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December 23, 2003

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

Subject: Comments on the HPV Test Plan for Alkyl-substituted Cyclohexanol Derivatives

Dear Administrator Leavitt:

The following comments on Cyclohexyl Derivatives Consortium's test plan for Alkyl-substituted Cyclohexanol Derivatives 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 Cyclohexyl Derivatives Consortium, a member of the Flavor and Fragrance High Production Volume Consortia, submitted its test plan on August 19, 2003 for the chemical category alkyl-substituted cyclohexanol derivatives, consisting of 4-*tert*-butylcyclohexanol (CAS No. 98-52-2) and 4-*tert*-butylcyclohexyl acetate (CAS No. 32210-23-4). The alcohol serves as a synthetic precursor of the acetate and both chemicals are used primarily in soap perfumes. The consortium has submitted a comprehensive analysis of alkyl-substituted cyclohexanol derivatives by compiling substantial amounts of existing data from a variety of sources. In addition, this consortium combined two substances with similar chemical, pharmacological, and toxicological properties into a single category for purposes of the HPV program. This approach demonstrates a thoughtful analysis by the Cyclohexyl Derivatives Consortium, in addition to being a scientifically valid analysis of a chemical's toxicity and adequate for a screening level program.

While most of the toxicity information was available for both substances, some of the endpoints for human health effects were appropriately filled using a "read-across" approach based on structurally related alkyl-substituted cyclohexanol and cyclohexanone derivatives. This approach is consistent with the EPA's stated goals of maximizing the use of existing data in order to limit additional animal testing. We support the formation of a category for alkyl-substituted cyclohexanol derivatives and concur that no additional testing is necessary under the HPV Challenge program.

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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