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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 2-Pyrrolidone

Dear Administrator Whitman:

The following comments on the 2-Pyrrolidone Consortium's (BPPB Consortium) test plan for 2-Pyrrolidone 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 2-Pyrrolidone Consortium submitted its test plan on January 31, 2003 for the chemical 2-Pyrrolidone (CAS No. 616-45-5). This chemical is prepared from butyrolactone (CAS No. 96-48-0) and used most extensively as an intermediate in the production of vinylpyrrolidone but is also used as a high-boiling solvent in petroleum processing. A substantial number of physicochemical, fate, and toxicity studies have been conducted with 2-Pyrrolidone. 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 2-Pyrrolidone, to fulfill all SIDS endpoints in the HPV screening program. For instance, a weight-of-evidence analysis of developmental and subchronic 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 2-Pyrrolidone Consortium's efforts and concur that no additional testing is necessary for this chemical under the HPV Challenge Program. Although the available studies on 2-Pyrrolidone 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