

SIZE STANDARDS BY SIC INDUSTRY

SIC code and description		Size standards in number of employees or millions of dollars
DIVISION I—SERVICES		
7389	Business Services, N.E.C Except, Map Drafting Services, Mapmaking (Including Aerial) and Photogrammetric Mapping Services.	\$5.0 \$4.0
8711	Engineering Services Military and Aerospace Equipment and Military Weapons Contracts and Subcontracts for Engineering Services Awarded Under the National Energy Policy Act of 1992. Marine Engineering and Naval Architecture	\$4.0 \$20.0 \$20.0 \$13.5
8712	Architectural Services (Other than Naval)	\$4.0
8713	Surveying Services	\$4.0

Aida Alvarez,
Administrator.

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BILLING CODE 8025-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 91F-0399]

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 1,3-propanediamine, N,N'-1,2-ethanediybis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine as a light stabilizer for polypropylene and polyethylene complying with 21 CFR 177.1520. This action responds to a petition filed by 3-V Chemical Corp.

DATES: The regulation is effective May 14, 1999. Submit written objections and requests for a hearing by June 14, 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: Julius Smith, Center for Food Safety and Applied Nutrition (HFS-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3091.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of January 3, 1992 (57 FR 291), FDA announced that a petition (FAP 1B4277) had been filed by 3-V Chemical Corp., P.O. Box Drawer Y, Georgetown, SC 29442, proposing to amend § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010), to provide for the safe use of 1,3-propanediamine, N,N'-1,2-ethanediybis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine as a light stabilizer for polyethylene and polypropylene complying with 21 CFR 177.1520.

FDA has evaluated the 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 have the intended technical effect, and

therefore, that the regulations 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 14, 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 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) by alphabetically adding an entry under the headings "Substances" and "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

*	*	*	*	*
(b) * * *				

Substances	Limitations
* * * * *	* * * * *
1,3-Propanediamine, N,N'-1,2-ethanediybis-, polymer with N-butyl-2,2,6,6-tetramethyl-4-piperidinamine and 2,4,6-trichloro-1,3,5-triazine (CAS Reg. No. 136504-96-6).	For use only: 1. At levels not to exceed 0.3 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1, 1.2, and 1.3. 2. At levels not to exceed 0.2 percent by weight of olefin polymers having a density greater than or equal to 0.94 grams per cubic centimeter and complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, and 3.2. 3. At levels not to exceed 0.3 percent by weight of olefin polymers having a density less than 0.94 grams per cubic centimeter and complying with § 177.1520(c) of this chapter, items 2.1, 2.2, 2.3, 3.1, 3.2, 3.3, 3.4, 3.5, 3.6, and 4.0. The finished polymers are to contact food only under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, and when used in contact with fatty foods of Types III, IV-A, V, VII-A, and IX as described in Table 1 of § 176.170(c) of this chapter, the finished articles are to have a volume of at least 18.9 liters (5 gallons).
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Dated: May 3, 1999.
L. Robert Lake,
 Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.
 [FR Doc. 99-12177 Filed 5-13-99; 8:45 am]
 BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 640

[Docket No. 98N-0608]

Revision of Requirements Applicable to Albumin (Human), Plasma Protein Fraction (Human), and Immune Globulin (Human)

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the biologics regulations by removing, revising, or updating specific regulations applicable to blood

derivative products to be more consistent with current practices and to remove unnecessary or outdated requirements. FDA is issuing these amendments directly as a final rule because the agency believes they are noncontroversial and that there is little likelihood that there will be comments opposing the rule. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule under FDA's usual procedures for notice and comment in the event the agency receives any significant adverse comments. If any significant adverse comment is received sufficient to terminate the direct final rule within 30 days after the comment period ends, FDA will consider such comments on the proposed rule in developing the final rule. FDA is issuing this rule as