

201-14512

May 28, 2003

Christine Todd Whitman, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building
Room 3000, #1101-A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

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Subject: Comments on the HPV Test Plan for gamma-Butyrolactone

Dear Administrator Whitman:

The following comments on the gamma Butyrolactone Consortium's (BPPB Consortium) test plan for gamma-Butyrolactone 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.

The gamma Butyrolactone Consortium submitted its test plan on January 30, 2003 for the chemical gamma-Butyrolactone (CAS No. 96-48-0). The chemical structure and solvent properties of this liquid allow numerous industrial applications. For example, gamma-Butyrolactone is used in the manufacturing of herbicides and vitamin B1 and serves as a solvent in sun lotions and printing inks. A substantial number of physicochemical, fate, and toxicity studies have been conducted with gamma-Butyrolactone. In addition, worker exposure to this chemical in industrial applications is limited due to good industrial hygiene practices. This test plan fully utilizes existing studies, as well as other data on gamma-Butyrolactone, to fulfill all SIDS endpoints in the HPV screening program. In particular, a weight-of-evidence analysis of developmental and both subchronic and chronic studies is used to meet the SIDS requirement for a reproductive toxicity study, thus avoiding a checklist approach to toxicology. This is a scientifically valid analysis and adequate for a screening level program.

We applaud the gamma Butyrolactone Consortium's efforts and concur that no additional testing is necessary for gamma-Butyrolactone under the HPV Challenge Program. Although the available studies on gamma-Butyrolactone do not meet all the current OECD guidelines, we commend this group for its thoughtful analysis and conclusion that additional studies will not add to our understanding of this chemical's toxicity. This approach is consistent with the EPA's stated goal of maximizing the use of existing data in order to limit additional animal testing and to avoid a mere box-checking approach to

toxicology. 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 Research