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May 24, 2002

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

Subject: Comments on the ACC's HPV Test Plan for Resin Oils and Cyclodiene Dimer Concentrates Category

Dear Administrator Whitman:

The following comments on the test plan for the American Chemistry Council's (ACC's) test plan for the category resin oils and cyclodiene dimer concentrates 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 nine million Americans.

The ACC has developed a category of mixed hydrocarbon streams consisting mainly of C8 to C12 cycloalkenes and aromatic hydrocarbons. The ACC is proposing three *in vitro* mutagenicity tests, three *in vivo* genetic toxicity tests, three combined repeat dose/reproductive/developmental toxicity tests, and up to three acute fish toxicity tests. These tests could kill as many as 1,560 animals.

This test plan violates the following terms of the October 1999 Agreement among the EPA, industry, and health, animal protection, and environmental organizations:

1. In analyzing the adequacy of existing data, participants shall conduct a thoughtful, qualitative analysis rather than use a rote checklist approach. Participants may conclude that there is sufficient data, given the totality of what is known about a chemical, including human experience, that certain endpoints need not be tested.
2. Participants shall maximize the use of existing and scientifically adequate data to minimize further testing.
5. Participants are encouraged to use *in vitro* genetic toxicity testing to generate any needed genetic toxicity screening data, unless known chemical properties preclude its use.

The ACC has developed a category of mixed hydrocarbon streams consisting mainly of C8 to C12 cycloalkenes and aromatic hydrocarbons. The main toxicological driver of the stream is dicyclopentadiene (DCPD) (CAS #77-37-6). **A complete SIDS battery exists for DCPD.** In addition, there is extensive available informa-

tion, far beyond the screening-level SIDS tests for this chemical. DCPD has been shown to be acutely toxic to the central nervous system. It is a skin and eye irritant, as well as a possible respiratory irritant. Repeat dose animal experiments with DCPD have indicated that it is toxic to kidneys of rats. However, the ACC acknowledges that the mechanism of toxicity is not relevant to humans. Toxicity to the kidneys of rats is due to hyaline droplet nephropathy, a condition commonly observed in male rats dosed with hydrocarbons, but not considered relevant to humans.

It is unlikely that any additional SIDS health effects tests on these industrial streams will produce meaningful data for human health, as none of them has been properly validated, i.e., shown to be reproducible, and relevant to the human condition.

Conducting *in vivo* genetic toxicity tests is inappropriate and constitutes a violation of the October 1999 Agreement. To test chromosomal aberrations, we strongly recommend the ACC conduct the *in vitro* mammalian cytogenetic test for chromosomal aberrations (OECD TG 473). Furthermore, DCPD, the main toxicological driver of these streams is not toxic to genetic mechanisms either in bacterial or mammalian systems. Tests for mutations and chromosomal effects have been negative for DCPD. Even the Organisation for Economic Co-operation and Development's (OECD's) decision tree for the assessment of genetic toxicity specifically states that substances that produce negative results in *in vitro* tests for point mutation and chromosomal aberration require no further genotoxicity testing.<sup>1</sup> The ACC should not conduct additional *in vivo* genetic toxicity tests, given the totality of what is known about these chemicals.

Conducting screening-level tests on mixed composition industrial streams when the toxicity of individual components is already well understood is inappropriate. We have addressed this issue in detail in our previous petroleum gas and crude butadiene comments, and low 1,3-butadiene category.<sup>1-3</sup> The ACC has presented much information in its test plan to show that the C8 to C12 cycloalkanes exhibit similar toxicological effects as the C8 to C12 aromatic hydrocarbons. In addition, the ACC has presented information demonstrating that the biological activity of DCPD is similar to that of other physiochemically similar C8 to C12 cycloalkanes. Some other components of these industrial chemicals and related chemicals are covered in the ACC's C5 Noncyclics category and the test plan for C6-C12 alkyl derivatives, developed by Council for LAB/LAS Environmental Research.

We commend the ACC's thoughtful analysis of the physicochemical and toxicological properties of the components of these industrial streams, but maintain that it does not take its analysis far enough. The available health and safety information on the components of these industrial streams is sufficient for characterizing the potential health effects of these substances, without conducting additional tests on animals.

Thank you for your attention to these comments. I can be reached at 202-686-2210, ext. 302, or via e-mail at [ncardello@pcrm.org](mailto:ncardello@pcrm.org). Correspondence may be sent to my attention to PCRM, 5100 Wisconsin Ave., N.W., Suite 400, Washington, DC 20016.

Sincerely,

Nicole Cardello, M.H.S.  
Staff Scientist

1. Organisation for Economic Co-operation and Development. OECD Proposals for the Initial Assessment of Genetic Toxicity. Table 1. May 1996.