Food and Drug Administration, HHS

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[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24899, June 12, 1989]

\S 189.140 Diethylpyrocarbonate (DEPC).

- (a) Diethylpyrocarbonate is the chemical pyrocarbonic acid diethyl ester, $C_6H_{10}O_5$. It is a synthetic chemical not found in natural products at levels detectable by available methodology and has been used as a ferment inhibitor in alcoholic and nonalcoholic beverages.
- (b) Food containing any added or detectable level of DEPC is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of August 2, 1972 (37 FR 15426).

§189.145 Dulcin.

- (a) Dulcin is the chemical 4-ethoxyphenylurea, $C_9H_{12}N_2O_2$. It is a synthetic chemical having a sweet taste about 250 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.
- (b) Food containing any added or detectable level of dulcin is deemed to be adulterated in violation of the act, based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).
- (c) The analytical methods used for detecting dulcin in food are in sections 20.173-20.176 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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: www.archives.gov/federal register/ code of federal regulations/ ibr locations.html.
- [42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24899, June 12, 1999]

§ 189.155 Monochloroacetic acid.

- (a) Monochloroacetic acid is the chemical chloroacetic acid, $C_2H_3C1O_2$. It is a synthetic chemical not found in natural products, and has been proposed as a preservative in alcoholic and nonalcoholic beverages. Monochloroacetic acid is permitted in food package adhesives with an accepted migration level up to 10 parts per billion (ppb) under §175.105 of this chapter. The official methods do not detect monochloroacetic acid at the 10 ppb level.
- (b) Food containing any added or detectable level of monochloroacetic acid is deemed to be adulterated in violation of the act based upon trade correspondence dated December 29, 1941 (TC-377).
- (c) The analytical methods used for detecting monochloroacetic acid in food are in sections 20.067-20.072 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTER-NATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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/ $code_of_federal_regula\overline{ti}ons/$ ibr locations.html.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24899, June 12, 1989]

§ 189.165 Nordihydroguaiaretic acid (NDGA).

- (a) Nordihydroguaiaretic acid is the chemical 4.4'-(2.3-dimethyltetramethylene) dipyrocatechol, $C_{18}H_{22}O_4$. It occurs naturally in the resinous exudates of certain plants. The commercial product, which is synthesized, has been used as an antioxidant in foods
- (b) Food containing any added NDGA is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of April 11, 1968 (33 FR 5619).
- (c) The analytical method used for detecting NDGA in food is in section 20.008(b) of the "Official Methods of

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Analysis of the AOAC INTERNATIONAL," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTER-NATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24900, June 12, 1989]

§ 189.175 P-4000.

- (a) P-4000 is the chemical 5-nitro-2-n-propoxyaniline, $C_9H_{12}N_2O_3$. It is a synthetic chemical having a sweet taste about 4000 times that of sucrose, is not found in natural products at levels detectable by the official methodology, and has been proposed for use as an artificial sweetener.
- (b) Food containing any added or detectable level of P-4000 is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of January 19, 1950 (15 FR 321).
- (c) The analytical methods used for detecting P-4000 in food are in sections 20.177-20.181 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980), which is incorporated by reference. Copies may be obtained from the AOAC INTERNATIONAL, 481 North Frederick Ave., suite 500, Gaithersburg, MD 20877, or may be examined 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/ $code_of_federal_regula\overline{ti}ons/$ ibr locations.html.

[42 FR 14659, Mar. 15, 1977, as amended at 49 FR 10114, Mar. 19, 1984; 54 FR 24900, June 12, 1989]

§189.180 Safrole.

(a) Safrole is the chemical 4-allyl-1,2-methylenedioxy-benzene, $C_{10}H_{10}O_2$. It is a natural constituent of the sassafras plant. Oil of sassafras is about 80 per-

cent safrole. Isosafrole and dihydrosafrole are derivatives of safrole, and have been used as flavoring compounds.

- (b) Food containing any added safrole, oil of sassafras, isosafrole, or dihydrosafrole, as such, or food containing any safrole, oil of sassafras, isosafrole, or dihydrosafrole, e.g., sassafras bark, which is intended solely or primarily as a vehicle for imparting such substances to another food, e.g., sassafras tea, is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 3, 1960 (25 FR 12412).
- (c) The analytical method used for detecting safrole, isosafrole and dihydrosafrole is in the "Journal of the Association of Official Analytical Chemists," Volume 54 (Number 4), pages 900 to 902, July 1971, which is incorporated by reference. Copies are available from the Office of Food Additive Safety (HFS-200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200, 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/

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[42 FR 14659, Mar. 15, 1977, as amended at 42 FR 56729, Oct. 28, 1977; 47 FR 11855, Mar. 19, 1982; 54 FR 24900, June 12, 1989; 78 FR 14667, Mar. 7, 2013]

§ 189.190 Thiourea.

- (a) Thiourea is the chemical thiocarbamide, CH_4N_2S . It is a synthetic chemical, is not found in natural products at levels detectable by the official methodology, and has been proposed as an antimycotic for use in dipping citrus.
- (b) Food containing any added or detectable level of thiourea is deemed to be adulterated under the act.
- (c) The analytical methods used for detecting thiourea are in sections 20.115-20.126 of the "Official Methods of Analysis of the Association of Official Analytical Chemists," 13th Ed. (1980),