safe use of 2,2'-[1,2-ethanediylbis(oxy-2,1-phenyleneazo)]bis[N-(2,3-dihydro-2-oxo-1*H*-benzimidazol-5-yl)]-3-oxo-butanamide (C.I. Pigment Yellow 180) as a colorant in polymers that are intended to contact food.

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 § 178.3297 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 May 5, 1993, 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, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.3297 is amended in the table in paragraph (e) by revising the entry for "2,2'-[1,2-Ethanediylbis(oxy-2,1-phenyleneazo)]bis[N-(2,3-dihydro-2-oxo-1*H*-benzimidazol-5-yl)]-3-oxo-butanamide * * *," under the heading "Limitations" to read as follows:

§ 178.3297 Colorants for polymers.

* * * * *

(e) * * *

Substances	Limitations
* * *	* * * *
2,2'-[1,2-Ethanediylbis(oxy-2,1-phenyleneazo)]bis[N-(2,3-dihydro-2-oxo-1*H*-benzimidazol-5-yl)]-3-oxo-butanamide (C.I. Pigment Yellow 180, CAS Reg. No. 77804-81-0).	For use at levels not to exceed 1.0 percent by weight of polymers. The finished articles are to contact food only under conditions of use B through G described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: March 9, 1993.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 93-7768 Filed 4-2-93; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 178

[Docket No. 92F-0014]

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 increase the level of safe use of 2-(2*H*-benzotriazol-2-yl)-4,6-bis(1-methyl-1-phenylethyl)phenol as a stabilizer in polycarbonate resins intended for contact with food. This action responds to a petition filed by Ciba-Geigy Corp.

DATES: Effective April 5, 1993; written objections and requests for a hearing by May 5, 1993.

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: Helen R. Thorsheim, Center for Food Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9511.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of February 11, 1992 (57 FR 5005), FDA announced that a food additive petition (FAP 2B4306) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532-2188, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to increase the level of safe use of 2-(2*H*-benzotriazol-2-yl)-4,6-bis(1-methyl-1-phenylethyl)phenol as a stabilizer in polycarbonate resins intended for contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the food additive is safe 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.