

§ 189.250

of the Federal Food, Drug, and Cosmetic Act, based upon an order published in the FEDERAL REGISTER of June 27, 1995.

[60 FR 33109, June 27, 1995]

§ 189.250 Mercaptoimidazoline and 2-mercaptoimidazoline.

(a) Mercaptoimidazoline and 2-mercaptoimidazoline both have the molecular formula $C_3H_6N_2S$. They are synthetic chemicals not found in natural products and have been used in the production of rubber articles that may come into contact with food.

(b) Food containing any added or detectable levels of these substances is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of November 30, 1973 (38 FR 33072).

§ 189.280 4,4'-Methylenebis (2-chloroaniline).

(a) 4,4'-Methylenebis (2-chloroaniline) has the molecular formula, $C_{13}H_{12}Cl_2N_2$. It is a synthetic chemical not found in natural products and has been used as a polyurethane curing agent and as a component of food packaging adhesives and polyurethane resins.

(b) Food containing any added or detectable level of this substance is deemed to be adulterated in violation of the act based upon an order published in the FEDERAL REGISTER of December 2, 1969 (34 FR 19073).

§ 189.300 Hydrogenated 4,4'-isopropylidene-diphenolphosphite ester resins.

(a) Hydrogenated 4,4'-isopropylidene-diphenolphosphite ester resins are the condensation product of 1 mole of triphenyl phosphite and 1.5 moles of hydrogenated 4,4'-isopropylidene-diphenol such that the finished resins have a molecular weight in the range of 2,400 to 3,000. They are synthetic chemicals not found in natural products and have been used as antioxidants and as stabilizers in vinyl chloride polymer resins when such polymer resins are used in the manufacture of rigid vinyl chloride polymer bottles.

(b) Food containing any added or detectable levels of these substances is

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deemed to be adulterated and in violation of the Federal Food, Drug, and Cosmetic Act, based upon an order published in the FEDERAL REGISTER of September 9, 1987 (52 FR 33929).

[54 FR 7188, Feb. 17, 1989]

§ 189.301 Tin-coated lead foil capsules for wine bottles.

(a) Tin-coated lead foil is composed of a lead foil coated on one or both sides with a thin layer of tin. Tin-coated lead foil has been used as a capsule (i.e., as a covering applied over the cork and neck areas) on wine bottles to prevent insect infestation, as a barrier to oxygen, and for decorative purposes. Information received by the Food and Drug Administration establishes that the use of such a capsule on wine bottles may reasonably be expected to result in lead becoming a component of the wine.

(b) The capping of any bottles of wine after February 8, 1996, with a tin-coated lead foil capsule renders the wine adulterated and in violation of section 402(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act because lead from the capsule, which is an unsafe food additive within the meaning of section 409 of the act, may reasonably be expected to become a component of the wine.

[61 FR 4820, Feb. 8, 1996]

PART 190—DIETARY SUPPLEMENTS

Subpart A [Reserved]

Subpart B—New Dietary Ingredient Notification

Sec.

190.6 Requirement for premarket notification.

AUTHORITY: Secs. 201(ff), 301, 402, 413, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(ff), 331, 342, 350b, 371).

SOURCE: 62 FR 49891, Sept. 23, 1997, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 190 appear at 66 FR 56035, Nov. 6, 2001.

Subpart A [Reserved]

Subpart B—New Dietary Ingredient Notification**§ 190.6 Requirement for premarket notification.**

(a) At least 75 days before introducing or delivering for introduction into interstate commerce a dietary supplement that contains a new dietary ingredient that has not been present in the food supply as an article used for food in a form in which the food has not been chemically altered, the manufacturer or distributor of that supplement, or of the new dietary ingredient, shall submit to the Office of Nutritional Products, Labeling and Dietary Supplements (HFS-820), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, information including any citation to published articles that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe. An original and two copies of this notification shall be submitted.

(b) The notification required by paragraph (a) of this section shall include:

(1) The name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient;

(2) The name of the new dietary ingredient that is the subject of the premarket notification, including the Latin binomial name (including the author) of any herb or other botanical;

(3) A description of the dietary supplement or dietary supplements that contain the new dietary ingredient including:

(i) The level of the new dietary ingredient in the dietary supplement; and

(ii) The conditions of use recommended or suggested in the labeling of the dietary supplement, or if no conditions of use are recommended or suggested in the labeling of the dietary supplement, the ordinary conditions of use of the supplement;

(4) The history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or sug-

gested in the labeling of the dietary supplement, will reasonably be expected to be safe, including any citation to published articles or other evidence that is the basis on which the distributor or manufacturer of the dietary supplement that contains the new dietary ingredient has concluded that the new dietary supplement will reasonably be expected to be safe. Any reference to published information offered in support of the notification shall be accompanied by reprints or photostatic copies of such references. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation; and

(5) The signature of the person designated by the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient.

(c) FDA will acknowledge its receipt of a notification made under section 413 of the Federal Food, Drug, and Cosmetic Act (the act) and will notify the submitter of the date of receipt of such a notification. The date that the agency receives the notification submitted under paragraph (a) of this section is the filing date for the notification. For 75 days after the filing date, the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient shall not introduce, or deliver for introduction, into interstate commerce the dietary supplement that contains the new dietary ingredient.

(d) If the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient, provides additional information in support of the new dietary ingredient notification, the agency will review all submissions pertaining to that notification, including responses made to inquiries from the agency, to determine whether they are substantive and whether they require that the 75-day period be reset. If the agency determines that the new submission is a substantive amendment, FDA will assign a new filing date. FDA will acknowledge receipt of the additional information and, when applicable, notify the manufacturer of the new filing date, which is the date of receipt by FDA of the information that constitutes the substantive amendment.

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(e) FDA will not disclose the existence of, or the information contained in, the new dietary ingredient notification for 90 days after the filing date of the notification. After the 90th day, all information in the notification will be placed on public display, except for any information that is trade secret or otherwise confidential commercial information.

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(f) Failure of the agency to respond to a notification does not constitute a finding by the agency that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated under section 402 of the act.

[62 FR 49891, Sept. 23, 1997, as amended at 66 FR 17359, Mar. 30, 2001]

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