

201-15436

PCRM

P H Y S I C I A N S
C O M M I T T E E
F O R
R E S P O N S I B L E
M E D I C I N E

5100 WISCONSIN AVENUE, N.W., SUITE 400
WASHINGTON, DC 20016
T: (202) 686-2210 F: (202) 686-2216
PCRM@PCRM.ORG WWW.PCRM.ORG

July 2, 2004

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

RECEIVED
OPPT/CRIC
04 JUL -9 AM 9:22

Subject: Comments on the HPV Test Plan for 1,3-Isobenzofurandione,4,5,6,7-tetrabromo-

Dear Administrator Leavitt:

The following comments on Great Lakes and Albemarle's test plan for the chemical 1,3-Isobenzofurandione,4,5,6,7-tetrabromo- 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.

Great Lakes Chemical Corporation and Albemarle Corporation submitted its test plan on February 3, 2004, for the chemical 1,3-Isobenzofurandione,4,5,6,7-tetrabromo- (CAS No. 632-79-1). This chemical is primarily used as a flame retardant in the production of unsaturated polyester resins and is sold under the trade names Great Lakes PHT4 and Saytex® RB49. We are encouraged and delighted by the collaboration between Great Lakes and Albemarle. 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 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 animal testing is required under the HPV Challenge program.

Great Lakes and Albemarle have submitted a comprehensive analysis of 1,3-Isobenzofurandione,4,5,6,7-tetrabromo- by compiling substantial amounts of existing data from a variety of sources. Both companies used data on reproductive organs from two repeated dose studies and reproductive parameters analyzed in the developmental study to fulfill the SIDS endpoint for reproductive toxicity. This approach demonstrates a thoughtful analysis by both companies, in addition to being a scientifically valid analysis of a chemical's toxicity and adequate for a screening level 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.

Sincerely,

Megha Even, M.S.
Research Analyst

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

References

Wayland, S.H., Letter to manufacturers/importers, October 14, 1999,
<http://www.epa.gov/chemrtk/ceoltr2.htm>.