

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73, 172, 175, 176, 177, 178, 184, and 186

[Docket No. 2004N-0076]

Food and Color Additives and Generally Recognized As Safe Substances; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations that address food and color additives and generally recognized as safe (GRAS) substances. The purpose of the amendments is to correct minor errors and inadvertent omissions in the Code of Federal Regulations (CFR). The technical amendments made by this final rule are editorial in nature and are intended to provide accuracy and clarity to the agency's regulations.

DATES: Effective May 4, 2004.

FOR FURTHER INFORMATION CONTACT: Ellen M. Waldron, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 202-418-3089.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations for parts 73, 172, 175, 176, 177, 178, 184, and 186 (21 CFR parts 73, 172, 175, 176, 177, 178, 184, and 186). FDA discovered that minor errors and omissions were inadvertently published in the CFR affecting its regulations that address food and color additives (parts 73, 172, 175, 176, 177, and 178) and GRAS substances (parts 184 and 186). This document makes the needed corrections.

The final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required. The changes addressed in this document are as follows:

1. In § 73.1(b)(2), the regulatory section citation for the identification of rosin and rosin derivatives is currently erroneously written as § 172.820 and is corrected to read § 172.615.

2. The listing for "oak moss" in the table in § 172.510(b) is being corrected. The entry under "Limitations" for this listing was amended to "Finished food thujone free¹" in the **Federal Register** of September 6, 1967 (32 FR 12751).

Subsequently in the 1972 edition of the Code of Federal Regulations (CFR) the word "free¹" was inadvertently dropped from the limitation. This document adds this phrase.

3. The agency is also correcting several Chemical Abstract Service registry numbers (CAS Reg. No.) that are incorrectly listed. The agency is correcting registry numbers found in § 73.3125 *Iron oxides*; § 175.105 *Adhesives*; § 176.300 *Slimicides*; § 177.1632 *Poly (phenyleneterephthalamide) resins*; § 178.1010 *Sanitizing solutions*; § 178.2010 *Antioxidants and/or stabilizers for polymers*; § 178.3400 *Emulsifiers and/or surface-active agents*; § 178.3770 *Polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids*; § 178.3910 *Surface lubricants used in the manufacture of metallic articles*; § 184.1034 *Catalase (bovine liver)*; § 184.1307a *Ferrous ascorbate*; § 184.1434 *Magnesium phosphate*; and, § 186.1374 *Iron oxides*.

4. Finally, the agency is also correcting several typographical errors. Two misspelled terms are being corrected: "Hydroxycitronellol; 3,7-dimethyl-1,7-octanediol" in § 172.515 *Synthetic flavoring substances and adjuvants* and "Methyl ethers of mono-, di- and tripropylene glycol" in § 176.180 *Components of paper and paperboard in contact with dry food*. In § 177.1500 *Nylon resins* an incorrect reference to a paragraph is being corrected as well as a typographical error in the described melting point of "Nylon 46 resins." Finally, in § 184.1090 *Stearic acid* the incorrect chemical notation for stearic acid is being corrected.

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because these amendments are merely correcting nonsubstantive errors.

List of Subjects

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

21 CFR Part 175

Adhesives, Food additives, Food packaging.

21 CFR Parts 176, 177, and 178

Food additives, Food packaging.

21 CFR 184

Food additives.

21 CFR 186

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 parts 73, 172, 175, 176, 177, 178, 184, and 186 are amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 73.1 [Amended]

■ 2. Section 73.1 *Diluents in color additive mixtures for food use exempt from certification* is amended in paragraph (b)(2) by removing "Rosin and rosin derivatives (as identified in § 172.820 of this chapter)." and by adding in its place "Rosin and rosin derivatives (as identified in § 172.615 of this chapter)."

§ 73.3125 [Amended]

■ 3. Section 73.3125 *Iron oxides* is amended in paragraph (a) by removing "(CAS Reg. No. 977053-38-5)" and by adding in its place "(CAS Reg. No. 1332-37-2)".

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 4. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

§ 172.510 [Amended]

■ 5. Section 172.510 *Natural flavoring substances and natural substances used in conjunction with flavors* is amended in the table in paragraph (b) in the entry for "Oak moss" under the heading "Limitations" by adding "free¹" after "thujone".

§ 172.515 [Amended]

■ 6. Section 172.515 *Synthetic flavoring substances and adjuvants* is amended in paragraph (b) by removing "Hydroxycitronellal; 3,7-dimethyl-1,7-octanediol" and adding in its place "Hydroxycitronellol; 3,7-dimethyl-1,7-octanediol".

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

■ 7. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 175.105 [Amended]

■ 8. Section 175.105 *Adhesives* is amended in the table in paragraph (c)(5) in the entry for “Isodecyl benzoate” under the heading “Substances” by removing “(CAS Reg. No. 131298–44–77)” and adding in its place “(CAS Reg. No. 131298–44–7)”.

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

■ 9. The authority citation for 21 CFR part 176 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 346, 348, 379e.

§ 176.180 [Amended]

■ 10. Section 176.180 *Components of paper and paperboard in contact with dry food* is amended in the table in paragraph (b)(2) by removing the entry for “Methyl esters of mono-, di- and tripropylene glycol” and adding in its place “Methyl ethers of mono-, di- and tripropylene glycol”.

§ 176.300 [Amended]

■ 11. Section 176.300 *Slimicides* is amended in the table in paragraph (c) in the entry for “4-(Diiodomethylsulfonyl) toluene” under the heading “List of substances” by removing “(CAS Reg. No. 20018–09–01)” and adding in its place “(CAS Reg. No. 20018–09–1)”.

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

■ 12. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 177.1500 [Amended]

■ 13. Section 177.1500 *Nylon resins* is amended in paragraph (a) by removing “methods described in paragraph (c)” and adding in its place “methods described in paragraph (d)”, and in the table in paragraph (b) in entry 15 for “Nylon 46 resins” under the heading “Melting point (degrees Fahrenheit)” by removing “551–09592” and adding in its place “551–592”.

§ 177.1632 [Amended]

■ 14. Section 177.1632 *Poly (phenyleneterephthalamide) resins* is amended in the table in paragraph (b)(2) in the entry for “Poly(oxyethylene

mono(nonylphenyl)ether” under the heading “List of substances” by removing “(CAS Reg. No. 9019–45–9)” and adding in its place “(CAS Reg. No. 9016–45–9)”.

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

■ 15. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

§ 178.1010 [Amended]

■ 16. Section 178.1010 *Sanitizing solutions* is amended in paragraph (b)(36) by removing “1,2–octanedisulfonic acid (CAS Reg. No. 1934210)” and adding in its place “1,2–octanedisulfonic acid (CAS Reg. No. 113669–58–2)”.

§ 178.2010 [Amended]

■ 17. Section 178.2010 *Antioxidants and/or stabilizers for polymers* is amended in the table in paragraph (b) in the entry for “2–Hydroxy–4–isooctoxybenzophenone” under the heading “Substances” by removing “CA Registry No. 330:59–05–1” and adding in its place “CAS Registry No. 33059–05–1”.

§ 178.3400 [Amended]

■ 18. Section 178.3400 *Emulsifiers and/or surface-active agents* is amended in the table in paragraph (c) in the entry for “Alpha-sulfo-omega-(dodecyloxy)poly(oxyethylene) ammonium salt” under the heading “List of substances” by removing “(CAS Reg. No. 30174–67–5)” and adding in its place “(CAS Reg. No. 32612–48–9)”.

§ 178.3770 [Amended]

■ 19. Section 178.3770 *Polyhydric alcohol esters of oxidatively refined (Gersthofen process) montan wax acids* is amended in paragraph (c)(1) by removing “(CAS Reg. No. 9005–98–2)” and adding in its place “(CAS Reg. No. 9004–98–2)”.

§ 178.3910 [Amended]

■ 20. Section 178.3910 *Surface lubricants used in the manufacture of metallic articles* is amended in the table in paragraph (a)(2) in the entry for “Sodium petroleum sulfonate” under the heading “Listing of substances” by removing “(CAS Reg. No. 68608–24–4)” and adding in its place “(CAS Reg. No. 68608–26–4)”.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 21. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

§ 184.1034 [Amended]

■ 22. Section 184.1034 *Catalase (bovine liver)* is amended in paragraph (a) by removing “(CAS Reg. No. 9001–05–2)” and adding in its place “(CAS Reg. No. 81457–95–6)”.

§ 184.1090 [Amended]

■ 23. Section 184.1090 *Stearic acid* is amended in paragraph (a) by removing “C₁₆H₃₆O₂” and adding in its place “C₁₈H₃₆O₂”.

§ 184.1307a [Amended]

■ 24. Section 184.1307a *Ferrous ascorbate* is amended in paragraph (a) by removing “(CAS Reg. No. 14536–17–5)” and adding in its place “(CAS Reg. No. 24808–52–4)”.

§ 184.1434 [Amended]

■ 25. Section 184.1434 *Magnesium phosphate* is amended in paragraph (a) by removing “CAS Reg. No. 7727–0987–091” and adding in its place “CAS Reg. No. 7757–87–1”.

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 26. The authority citation for 21 CFR part 186 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

§ 186.1374 [Amended]

■ 27. Section 186.1374 *Iron oxides* is amended in paragraph (a) by removing “CAS Reg. No. 97705–33–85” and adding in its place “CAS Reg. No. 1332–37–2”.

Dated: March 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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