

4110-03

Hearing Clerk's Office  
5600 Fishers Lane  
Rockville, Maryland 20857  
Rm 4-65  
(HFA-305)

TITLE 21--FOOD AND DRUGS

DUPLICATE OF THE ORIGINAL

CHAPTER I--FOOD AND DRUG ADMINISTRATION,  
DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER B--FOOD FOR HUMAN CONSUMPTION

[DOCKET NO. 80F-0164]

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

4-[[4,6-BIS(OCTYLTHIO)-S-TRIAZIN-2-YL]AMINO]-2,  
6-DI-TERT-BUTYLPHENOL

46 FR 3830  
1-16-81

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 4-[[4,6-bis(octylthio)-s-triazin-2-yl]amino]-2,6-di-tert-butylphenol as an antioxidant and thermal stabilizer for styrene block copolymers, polystyrene, and rubber-modified polystyrene polymers. Ciba-Geigy Corp. petitioned for this use.

DATES: Effective (insert date of publication in the FEDERAL REGISTER); objections by (insert date 30 days after date of publication in the FEDERAL REGISTER).

ADDRESS: Written objections to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

80-622

80F-0164

NFRI

81-02-17

FOR FURTHER INFORMATION CONTACT:

Mary W. Lipien,  
Bureau of Foods (HFF-334),  
Food and Drug Administration,  
200 C St. SW.,  
Washington, DC 20204,  
202-472-5740.

SUPPLEMENTARY INFORMATION: FDA issued a notice in the FEDERAL REGISTER of June 10, 1980 (45 FR 39340) announcing that a food additive petition (FAP OB3509) had been filed by Ciba-Geigy Corp., Ardsley, NY 10502, proposing that § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) be amended to provide for the safe use of 4-[[4,6-bis(octylthio)-s-triazin-2-yl]amino]-2,6-di-tert-butylphenol as an antioxidant and thermal stabilizer for styrene block copolymers complying with § 177.1810 (21 CFR 177.1810) and polystyrene and rubber-modified polystyrene polymers complying with § 177.1640 (21 CFR 177.1640).

FDA has evaluated data in the petition and other relevant material and concludes that § 178.2010 should be amended as set forth below to include the petitioned additive.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s) and 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s) and 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 178 is amended in § 178.2010(b) by inserting a new entry alphabetically in the table, to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

\* \* \* \* \*

(b) \* \* \*

---

<u>Substances</u>	<u>Limitations</u>
* * * * *	* * * * *
4-[[4,6-Bis(octylthio)-s-triazin-2-yl]amino]-2,6-di- <u>tert</u> -butylphenol (CAS Reg. No. 991-84-4).	For use only: 1. At levels not to exceed 0.5 percent by weight in styrene block copolymers complying with § 177.1810 of this chapter: <u>Provided</u> , That the finished styrene block copolymers contact food identified as types I, II, IV-B, VI, VII-B, and VIII in table 1 of § 176.170(c) of this chapter under conditions of use D, E, F, and G described in table 2 of § 176.170(c) of this chapter.

Substances

Limitations

2. At levels not to exceed 0.1 percent by weight in polystyrene and rubber-modified polystyrene complying with § 177.1640 of this chapter: Provided, That the finished polystyrene and rubber-modified polystyrene polymers contact food only under conditions of use D, E, F, and G described in table 2 of § 176.170(c) of this chapter.

\*

\*

\*

\*

\*

---

Any person who will be adversely affected by the foregoing regulation may at any time on or before (insert date 30 days after date of publication in the FEDERAL REGISTER) submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation becomes effective (insert date of publication in the FEDERAL REGISTER).

(Secs. 201(s) and 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s) and 348).)

Dated: Jan. 12, 1981.

JAN 12 1981

William F. Randolph

William F. Randolph  
Acting Associate Commissioner for  
Regulatory Affairs

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Marcia Rosenberg