

FINDING OF NO SIGNIFICANT IMPACT  
FOR

Food Additive Petition 6B4512, submitted by Ciba-Geigy Corporation, to amend 21 *CFR* 178.3297 to permit the safe use of 2,9-dichloro-5,12-dihydroquinone[2,3-b] acridine-7, 14-dione (C.I. Pigment Red 202) as a colorant for all polymers intended for use in contact with food.

The Environmental Impact Team, Center for Food Safety and Applied Nutrition, has determined that the approval of this petition will not significantly affect the quality of the human environment and therefore will not require the preparation of an environmental impact statement. This finding is based on information submitted by the petitioner in an environmental assessment prepared using the format described in 21 *CFR* 25.31a(b)(1); market volume information submitted by the petitioner; and the following:

1. Only a very small amount, if any, of the subject additive is expected to enter the environment as a result of the landfill disposal of food-packaging materials containing the subject additive. This finding is based on the Environmental Protection Agency's (EPA's) regulations governing municipal solid waste landfills.<sup>1</sup>
2. When this regulation is promulgated, the subject colorant may be used in all polymers intended for use in contact with foods. Such broad usage could mean that the subject colorant might be used in a polymeric food container that is recycled. Since we are aware of problems with recycling colored polymeric articles,<sup>2, 3, and 4</sup>, we have considered the potential for effects on the recycling of HDPE and PET that may result from the

---

<sup>1</sup> EPA's regulations require new municipal solid waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems (40 *CFR* Part 258). Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993, are not required to retrofit liners and leachate collection systems, they are required to monitor groundwater and to take corrective action as appropriate.

<sup>2</sup> *Chemical and Engineering News*, October 21, 1985, page 25.

<sup>3</sup> Sabourin, Dennis, "PET Beverage Bottle Recycling Today and the Future," in *Plastics Recycling as a Future Business Opportunity, Proceedings of RECYCLINGPLAS III - Conference*, May 25-26, 1988, Technomic Publishing Company, Inc., Lancaster, PA 17604.

<sup>4</sup> Leaversuch, R.D., "Color-sortation Technologies Improve PCR Quality and Value," *Modern Plastics*, June 1993, page 100.

promulgation of this regulation. PET and HDPE were considered because these two polymers are currently the most highly recycled plastics.<sup>5</sup>

a. HDPE Recycling

The petitioner stated that the subject additive is intended for the same uses as other colorants already in use. Therefore, it is reasonable to expect that the subject additive will replace other colorants currently in use, so that approval of this petition is not likely to result in a significant increase in the quantity of colored HDPE containers in the municipal waste stream. Even if there is some increase in the number of colored containers, this increase will not affect the recycling of HDPE containers because mixed color HDPE containers are currently being recycled.<sup>6</sup> Since HDPE bottle waste consists of opaque material in a wide range of colors, recycled HDPE is generally used in applications in which color is not critical.<sup>7</sup> Such applications include base cups, flower pots, trash cans, kitchen drainboards, beverage bottle crates, etc<sup>6</sup>.

b. PET Recycling

The petitioner states that very little, if any, of the subject colorant is expected to be used in PET soda bottles. However, because we do not know the extent to which this colorant may penetrate the market for PET bottles, we have made a worst-case estimate of the impact of regulating the subject colorant on PET recycling as follows: We have assumed that 1) the entire market volume of the subject colorant will be used in PET beverage bottles, 2) the colorant will not replace existing colorants for this use, and 3) colored PET bottles are not recycled. Under these conditions, PET beverage bottles not recycled because of the presence of the subject additive would be an extremely small percentage of the total quantity of PET currently recycled. This estimate is a gross exaggeration because 1) very little, if any, of the market volume of the subject colorant is expected to be used in PET beverage bottles; 2) to the extent that the subject colorant replaces existing colorants, there will be no increase in the number of colored PET beverage bottles currently produced; and 3) there is some recycling of mixed color PET now.<sup>5</sup>

---

<sup>5</sup> Environmental Protection Agency, *Characterization of Municipal Solid Waste in the United States: 1992 Update*, EPA/530-R-92-019, July 1992, pages 2-38 and 2-41.

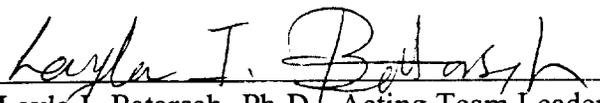
<sup>6</sup> Rabasca, Lisa, "The Markets Page," in *Waste Age's Recycling Times*, Vol 5, No. 17, August 24, 1993, page 5.

<sup>7</sup> Leaversuch, R., "HDPE Recycling: It's a Big-volume Opportunity Waiting to Happen," *Modern Plastics*, August 1988, pages 44-47.

Based on the above discussion, we believe that promulgation of this regulation will not interfere significantly with current or future recycling of HDPE or PET recycling.

3. Based on confidential market volume information submitted by the petitioner, FDA has determined that approval of the petition will result in a very small increase in the amount of chlorine entering the municipal waste stream. This amount is a very small fraction of the amount of chlorine currently available to form acid gas during incineration of municipal solid waste. Therefore, no significant increase in incinerator emissions is expected following the approval of this petition.

Prepared by:  Date: August 28, 1997  
Mark A. Hepp, Ph.D., Consumer Safety Officer  
Division of Petition Control

Approved by:  Date: August 28, 1997  
Layla I. Batarseh, Ph.D., Acting Team Leader  
Chemistry and Environmental Review Team

RD:HFS-215:MAHepp:8/22/97  
c:\office\...\spt\6B4512.fon  
FT:HFS-215:MAHepp:8/28/97