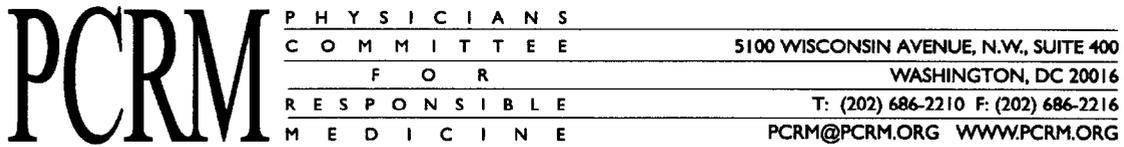


201-15740



December 21, 2004

Michael O. Leavitt, Administrator  
U.S. Environmental Protection Agency  
Ariel Rios Building, 1101-A  
1200 Pennsylvania Ave., N.W.  
Washington, DC 20460

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Subject: Comments on the HPV Test Plan for IRGANOX 1330/ ETHANOX 330

Dear Administrator Leavitt:

The following comments on Ciba and Albemarle's test plan for the chemical 1,3,5-trimethyl-2,4,6-tris(3,5-di-t-butyl-4-hydroxybenzyl) benzene are submitted on behalf of the Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

Ciba Specialty Chemicals Corporation and Albemarle Corporation submitted their test plan on July 27, 2004, for the chemical 1,3,5-trimethyl-2,4,6-tris(3,5-di-t-butyl-4-hydroxybenzyl) benzene (CAS No. 1709-70-2), also known by the tradenames IRGANOX 1330 (Ciba) and ETHANOX 330 (Albemarle). This chemical is used as an antioxidant that protects against thermo-oxidative degradation. According to the sponsors, IRGANOX 1330/ETHANOX 330 has been regulated by the FDA and once incorporated into a polymer matrix, it is relatively immobile and release and/or exposure to humans or the environment is minimal.

We are encouraged by the collaboration between Ciba and Albemarle on the HPV test plan for this chemical. Substantial amounts of existing data were compiled from a variety of sources to fulfill all SIDS endpoints. This approach to hazard assessment avoids separate and/or duplicative testing which would violate the basic tenets of animal welfare and the HPV program. For this test plan, both companies have adhered to animal welfare principles set forth by the EPA, including EPA's stated goal that HPV participants "maximize the use of existing and scientifically adequate data to minimize further testing" (Wayland 1999).

We concur that no additional testing is needed for the purposes of the HPV program. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 327, or via e-mail at [meven@pcrm.org](mailto:meven@pcrm.org).

Sincerely,

Megha Even, M.S.  
Research Analyst

Chad B. Sandusky, Ph.D.  
Director of Toxicology and Research