

France, AD No. T98-551-039(A), dated December 31, 1998.

Issued in Fort Worth, Texas, on May 10, 1999.

Eric Bries,

*Acting Manager, Rotorcraft Directorate,
Aircraft Certification Service.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 173

[Docket No. 98F-0342]

Secondary Direct Food Additives Permitted in Food for Human Consumption

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 acidified solutions of sodium chlorite as an antimicrobial agent in poultry processing. This action is in response to a petition filed by Alcide Corp.

DATES: This regulation is effective May 18, 1999. Submit written objections and requests for a hearing by June 17, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Robert L. Martin, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204-0001, 202-418-3074.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 4, 1998 (63 FR 30498), FDA announced that a food additive petition (FMY 8A4591) had been filed by Alcide Corp., 8561 154th Ave. NE., Redmond, WA 98052. The petition proposed to amend the food additive regulation in § 173.325 (21 CFR 173.325) to provide for a lower pH in the use of acidified sodium chlorite solutions as an antimicrobial agent in poultry processing.

FDA has evaluated data in the petition and other relevant material. The agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and, therefore, (3) the

regulation in § 173.325 should be amended 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 § 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.

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.

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

Any person who will be adversely affected by this regulation may at any time on or before June 17, 1999, 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 173

Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 173 is amended as follows:

PART 173—SECONDARY DIRECT FOOD ADDITIVES PERMITTED IN FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 173 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 173.325 is amended by revising paragraph (b)(1) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(b) * * *

(1) When used in a carcass spray or dip solution, the additive is used at levels that result in sodium chlorite concentrations between 500 and 1,200 parts per million (ppm), in combination with any GRAS acid at levels sufficient to achieve a solution pH of 2.3 to 2.9.

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Dated: May 10, 1999.

William K. Hubbard,

*Associate Commissioner for Policy
Coordination.*

[FR Doc. 99-12391 Filed 5-17-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 98F-0824]

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 anthra(2,1,9-def;6,5,10-d'e'f')diisoquinoline-1,3,8,10 (2H,9H)-tetrone (C.I. Pigment Violet 29) as a colorant for polymers intended for use in contact with food. This action is in response to a petition filed by BASF Corp.

DATES: Effective May 18, 1999; written objections and requests for a hearing by June 17, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 6, 1998 (63 FR 53679), FDA announced that a food additive petition (FAP 8B4626) had been filed by BASF Corp., 3000 Continental Dr. North, Mt. Olive, NJ 07828-1234. The petition proposed to amend the food additive regulations in § 178.3297 *Colorants for polymers* (21 CFR 178.3297) to provide for the safe use of anthra(2,1,9-def:6,5,10-d'e'f')diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29) as a colorant for polymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that the proposed use of the additive as a colorant for all polymers intended for use in contact with food is safe and that the additive will have the intended technical effect. Therefore, the regulations in § 178.3297 should be amended as set forth below.

In accordance with § 171.1(h) (21CFR 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 § 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.

The agency has previously considered the potential environmental effects of this rule as announced in the notice of filing for the petition. 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.

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.

Any person who will be adversely affected by this regulation may at any time on or before June 17, 1999 file with the Dockets Management Branch (address above) a written objection 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 objection 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: 21 U.S.C. 321, 342, 348, 379e.
- 2. Section 178.3297 is amended in the table in paragraph (e), by alphabetically adding an entry for anthra(2,1,9-def:6,5,10-d'e'f')diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29) under the headings "Substances" and "Limitations" to read as follows:

§ 178.3297 Colorants for polymers.
* * * * *
(e) * * *

Substances	Limitations
* * *	* * *
Anthra(2,1,9-def:6,5,10-d'e'f')diisoquinoline-1,3,8,10(2H,9H)-tetrone (C.I. Pigment Violet 29; CAS Reg. No. 81-33-4)	For use at levels not to exceed 1% by weight of polymers. The finished articles are to contact food only under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter.
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Dated: May 5, 1999.
L. Robert Lake,
Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.
[FR Doc. 99-12396 Filed 5-17-99 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
21 CFR Part 178
[Docket No. 92F-0285]
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 expanded safe use of bis(p-ethylbenzylidene) sorbitol as a clarifying agent for polypropylene articles intended for use in contact with food. This action responds to a petition filed by Mitsui Toatsu Chemicals, Inc. (now Mitsui Chemicals, Inc.).