

DMB

Display Date	8-5-99
Publication Date	8-6-99
Certifier	SNReese

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99F-2535]

Ciba Specialty Chemicals Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Ciba Specialty Chemicals Corp. has filed a petition proposing that the food additive regulations be amended to provide for the expanded safe use of 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with o-xylene as an antioxidant and/or stabilizer in olefin polymers, adhesives, pressure-sensitive adhesives, and ethylene-vinyl acetate copolymers intended for use in contact with food.

FOR FURTHER INFORMATION CONTACT:

Ellen M. Waldron,
Center for Food Safety and Applied Nutrition (HFS-215),
Food and Drug Administration,
200 C St. SW.,
Washington, DC 20204,
202-418-3089.

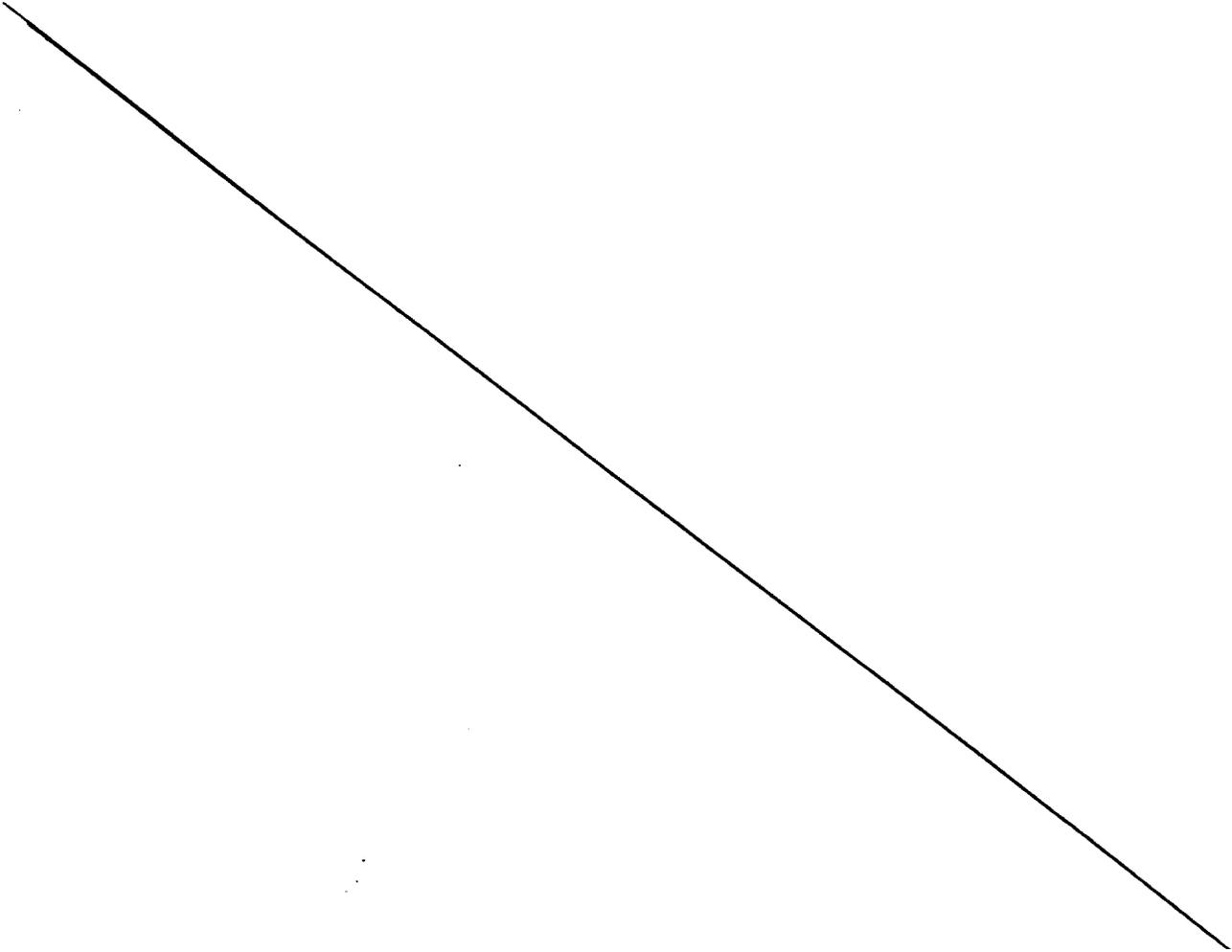
SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5) (21 U.S.C. 348(b)(5))), notice is given that a food additive petition (FAP 9B4680) has been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY

cf99125

NFL 1

10591-9005. The petition proposes 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 5,7-bis(1,1-dimethylethyl)-3-hydroxy-2(3H)-benzofuranone, reaction products with o-xylene as an antioxidant and/or stabilizer for olefin polymers complying with 21 CFR 177.1520, adhesives complying with 21 CFR 175.105, pressure-sensitive adhesives complying with 21 CFR 175.125, and ethylene-vinyl acetate copolymers complying with 21 CFR 177.1350 intended for use in contact with food.

The agency has determined under 21 CFR 25.32(i) that this action is of a type that does not individually or



cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: July 13, 1999
July 13, 1999
Laura M. Tarantino

Laura M. Tarantino
Deputy Director, Office of Premarket Approval
Center of Food Safety and Applied Nutrition

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Stephanie N. Reese