stabilized color additive mixture. Color additive mixtures for fish feed use made with astaxanthin 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*. Astaxanthin 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:

Physical state, solid.
0.05 percent solution in chloroform, complete and clear.
Absorption maximum wavelength 484–493 nanometers (in chloroform).
Residue on ignition, not more than 0.1 percent.
Total carotenoids other than astaxanthin, not more than 4 percent.
Lead, not more than 5 parts per million.
Arsenic, not more than 2 parts per million.
Mercury, not more than 1 part per million.
Heavy metals, not more than 10 parts per million.
Assay, minimum 96 percent.

(c) *Uses and restrictions*. Astaxanthin may be safely used in the feed of salmonid fish in accordance with the following prescribed conditions:

(1) The color additive is used to enhance the pink to orange-red color of the flesh of salmonid fish.

(2) The quantity of color additive in feed is such that the color additive shall not exceed 80 milligrams per kilogram (72 grams per ton) of finished feed.

(d) *Labeling requirements*. (1) The labeling of the color additive and any premixes prepared therefrom shall bear expiration dates for the sealed and open container (established through generally accepted stability testing methods), other information required by § 70.25 of this chapter, and adequate directions to prepare a final product complying with the limitations prescribed in paragraph (c) of this section.

(2) The presence of the color additive in finished fish feed prepared according to paragraph (c) of this section shall be declared in accordance with § 501.4 of this chapter.

(3) The presence of the color additive in salmonid fish that have been fed feeds containing astaxanthin shall be declared in accordance with §§ 101.22(k)(2) and 101.100(a)(2) 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: April 10, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95–9178 Filed 4–12–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 178

[Docket No. 91F–0465]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of an aqueous solution of citric acid, disodium ethylenediaminetetraacetate (disodium EDTA), sodium lauryl sulfate (SLS), and monosodium phosphate as a sanitizing solution to be used on food-processing equipment and utensils, including dairy-processing equipment. This action responds to a petition filed by Gycor International, Ltd.

DATES: Effective April 13, 1995; written objections and requests for a hearing by May 15, 1995.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mitchell A. Cheeseman, Center for Food Safety and Applied Nutrition (HFS–216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3083.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of January 3, 1992 (57 FR 291), FDA announced that a food additive petition (FAP 2B4301) had been filed by Gycor International Ltd., c/o Hogan & Hartson, 555 13th St. NW., Washington, DC 20004. The petition proposed that the food additive regulations be amended in § 178.1010 *Sanitizing solutions* (21 CFR 178.1010) to provide for the safe use of of citric acid, disodium EDTA, SLS, and monosodium phosphate as components of a sanitizing solution intended for general use on food-contact surfaces. The petitioner subsequently amended the petition to limit use of the sanitizer on only food-processing equipment and utensils, including dairy processing equipment.

I. Safety and Functional Effect of Petitioned Use of the Additives

Sanitizing solutions are regulated as mixtures of chemicals that function together to sanitize food-contact surfaces. Each listed component in a sanitizing solution has a functional effect, and the agency evaluates the data submitted in support of the efficacy of the entire sanitizing solution. In addition, FDA regulations permit the addition to a sanitizing solution of any substance that is generally recognized as safe (GRAS) for use in food (§ 178.1010(b)). The subject sanitizing solution is an aqueous solution of citric acid, disodium EDTA, SLS, and monosodium phosphate. The function of these components and the basis for FDA's determination of the safety of these components in the subject sanitizer are described below.

A. Citric Acid

Citric acid functions as an antimicrobial agent in the subject sanitizing solution. Citric acid is listed as GRAS for use in human food under 21 CFR 182.1033. FDA regulations permit the addition to a sanitizing solution of any substance that is GRAS for use in food. On the basis of the data submitted in support of the already-regulated uses of citric acid, and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of citric acid in the subject sanitizing solution is safe (Ref. 1).

B. Disodium Ethylenediaminetetraacetate

Disodium EDTA functions as a chelator in the subject sanitizing solution. Disodium EDTA is regulated as a direct food additive under 21 CFR 172.135. On the basis of the data submitted in support of the already-regulated uses of disodium EDTA and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of disodium EDTA in the subject sanitizing solution is safe (Ref. 1).

C. Sodium Lauryl Sulfate

SLS functions as a surfactant in the subject sanitizing solution. SLS is present in regulated sanitizing solutions under § 178.1010(b)(3), (b)(10), and (b)(37). On the basis of the data submitted in support of the already-regulated uses of SLS and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of SLS in the subject sanitizing solution is safe (Ref. 1).

D. Monosodium Phosphate

Monosodium phosphate functions as a buffer in the subject sanitizing solution. Monosodium phosphate is listed as GRAS for use in human food under 21 CFR 182.1778. FDA regulations permit the addition to a sanitizing solution of any substance that is GRAS for use in food. On the basis of the data submitted in support of the already-regulated uses of monosodium phosphate and the data contained in the food additive petition submitted in support of this sanitizing solution, FDA finds that the use of monosodium phosphate in the subject sanitizing solution is safe (Ref. 1).

E. Conclusion on Safety

As discussed above, FDA has evaluated the data in the petition and other relevant materials. On the basis of this evaluation, the agency concludes that these data and materials establish the use of the additive as a sanitizing solution on food-processing equipment and utensils and on dairy-processing equipment is safe and that it will have its intended technical effect. Therefore, FDA is amending its regulations in § 178.1010 as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), 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 by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

II. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

III. Reference

The following reference has 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. Memorandum entitled ''Toxicological Evaluation of Citric Acid, Disodium EDTA, Sodium Lauryl Sulfate, and Monosodium Phosphate as Sanitizer Components,'' dated March 24, 1994.

IV. Filing of Objections

Any person who will be adversely affected by this regulation may at any time on or before May 15, 1995, file with the Dockets Management Branch (address above) written objections thereto. 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 shall be submitted and shall 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.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging.

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 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

2. Section 178.1010 is amended by adding new paragraphs (b)(44) and (c)(38) to read as follows:

§ 178.1010 Sanitizing solutions.

* * * * *

(b) * * *

(44) An aqueous solution of citric acid, disodium ethylenediaminetetraacetate, sodium lauryl sulfate, and monosodium phosphate. In addition to use on food-processing equipment and utensils, this solution may be used on dairy-processing equipment.

* * * * *

(c) * * *

(38) The solution identified in paragraph (b)(44) of this section shall provide, when ready for use, at least 16,450 parts per million and not more than 32,900 parts per million of citric acid; at least 700 parts per million and not more than 1,400 parts per million of disodium ethylenediaminetetraacetate; at least 175 parts per million and not more than 350 parts per million of sodium lauryl sulfate; and at least 175 parts per million and not more than 350 parts per million of monosodium phosphate.

* * * * *

Dated: April 3, 1995.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–9089 Filed 4–12–95; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 558

New Animal Drugs; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the correct drug labeler code for Rhone Poulenc, Inc. The agency codified an incorrect drug labeler code. This document corrects that error.

EFFECTIVE DATE: April 13, 1995.

FOR FURTHER INFORMATION CONTACT: Judith M. O'Haro, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 28, 1994 (59 FR 33196), FDA published a document to correct the drug labeler code for Hess & Clark, Inc., from 011801 to 050749. Several regulations were amended including those for roxarsone used in combinations in 21 CFR 558.95, 558.311, 558.355, and 558.550. This amendment inadvertently created an error in the regulations. However, in the