

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 184

DDM

Display Date 2-13-08

Publication Date 2-14-08

Certifier D. Hawkins

[Docket No. FDA-2008-N-0068]

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 certain regulations regarding generally recognized as safe (GRAS) substances to remove references to FDA development of food-grade specifications in cooperation with the National Academy of Sciences (NAS, now the National Academies). This action is editorial in nature and is intended to ensure the accuracy of the agency's regulations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Daniel E. Folmer, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740-3835, 301-436-1274.

SUPPLEMENTARY INFORMATION: FDA is amending its regulations in part 184 (21 CFR part 184). Several sections in part 184 state that FDA is developing food-grade specifications in cooperation with the National Academy of Sciences (NAS, now the National Academies). However, the National Academies is no longer developing food-grade specifications for food additives and ingredients. Therefore, this rule removes the obsolete information.

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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.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). These amendments remove obsolete information and are nonsubstantive. FDA therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

List of Subjects in 21 CFR Part 184

Food additives.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 184 is amended as follows:

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

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

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

■ 2. Section 184.1065 is amended by revising paragraph (b) to read as follows:

§ 184.1065 Linoleic acid.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use. The ingredient must also meet the specifications in § 172.860(b) of this chapter.

* * * * *

■ 3. Section 184.1140 is amended by revising paragraph (b) to read as follows:

§ 184.1140 Ammonium citrate, dibasic.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 4. Section 184.1155 is amended by revising paragraph (b) to read as follows:

§ 184.1155 Bentonite.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

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■ 5. Section 184.1165 is amended by revising paragraph (b) to read as follows:

§ 184.1165 n-Butane and iso-butane.

* * * * *

(b) The ingredients must be of a purity suitable for their intended use.

* * * * *

■ 6. Section 184.1240 is amended by revising paragraph (b) to read as follows:

§ 184.1240 Carbon dioxide.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 7. Section 184.1261 is amended by revising paragraph (b) to read as follows:

§ 184.1261 Copper sulfate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 8. Section 184.1262 is amended by revising paragraph (b) to read as follows:

§ 184.1262 Corn silk and corn silk extract.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 9. Section 184.1265 is amended by revising paragraph (b) to read as follows:

§ 184.1265 Cuprous iodide.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

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■ 10. Section 184.1287 is amended by revising paragraph (b) to read as follows:

§ 184.1287 Enzyme-modified fats.

* * * * *

(b) The ingredients must be of a purity suitable for their intended use.

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■ 11. Section 184.1297 is amended by revising paragraph (b) to read as follows:

§ 184.1297 Ferric chloride.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 12. Section 184.1298 is amended by revising paragraph (b) to read as follows:

§ 184.1298 Ferric citrate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 13. Section 184.1307 is amended by revising paragraph (b) to read as follows:

§ 184.1307 Ferric sulfate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

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■ 14. Section 184.1307a is amended by revising paragraph (b) to read as follows:

§ 184.1307a Ferrous ascorbate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

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■ 15. Section 184.1307b is amended by revising paragraph (b) to read as follows:

§ 184.1307b Ferrous carbonate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 16. Section 184.1307c is amended by revising paragraph (b) to read as follows:

§ 184.1307c Ferrous citrate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 17. Section 184.1321 is amended by revising paragraph (b) to read as follows:

§ 184.1321 Corn gluten.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 18. Section 184.1322 is amended by revising paragraph (b) to read as follows:

§ 184.1322 Wheat gluten.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

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■ 19. Section 184.1323 is amended by revising paragraph (b) to read as follows:

§ 184.1323 Glyceryl monooleate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

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■ 20. Section 184.1324 is amended by revising paragraph (b) to read as follows:

§ 184.1324 Glyceryl monostearate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

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■ 21. Section 184.1355 is amended by revising paragraph (b) to read as follows:

§ 184.1355 Helium.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

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■ 22. Section 184.1386 is amended by revising paragraph (b) to read as follows:

§ 184.1386 Isopropyl citrate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

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■ 23. Section 184.1445 is amended by revising paragraph (b) to read as follows:

§ 184.1445 Malt syrup (malt extract).

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 24. Section 184.1449 is amended by revising paragraph (b) to read as follows:

§ 184.1449 Manganese citrate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

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■ 25. Section 184.1521 is amended by revising paragraph (b) to read as follows:

§ 184.1521 Monosodium phosphate derivatives of mono- and diglycerides.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 26. Section 184.1537 is amended by revising paragraph (b) to read as follows:

§ 184.1537 Nickel.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 27. Section 184.1540 is amended by revising paragraph (b) to read as follows:

§ 184.1540 Nitrogen.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 28. Section 184.1545 is amended by revising paragraph (b) to read as follows:

§ 184.1545 Nitrous oxide.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 29. Section 184.1553 is amended by revising paragraph (b) to read as follows:

§ 184.1553 Peptones.

* * * * *

(b) The ingredients must be of a purity suitable for their intended use.

* * * * *

■ 30. Section 184.1555 is amended by revising paragraph (c)(3) to read as follows:

§ 184.1555 Rapeseed oil.

* * * * *

(c) * * *

(3) In addition to limiting the content of erucic acid to a level not exceeding 2 percent of the component fatty acids, low erucic acid rapeseed oil and partially hydrogenated low erucic acid rapeseed oil must be of a purity suitable for their intended use.

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■ 31. Section 184.1639 is amended by revising paragraph (b) to read as follows:

§ 184.1639 Potassium lactate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 32. Section 184.1655 is amended by revising paragraph (b) to read as follows:

§ 184.1655 Propane.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 33. Section 184.1764 is amended by revising paragraph (b) to read as follows:

§ 184.1764 Sodium hypophosphite.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 34. Section 184.1768 is amended by revising paragraph (b) to read as follows:

§ 184.1768 Sodium lactate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 35. Section 184.1769a is amended by revising paragraph (b) to read as follows:

§ 184.1769a Sodium metasilicate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 36. Section 184.1848 is amended by revising paragraph (b) to read as follows:

§ 184.1848 Starter distillate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 37. Section 184.1851 is amended by revising paragraph (b) to read as follows:

§ 184.1851 Stearyl citrate.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 38. Section 184.1854 is amended by revising paragraph (b) to read as follows:

§ 184.1854 Sucrose.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 39. Section 184.1859 is amended by revising paragraph (b) to read as follows:

§ 184.1859 Invert sugar.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 40. Section 184.1865 is amended by revising paragraph (b) to read as follows:

§ 184.1865 Corn syrup.

* * * * *

(b) The ingredient meets the specifications as defined and determined in § 168.120(b) or § 168.121(a) of this chapter, as appropriate.

* * * * *

■ 41. Section 184.1923 is amended by revising paragraph (b) to read as follows:

§ 184.1923 Urea.

* * * * *

(b) The ingredient must be of a purity suitable for its intended use.

* * * * *

■ 42. Section 184.1950 is amended by revising paragraph (b) to read as follows:

§ 184.1950 Vitamin D.

* * * * *

(b) Vitamin D₂ and vitamin D₃ as crystals meet the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 344 and 345, which is incorporated by reference. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html. Vitamin D₂ resin and vitamin D₃ resin must be of a purity suitable for their intended use.

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■ 43. Section 184.1984 is amended by revising paragraph (b) to read as follows:

§ 184.1984 Zein.

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(b) The ingredient must be of a purity suitable for its intended use.

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Dated: _____

February 8, 2008.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

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