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July 19, 2004

Michael O. Leavitt, Administrator
 US Environmental Protection Agency
 Ariel Rios Building
 Room 3000, #1101-A
 1200 Pennsylvania Avenue, NW
 Washington, DC 20460

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Subject: Comments on the HPV test plan for Ethanol, 2-(hydroxymethylamino)-

Dear Administrator Leavitt:

The following comments on the Troy Chemical Company (Troy) test plan for Ethanol, 2-(hydroxymethylamino)- 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.

Troy submitted its test plan on February 21, 2005 for the chemical Ethanol, 2-(hydroxymethylamino)- (CAS RN 34375-28-5), also known as Troysan 174. Existing data fulfills the OECD SIDS data endpoints required by the program, and no new animal testing is proposed. Troysan 174 is currently regulated under FIFRA as a water-soluble liquid bactericide used for metalworking fluids. Troy has prepared a short but comprehensive discussion of the chemical, its common uses, and chemical structure. Following this page are the robust summaries to address each SIDS endpoint.

Unfortunately, the test plan does not discuss the available studies contained in the robust summaries. Since a reproductive toxicity study is lacking, we assume that Troy plans to fulfill the endpoint by using the available data from a 13-week dermal study (histopathology of the reproductive organs) in combination with a negative developmental study. We applaud this strategy, which has been used in the past by other companies, and accepted by the EPA, to reduce HPV-required mammalian studies.

We concur that no additional animal testing is necessary under the scope of the HPV program. Thank you for your attention to these comments. I may be reached at 202-686-2210, ext. 335, or via e-mail at kstoick@pcrm.org.

Sincerely,

Kristie M Stoick, M.P.H.
 Research Analyst

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