

**§ 922.164 Additional activity regulations by Sanctuary area.**

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(g) Anchoring on Tortugas Bank. Vessels 50 meters or greater in registered length are prohibited from anchoring on the Tortugas Bank. The coordinates of the area on the Tortugas Bank, west of the Dry Tortugas National Park, closed to anchoring by vessels 50 meters or greater in registered length are:

- (1) 24° 45.75'N 82° 54.40'W
- (2) 24° 45.60'N 82° 54.40'W
- (3) 24° 39.70'N 83° 00.05'W
- (4) 24° 32.00'N 83° 00.05'W
- (5) 24° 37.00'N 83° 06.00'W
- (6) 24° 40.00'N 83° 06.00'W

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Part 178**

[Docket No. 97F-0467]

**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 benzenesulfonic acid, 4-chloro-5-methyl-2-[[4,5-dihydro-3-methyl-5-oxo-1-(3-sulfophenyl)-1H-pyrazo-4-yl]azo], ammonium salt (C.I. Pigment Yellow 191:1) as a colorant in polymers intended for use in contact with food. This action is in response to a petition filed by Ciba Specialty Chemicals Corp.

**DATES:** The regulation is effective August 17, 1998. Submit written objections and requests for a hearing by September 16, 1998.

**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 November 19, 1997 (62 FR 61823), FDA announced that a food additive petition (FAP 8B4566) had been filed by Ciba Specialty Chemicals Corp., 335 Water St., Newport, DE 19804 (presently, c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001). 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 benzenesulfonic acid, 4-chloro-5-methyl-2-[[4,5-dihydro-3-methyl-5-oxo-1-(3-sulfophenyl)-1H-pyrazo-4-yl]azo], ammonium salt (C.I. Pigment Yellow 191:1) as a colorant in polymers intended for use in contact with food. In this final rule the agency is using the alternate name 4-chloro-2-[[5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl]azo]-5-methylbenzenesulfonic acid, diammonium salt (1:2), (C.I. Pigment Yellow 191:1).

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 is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.3297 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 rule as announced in the notice of filing for FAP 8B4566 (62 FR 61823). 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 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 September 16, 1998, 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:** 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 under the headings "Substances" and "Limitations" to read as follows:

**§ 178.3297 Colorants for polymers.**

\* \* \* \* \*

(e) \* \* \*

Substances	Limitations
<p style="text-align: center;">* * *</p> <p>4-Chloro-2-[[5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl]azo]-5-methylbenzenesulfonic acid, diammonium salt (1:2): (C.I. Pigment Yellow 191:1, CAS Reg. No. 154946-66-4).</p> <p style="text-align: center;">* * *</p>	<p style="text-align: center;">* * *</p> <p>For use at levels not to exceed 0.5 percent by weight of polymers. The finished articles are to contact food under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.</p> <p style="text-align: center;">* * *</p>

Dated: July 30, 1998.  
**Janice F. Oliver,**  
*Deputy Director for Systems and Support,*  
*Center for Food Safety and Applied Nutrition.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 178**

[Docket No. 98F-0055]

**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 2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol as a light stabilizer/ultraviolet (UV) absorber for polyethylene phthalate polymers intended for use in contact with food. This action is in response to a petition filed by Ciba Specialty Chemicals Corp.

**DATES:** The regulation is effective August 17, 1998; written objections and requests for a hearing by September 16, 1998.

**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 February 4, 1998 (63 FR 5809), FDA announced that a food additive petition (FAP 8B4573) had been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591-9005. The petition proposed to amend the

food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of 2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol as a light stabilizer/UV absorber for polyethylene phthalate polymers complying with 21 CFR 177.1630 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 is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.2010 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 rule as announced in the notice of filing for FAP 8B4573 (63 FR 5809). 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 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 September 16, 1998, 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 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 178.2010 is amended in the table in paragraph (b) in the entry for "2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol" by adding entry "3." under the heading "Limitations" to read as follows:

**§ 178.2010 Antioxidants and/or stabilizers for polymers.**

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