

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

OMB

Display Date 5-17-02

Publication Date 5-20-02

Certifier G. Pressley

[Docket No. 00C-0929]

**Listing of Color Additives Exempt From Certification; Sodium Copper Chlorophyllin**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the color additive regulations to provide for the safe use of sodium copper chlorophyllin as a color additive in citrus-based dry beverage mixes. This action is in response to a petition filed by Kraft Foods, Inc.

**DATES:** This rule is effective [*insert date 30 days plus 1 business day after date of publication in the Federal Register*]; except as to any provisions that may be stayed by the filing of proper objections. Submit written or electronic objections and requests for a hearing by [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic objections and requests for a hearing to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Aydin Örstan, Center for Food Safety and Applied Nutrition (HFS-265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 202-418-3076.

**SUPPLEMENTARY INFORMATION:**

cf0136

NFR1

## **I. Introduction**

In a notice published in the **Federal Register** of March 14, 2000 (65 FR 13770), FDA announced that a color additive petition (CAP 0C0270) had been filed by Kraft Foods, Inc., c/o Flamm Associates, 622 Beachland Blvd., Vero Beach, FL 32963. The petition proposed to amend the color additive regulations to provide for the safe use of sodium copper chlorophyllin to color citrus-based dry beverage mixes.

## **II. Identity**

Sodium copper chlorophyllin is manufactured from chlorophyll, the common pigment of green plants. The manufacturing process consists of three main steps: (1) Extraction of chlorophyll from plant material with an appropriate solvent, (2) preparation of water-soluble derivatives by alkaline hydrolysis of ester groups of chlorophyll (saponification), and (3) replacement of the magnesium ion of natural chlorophyll with copper. The final color additive product sodium copper chlorophyllin is a complex mixture of chlorophyll derivatives (Ref. 1). The petitioner specified the source of chlorophyll used to make sodium copper chlorophyllin as alfalfa (*Medicago sativa*) and provided data showing that sodium copper chlorophyllin prepared from chlorophyll extracted from alfalfa meets the proposed specifications. Therefore, in new § 73.125 (21 CFR 73.125) FDA is limiting the source of chlorophyll used to make sodium copper chlorophyllin to alfalfa.

The agency notes that the intended coloring effect of citrus-based dry beverage mixes is achieved when sodium copper chlorophyllin is used in an amount not exceeding 0.2 percent. Therefore, in new § 73.125 the agency is limiting the amount of sodium copper chlorophyllin in the dry mix to 0.2 percent.

## **III. Safety Evaluation**

In evaluating the safety of the use of sodium copper chlorophyllin to color citrus-based dry beverage mixes, the agency considered: (1) The safety of chlorophyll and copper chlorophyllins,

including the manufacturing process of sodium copper chlorophyllin; and (2) the safety of copper in sodium copper chlorophyllin.

#### *A. Safety of Chlorophyll and Copper Chlorophyllins*

Chlorophyll occurs naturally in green vegetables and as such constitutes a normal part of the human diet. Various derivatives of chlorophyll, generally referred to as copper chlorophyllins or chlorophyllin copper complexes, including sodium copper chlorophyllin, are commonly used food colors (Refs. 1 and 2). In the United States, potassium sodium copper chlorophyllin has been listed for use as a color additive in dentifrices that are either drugs (21 CFR 73.1125) or cosmetics (21 CFR 73.2125). In addition, FDA permits over-the-counter use of chlorophyllin copper complex as an internal deodorant in doses up to 300 milligrams (mg) daily (21 CFR 357.850).

FDA calculated the estimated daily intake (EDI) of sodium copper chlorophyllin that will result from the petitioned use for 90th percentile consumers older than 2 years as 90 mg/person/day(d). During this calculation, the agency also considered the exposure to the color additive from its uses in dentifrices, and determined that such exposure would be negligible. The agency reviewed a published study submitted with the petition in which potassium sodium copper chlorophyllin was fed to rats at levels up to 3 percent in the feed for up to 2 years (Ref. 3). The agency determined that the results of the study showed no indications of adverse effects in rats at any of the doses tested from the prolonged consumption of the color additive. In addition, there was no evidence of metal toxicity. Moreover, evaluating the same study, the Joint Food and Agriculture Organization/World Health Organization (FAO/WHO) Expert Committee on Food Additives (JECFA) also found no adverse effects and established 1,500 mg/kilogram (kg) body weight/d as the no observed effect level (NOEL) of sodium copper chlorophyllin (Ref. 4). By applying a 200-fold safety factor to this NOEL, the agency calculated the acceptable daily intake (ADI) for sodium copper chlorophyllin for a 60-kg human as 450 mg/person/d. The agency notes that the EDI of sodium copper chlorophyllin that will result from the petitioned use for 90th percentile

consumers is one-fifth of this ADI. Therefore, FDA concludes that the exposure to sodium copper chlorophyllin from the petitioned use does not pose a safety concern (Ref. 5).

During its safety review, FDA also evaluated the manufacturing process of sodium copper chlorophyllin. The agency is specifying in new § 73.125 the solvents that may be used to manufacture sodium copper chlorophyllin and is establishing a specification for the residues of these solvents that do not present a safety concern and thus may be present in the final product.

#### *B. Safety of Copper in Sodium Copper Chlorophyllin*

The petitioner provided data showing that the amount of free (ionizable) copper in sodium copper chlorophyllin does not exceed 200 parts per million (ppm). Therefore, new § 73.125 specifies the amount of free copper in sodium copper chlorophyllin as not more than 200 ppm. Using this limit, FDA calculated the EDI of free copper from the consumption of sodium copper chlorophyllin for 90th percentile consumers older than 2 years as 0.018 mg/person/d. The agency also considered the exposure to copper from the uses of the color additive in dentifrices and determined that this exposure would be negligible. The agency notes that copper is an essential element and a dose of 2 mg/d is the reference daily intake (RDI) (21 CFR 101.9(c)(8)(iv)). Because the EDI for 90th percentile consumers is less than 1 percent of the RDI, the agency believes that the additional exposure of 0.018 mg/d to copper from the petitioned use will not pose a safety concern (Ref. 6).

#### **IV. Conclusion**

Based on the data in the petition and other relevant material, FDA concludes that the petitioned use of sodium copper chlorophyllin as a color additive in citrus-based dry beverage mixes is safe, the additive will achieve its intended technical effect, and thus, it is suitable for this use. FDA concludes that 21 CFR part 73 should be amended as set forth below. In addition, based upon the factors listed in 21 CFR 71.20(b), FDA concludes that certification of sodium copper chlorophyllin is not necessary for the protection of the public health.

## **V. Inspection of Documents**

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (address above) by appointment with the information contact person listed above. As provided in § 71.15, FDA will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

## **VI. Environmental Impact**

The agency has previously considered the environmental effects of this rule as announced in the notice of filing for CAP 0C0270 (65 FR 13770, March 14, 2000). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

## **VII. Paperwork Reduction Act of 1995**

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## **VIII. Objections**

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the Federal Register*]. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific

factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday. FDA will publish notice of the objections that the agency has received or lack thereof in the **Federal Register**.

## IX. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Hendry, G. A. F., "Chlorophylls and Chlorophyll Derivatives," in "Natural Food Colorants," 2d ed., pp. 131–156, edited by Hendry, G. A. F. and J. D. Houghton, Blackie Academic & Professional, New York, 1996.
2. European Parliament and Council Directive 94/36/EC of June 30, 1994, on colours for use in foodstuffs, *Official Journal of the European Communities*, L 237:17–18, 1994.
3. Harrison, J. W. E., S. E. Levin, and B. Trabin, "The Safety and Fate of Potassium Sodium Copper Chlorophyllin and Other Copper Compounds," *Journal of the American Pharmaceutical Association*, 43:722–737, 1954.
4. "Toxicological Evaluation of Some Food Colours, Enzymes, Flavour Enhancers, Thickening Agents, and Certain Other Food Additives," Joint FAO/WHO Expert Committee on Food Additives, WHO Food Additives Series, No. 6, pp. 74–77, Geneva, 1975.
5. Ikeda, G. J., Memorandum entitled "Addendum to Toxicology Review Memorandum of June 14, 2000" from the Division of Food Contact Substance Notification Review (HFS–225) to the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, FDA, November 21, 2001.

6. Ikeda, G. J., Memorandum entitled “Toxicology Review; Use of Sodium Copper Chlorophyllin as a Colorant for Citrus-based Dry Beverage Mix” from the Division of Health Effects Evaluation (HFS–225) to the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, FDA, June 14, 2000.

### **List of Subjects in 21 CFR Part 73**

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 73 is amended as follows:

### **PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION**

1. The authority citation for 21 CFR part 73 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

2. Section 73.125 is added to subpart A to read as follows:

#### **§ 73.125 Sodium copper chlorophyllin.**

(a) *Identity.* (1) The color additive sodium copper chlorophyllin is a green to black powder prepared from chlorophyll by saponification and replacement of magnesium by copper. Chlorophyll is extracted from alfalfa (*Medicago sativa*) using any one or a combination of the solvents acetone, ethanol, and hexane.

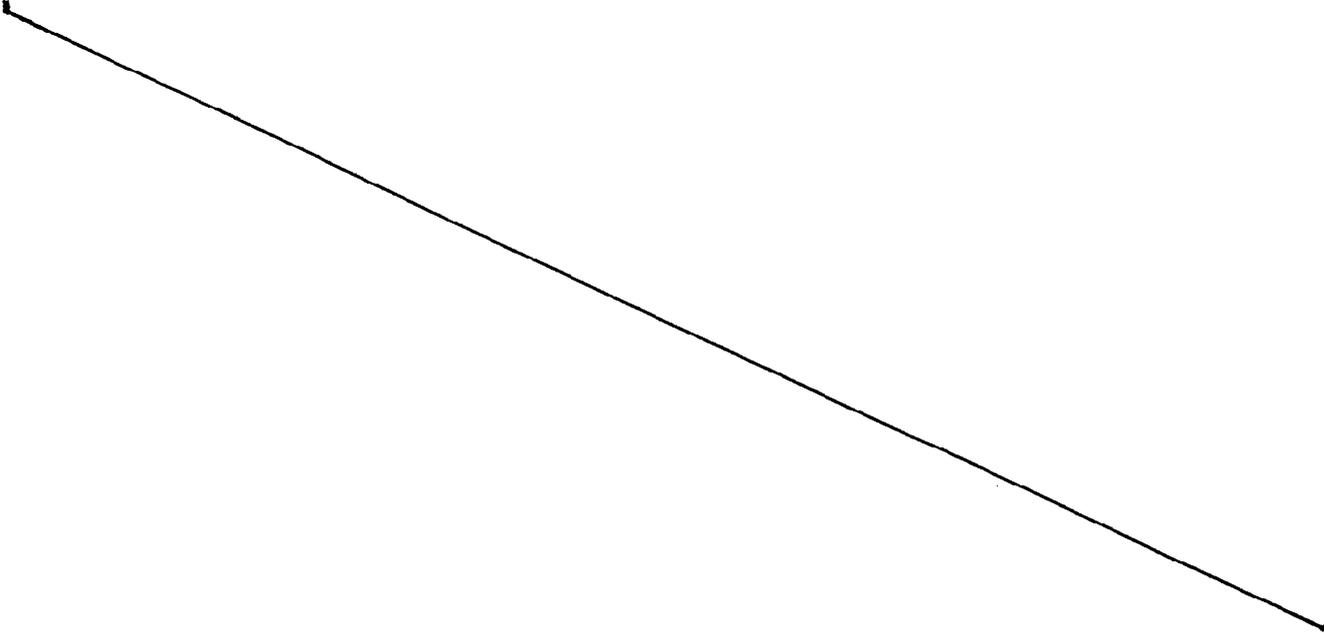
(2) Color additive mixtures made with sodium copper chlorophyllin may contain only those diluents that are suitable and are listed in this subpart as safe for use in color additive mixtures for coloring foods.

(b) *Specifications.* Sodium copper chlorophyllin shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by good manufacturing practice:

- (1) Moisture, not more than 5.0 percent.
- (2) Solvent residues (acetone, ethanol, and hexane), not more than 50 parts per million, singly or, in combination.
- (3) Total copper, not less than 4 percent and not more than 6 percent.
- (4) Free copper, not more than 200 parts per million.
- (5) Lead (as Pb), not more than 10 parts per million.
- (6) Arsenic (as As), not more than 3 parts per million.
- (7) Mercury (as Hg), not more than 0.5 part per million.
- (8) Ratio of absorbance at 405 nanometers (nm) to absorbance at 630 nm, not less than 3.4 and not more than 3.9.
- (9) Total copper chlorophyllins, not less than 95 percent of the sample dried at 100 °C for 1 hour.

(c) *Uses and restrictions.* Sodium copper chlorophyllin may be safely used to color citrus-based dry beverage mixes in an amount not exceeding 0.2 percent in the dry mix.

(d) *Labeling requirements.* The label of the color additive and any mixtures prepared therefrom shall conform to the requirements of § 70.25 of this chapter.



(e) *Exemption from certification.* Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

Dated: 4/25/02

April 25, 2002.

L. Robert Lake

L. Robert Lake,  
Director,  
Office of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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Gloria Penley