

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, 200 C St. SW., Washington, DC 20204, and from the American Oil Chemists' Society, P.O. Box 5037, Station A, Champaign, IL 61820, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(c) The food additive is used as a decolorizing agent in the clarification of refinery sugar liquors under the following limitations:

(1) The food additive described in paragraph (a)(1) of this section is added only at the defecation/clarification stage of sugar liquor refining in an amount not to exceed 700 parts per million by weight of sugar solids.

(2) The food additive described in paragraph (a)(2) of this section is used under the following conditions:

(i) The additive is adsorbed onto a support column composed of suitable polymers that are regulated for contact with aqueous food. Excess non-adsorbed additive shall be rinsed away with potable water prior to passage of sugar liquor through the column.

(ii) The residue of the additive in the decolorized sugar liquor prior to crystallization shall not exceed 1 part per million of sugar as determined by a method entitled "Colorimetric Determination of Residual Quaternary Ammonium Compounds (Arquad HTL8) in Sugar and Sugar Solutions," June 13, 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, 200 C St. SW., Washington, DC 20204, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(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.

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

### § 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 to relieve such use of the substance or article from compliance with any other provision of the Federal Food, Drug, and Cosmetic Act. For example, if a regulated food-packaging material were found on appropriate test to impart odor or taste to a specific food product such as to render it unfit within the meaning of section 402(a)(3) of

the Act, the regulation would not be construed to relieve such use from compliance with section 402(a)(3).

(c) The existence in this 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.

[42 FR 14534, Mar. 15, 1977]

**§ 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]

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

**Subpart A [Reserved]**

**Subpart B—Substances for Use Only as Components of Adhesives**

Sec.

175.105 Adhesives.

175.125 Pressure-sensitive adhesives.

**Subpart C—Substances for Use as Components of Coatings**

- 175.210 Acrylate ester copolymer coating.
- 175.230 Hot-melt strippable food coatings.
- 175.250 Paraffin (synthetic).
- 175.260 Partial phosphoric acid esters of polyester resins.
- 175.270 Poly(vinyl fluoride) resins.
- 175.300 Resinous and polymeric coatings.
- 175.320 Resinous and polymeric coatings for polyolefin films.
- 175.350 Vinyl acetate/crotonic acid copolymer.
- 175.360 Vinylidene chloride copolymer coatings for nylon film.
- 175.365 Vinylidene chloride copolymer coatings for polycarbonate film.
- 175.380 Xylene-formaldehyde resins condensed with 4,4'-isopropylidenediphenol-epichlorohydrin epoxy resins.
- 175.390 Zinc-silicon dioxide matrix coatings.

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

SOURCE: 42 FR 14534, Mar. 15, 1977, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 175 appear at 61 FR 14482, Apr. 2, 1996.

**Subpart A [Reserved]**

**Subpart B—Substances for Use Only as Components of Adhesives**

**§ 175.105 Adhesives.**

(a) Adhesives may be safely used as components of articles intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

(1) The adhesive is prepared from one or more of the optional substances named in paragraph (c) of this section, subject to any prescribed limitations.

(2) The adhesive is either separated from the food by a functional barrier or used subject to the following additional limitations:

(i) *In dry foods.* The quantity of adhesive that contacts packaged dry food shall not exceed the limits of good manufacturing practice.

(ii) *In fatty and aqueous foods.* (a) The quantity of adhesive that contacts packaged fatty and aqueous foods shall not exceed the trace amount at seams and at the edge exposure between packaging laminates that may occur within the limits of good manufacturing practice.