§ 173.400 Dimethyldialkylammonium chloride.

Dimethyldialkylammonium chloride may be safely used in food in accordance with the following prescribed conditions:

(a) The food additive is produced by one of the following methods:

(1) Ammonolysis of natural tallow fatty acids to form amines that are subsequently reacted with methyl chloride to form the quaternary ammonium compounds consisting primarily of dimethyldioctadecylammonium chloride and dimethyldihexadecylammonium chloride. The additive may contain residues of isopropyl alcohol not in excess of 18 percent by weight when used as a processing solvent.

(2) Ammonolysis of natural tallow fatty acids to form amines that are then reacted with 2-ethylhexanal, reduced, methylated, and subsequently reacted with methyl chloride to form the quaternary ammonium compound known as dimethyl(2-ethylhexyl) hydrogenated tallow ammonium chloride and consisting primarily of dimethyl(2-ethylhexyl)octadecylammonium chloride and dimethyl(2-ethylhexyl)hexadecylammonium chloride.

(b) The food additive described in paragraph (a)(1) of this section contains not more than a total of 2 percent by weight of free amine and amine hydrochloride. The food additive described in paragraph (a)(2) of this section contains not more than 3 percent by weight, each, of free amine and amine hydrochloride as determined by A.O.C.S. method Te 3a-64, "Acid Value and Free Amine Value of Fatty Quaternary Ammonium Chlorides," 2d printing including additions and revisions 1990, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, and from the American Oil Chemists’ Society, P.O. Box 5037, Station A, Champaign, IL 61820, 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.

(d) To assure safe use of the additive, the label and labeling of the additive shall bear, in addition to other information required by the Federal Food, Drug, and Cosmetic Act, adequate directions to assure use in compliance with paragraph (c) of this section.

[56 FR 42686, Aug. 29, 1991]

PART 174—INDIRECT FOOD ADDITIVES: GENERAL

Sec. 174.5 General provisions applicable to indirect food additives.
174.6 Threshold of regulation for substances used in food-contact articles.


§ 174.5 General provisions applicable to indirect food additives.

(a) Regulations prescribing conditions under which food additive substances may be safely used predicate usage under conditions of good manufacturing practice. For the purpose of this part and parts 175, 176, and 177 of this chapter, good manufacturing practice shall be defined to include the following restrictions:

(1) The quantity of any food additive substance that may be added to food as a result of use in articles that contact food shall not exceed, where no limits are specified, that which results from use of the substance in an amount not more than reasonably required to accomplish the intended physical or technical effect in the food-contact article; shall not exceed any prescribed limitations; and shall not be intended to accomplish any physical or technical effect in the food itself, except as such may be permitted by regulations in parts 170 through 189 of this chapter.

(2) Any substance used as a component of articles that contact food shall be of a purity suitable for its intended use.

(b) The existence in the subchapter B of a regulation prescribing safe conditions for the use of a substance as an article or component of articles that contact food shall not be construed as implying that such substance may be safely used as a direct additive in food.

(d) Substances that under conditions of good manufacturing practice may be safely used as components of articles that contact food include the following, subject to any prescribed limitations:

(1) Substances generally recognized as safe in or on food.

(2) Substances generally recognized as safe for their intended use in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances permitted for use by regulations in this part and parts 175, 176, 177, 178 and §179.45 of this chapter.

(5) Food contact substances used in accordance with an effective premarket notification for a food contact substance (FCN) submitted under section 409(h) of the act.


§ 174.6 Threshold of regulation for substances used in food-contact articles.

Substances used in food-contact articles (e.g., food-packaging or food-processing equipment) that migrate, or that may be expected to migrate, into food at negligible levels may be reviewed under §170.39 of this chapter. The Food and Drug Administration will exempt substances whose uses it determines meet the criteria in §170.39 of this chapter from regulation as food additives and, therefore, a food additive petition will not be required for the exempted use.

[60 FR 36596, July 17, 1995]