

DMB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date	10-22-98
Publication Date	10-23
Certifier	X B. S. S. S.

Food and Drug Administration

21 CFR Part 178

[Docket No. 96F-0164]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations for the use of sodium 2,2'-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food. When the regulation was last amended, the agency inadvertently omitted the limitation on the use level for the additive. This document corrects that inadvertent omission.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

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 the **Federal Register** of December 16, 1996 (61 FR 65942), FDA published a document amending the food additive regulations to provide for the expanded safe use of sodium 2,2'-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food. The limitation added by this document was inadvertently omitted from the December 16, 1996, final rule due to an administrative error. Limiting the use level of the additive to no more than 0.30 percent by weight of the olefin polymers

is supported by the administrative record of the final rule. Accordingly, FDA is amending the regulation to accord with the record.

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, 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 178.3295 is amended in the table in the entry for “Sodium 2,2'-methylenebis(4,6-di-*tert*-butylphenyl)phosphate” by revising entry “3.” under the heading “Limitations” to read as follows:

§ 178.3295 Clarifying agents for polymers.

* * * * *

Substances	Limitations
<p>Sodium 2,2'-methylenebis(4,6-di-<i>tert</i>-butylphenyl)phosphate (CAS Reg. No. 85209-91-2)</p>	<p>For use only: * * * * * 3. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.2, where the finished polymer contacts food only of types I, II, IV-B, VI-A, VI-B, and VII-B as identified in Table 1 of § 176.170(c) of this chapter, and limited to conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, or foods of types III, IV-A, V, VI-C, and VII-A as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.</p>

Dated: October 16, 1998
October 16, 1998



William K. Hubbard
Associate Commissioner
for Policy Coordination

[FR Doc. 98-???? Filed ??-??-98; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

